# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 10-Q/A

Amendment No. 1

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-37359

# **BLUEPRINT MEDICINES CORPORATION**

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)

26-3632015 (I.R.S. Employer Identification No.)

38 Sidney Street, Suite 200 Cambridge, Massachusetts (Address of Principal Executive Offices)

02139 (Zip Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\square \boxtimes$  No  $\square \square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T ( $\S$ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\square \boxtimes$  No  $\square \square$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer		Accelerated filer		
Non-accelerated filer	☑ (Do not check if a smaller reporting company)	Smaller reporting company		
Indicate by check mark whether the reg	istrant is a shell company (as defined	in Rule 12b-2 of the Exchange Act).	Yes □□	No □⊠
Number of shares of the registrant's cor	nmon stock, \$0.001 par value, outsta	nding on May 6, 2016; 27,238,661		

#### **EXPLANATORY NOTE**

Blueprint Medicines Corporation (the "Company") is filing this Amendment No. 1 on Form 10-Q/A (this "Amendment No. 1") to amend its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016, as filed with the Securities and Exchange Commission ("SEC") on May 10, 2016 (the "Quarterly Report"). This Amendment No. 1 is being filed solely to file revised redacted versions of Exhibits 10.1 and 10.2 (the "Exhibits"), which were previously filed with the Quarterly Report, in response to comments from the SEC regarding a confidential treatment request submitted to the SEC with respect to the Exhibits. The revised Exhibits attached to this Amendment No. 1 as Exhibit 10.1 and Exhibit 10.2, respectively, supersede and replace the versions of the Exhibits previously filed with the Quarterly Report. Certain portions of the information that was omitted from the Exhibits previously filed with the Quarterly Report have now been included as part of the revised Exhibits.

Except for the revised Exhibits, this Amendment No. 1 does not amend any information set forth in the Quarterly Report. This Amendment No. 1 speaks as of the original filing date of the Quarterly Report and does not reflect any events that occurred at a date subsequent to the filing of the Quarterly Report or modify or update those disclosures therein in any way. Accordingly, this Amendment No. 1 should be read in conjunction with the Company's Quarterly Report and any filings made with the SEC subsequent to the filing of the Quarterly Report. As required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, the Company is filing new certifications by its principal executive officer and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 as exhibits to this Amendment No. 1.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## **BLUEPRINT MEDICINES CORPORATION**

Date: July 22, 2016 By: /s/ Jeffrey W. Albers

Jeffrey W. Albers

President, Chief Executive Officer and Director (Principal

Executive Officer)

Date: July 22, 2016 By: /s/ Michael Landsittel

Michael Landsittel
Vice President of Finance

(Principal Financial and Accounting Officer)

## EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1†*	Master Collaboration Agreement, effective March 1, 2016, by and between Ventana Medical Systems, Inc. and the Registrant, including Project Schedule #1, effective March 1, 2016, Project Agreement #2, effective March 11, 2016, and Project Schedule #3, effective April 8, 2016
10.2†*	Collaboration and License Agreement, effective March 14, 2016, by and among F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and the Registrant, as amended by Amendment to Collaboration and License Agreement, effective April 15, 2016
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>†</sup> Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

<sup>\*</sup> Filed herewith.

<sup>+</sup> Previously furnished with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed with the Securities and Exchange Commission on May 10, 2016.

<sup>#</sup> Previously filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed with the Securities and Exchange Commission on May 10, 2016.

\*\*\*Text Omitted and Filed Separately with the Securities and Exchange Commission Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 230.406

**Execution Draft** 

#### MASTER COLLABORATION AGREEMENT

This Master Collaboration Agreement (this "<u>Agreement</u>") is effective March 1, 2016, (the "<u>Effective Date</u>"), by and between Ventana Medical Systems, Inc., a Delaware corporation with offices located at 1910 E. Innovation Park Drive, Tucson, AZ 85755 USA ("<u>Ventana</u>"), and Blueprint Medicines Corporation, a Delaware corporation with offices located at 38 Sidney Street, Suite 200, Cambridge, MA 02139 USA ("<u>Blueprint</u>").

Whereas, Ventana is engaged in the business of research, development, manufacture and Commercialization of *in vitro*, complementary and companion diagnostics in relation to the pharmaceutical industry;

Whereas, Blueprint is engaged in the research, development, manufacture and Commercialization of pharmaceutical and biological products and methods to treat patients with pharmaceutical products;

Whereas, from time to time Blueprint wishes to engage Ventana on the following terms and conditions in relation to one or more projects connected with the creation of *in vitro*, complementary or companion diagnostics for one or more Blueprint Products; and

Whereas, from time to time Ventana wishes to engage Blueprint on the following terms and conditions in connection with such projects.

Now, therefore, the Parties agree as follows:

#### 1. DEFINITIONS

In this Agreement the following terms, when capitalized, shall have the following meanings:

- 1.1. "AAA" has the meaning set forth in Section 15.2.
- 1.2. "Activities" means the activities to be performed by either Party under a particular Project Schedule.
- 1.3. "Affiliate" shall mean: (i) an organization, which directly or indirectly controls a Party to this Agreement, (ii) an organization, which is directly or indirectly controlled by a Party to this Agreement, and (iii) an organization which is controlled directly or indirectly by the ultimate parent company of a Party, where "control" as per (i) to (iii) is defined as owning fifty percent or more of the voting stock of a company or by having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization. With respect to Ventana, the term "Affiliate" shall include neither Chugai nor Foundation (nor their respective subsidiaries) unless Ventana opts for such inclusion of Chugai or Foundation by giving written notice to Blueprint.
  - 1.4. "Agreement" has the meaning set forth in the first paragraph of this Agreement.
- 1.5. "<u>Annotated Data</u>" means patient information associated with each Sample provided by or on behalf of Blueprint to Ventana for use in a Project under this Agreement; all such Annotated Data shall be Highly Sensitive Data of Blueprint.
- 1.6. "<u>Applicable Laws</u>" means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county,

city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the regulatory authorities that may be in effect from time to time.

- 1.7. "<u>Assay</u>" means an assay, which may be "*Research Use Only*" assay in a pre-clinical setting, or which may be an IVD, a complementary diagnostic, or a companion diagnostic (or an investigational or prototype version of the foregoing) that is directed to one or more Biomarkers, and shall include any biological materials, associated reagents, procedures, instrumentation and/or software necessary to perform the Assay, but shall exclude any Samples that the Assay is intended to test.
- 1.8. "<u>Background Intellectual Property</u>" means Intellectual Property, which is Controlled by a Party or its Subsidiaries, and (i) is in existence as of the effective date of the respective Project Schedule, or (ii) is conceived, discovered, reduced to practice or writing, generated or developed by such Party or its Subsidiaries, or otherwise coming into the Control of a Party or its Subsidiaries, during the Term independently of the respective Project, excluding Inventions and Project Results.
  - 1.9. "Biomarker" means one or more specific genes, genetic sequences, proteins or biomarkers.
- 1.10. "Biomarker Data" means data (or the results of analysis thereof) consisting of determinations of genomic alterations or variations that is derived from Samples or Clinical Trials using a Ventana Assay in the course of Development Activities performed under any Project Schedule, including any such data with respect to the relationship of a Biomarker to the presence, absence or risk of a specific disease or condition. Biomarker Data shall not include any Clinical Outcomes Data or other data pertaining to the Blueprint Compound.
- 1.11. "<u>BLA</u>" or "<u>Biologics License Application</u>" is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce pursuant to the FD&C Act.
- 1.12. "<u>Blueprint Background Intellectual Property</u>" means Background Intellectual Property in the Diagnostic Field which is Controlled by Blueprint (or a Blueprint Subsidiary) consisting of Know-How about an Assay or Biomarker that relates to the Blueprint Product that is necessary for the performance by Ventana of Activities under a particular Project Schedule, excluding, for clarity, any Inventions, Project Results and Specific Diagnostic Intellectual Property.
- 1.13. "Blueprint Compound" means: (i) a biological or chemical substance that is the active ingredient used or contained in a therapeutic product that is identified as the subject of a Project Schedule, and (ii) backup compounds to (i); [...\*\*\*...].
  - 1.14. "Blueprint Indemnitee" has the meaning set forth in Section 14.1.
  - 1.15. "Blueprint Inventions" has the meaning set forth in Section 8.4.
  - 1.16. "Blueprint Product" means any pharmaceutical product containing a Blueprint Compound.
  - 1.17. "Blueprint Project Results" has the meaning set forth in Section 8.2.
- 1.18. "Blueprint Trademark Rights" means any Trademark Rights used by Blueprint or its Affiliates in connection with the commercialization of the Blueprint Product (other than the Trademark Rights or corporate names Controlled by Ventana and its Affiliates) that are Controlled by Blueprint or its Affiliates as of the Effective Date or at any time during the Term.
- 1.19. "<u>Business Day</u>" means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York are permitted or required to be closed.
- 1.20. "<u>cGCP</u>" means the current good clinical practice applicable to the clinical development of any Blueprint Product or Ventana IVD used in a Project under Applicable Laws, including 21 CFR Parts 50, 54, 56, 312, and 812, as may be applicable, and applicable guidance documents published by the FDA and international standards.

- 1.21. "<u>cGMP</u>" or "<u>Good Manufacturing Practices</u>" means the standards that apply to the design and manufacture of any Blueprint Product or Ventana IVD used in a Project, including 21 CFR Parts 210, 211 and 820, as may be applicable, as well as all applicable guidance published from time-to-time by the FDA and the International Conference on Harmonisation ("ICH") Guidelines ICHQ7A Good Manufacturing Practice Guidance for API or the principles and guidelines of Good Manufacturing Practices for Medicinal Products as defined with EC Directive 2003/94/EC and associated EC Guide to Good Manufacturing Practice.
- 1.22. "<u>Chugai</u>" means Chugai Pharmaceutical Co., Ltd, with offices located at 1-1 Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo 103-8324, Japan, and its Subsidiaries, but excluding in any event Spring or any of its Subsidiaries.
- 1.23. "Clinical Outcomes Data" means data (or the results of analysis thereof) from Clinical Trials conducted by or on behalf of Blueprint or any of its Affiliates that is useful to select patients that will benefit from the use of, to de-select patients that will not benefit from the use of, or for whom the risks of use of the Blueprint Product would outweigh the benefits from, to determine or predict disease prognosis from the use of, or to otherwise affect health outcomes associated with, in each case, the Blueprint Product or with respect to any other therapeutic product used in combination with the Blueprint Product. For clarity, all such Clinical Outcomes Data shall be Highly Sensitive Data of Blueprint.
- 1.24. "<u>Clinical Trial</u>" means a clinical trial involving the Ventana IVD or the Blueprint Product that is referenced in a Project Schedule, including an investigation involving human subjects of a Blueprint Product undertaken or sponsored by Blueprint as part of the development of such pharmaceutical product to obtain information relating to patient outcome or selection for therapy with such pharmaceutical product, which includes the use of the Ventana IVD or any prototype of it developed in the respective Project.
- 1.25. "<u>Commercialization</u>" and "<u>Commercialize</u>" shall refer to all activities (including Activities) undertaken relating to the pre-marketing, marketing, distribution, importing/exporting, offering for sale, sale and support of a Blueprint Product or Ventana IVD, and manufacturing or having manufactured) a Blueprint Product or Ventana IVD for such purposes.
  - 1.26. "Commercialization Plan" has the meaning set forth in Section 5.6.
- 1.27. "<u>Commercially Reasonable Efforts</u>" means, with respect to a Party's Activities, good faith use of the efforts and resources which would customarily be used by that Party in performing those same Activities at an arms-length basis for Third Parties and its Affiliates; [...\*\*\*...].
- 1.28. "<u>Committee</u>" means the JSC, JDC, JCC, JPC or any other committee established by the JSC; "<u>Committees</u>" means two or more of the foregoing.
- 1.29. "Confidential Information" means: (i) confidential and proprietary data and information of a Party, which is provided by or on behalf of such Party to the other Party in connection with this Agreement, whether prior to, on or after the Effective Date, including data and information relating to any Assay, diagnostic, Biomarker, compound (including the Highly Sensitive Data), Materials, research project, work in process, future development, scientific, engineering, launch, manufacturing, marketing, business plan, financial or personnel matter relating to such Party, its present or future products, sales, suppliers, customers, employees, investors and business, and (ii) the terms and conditions of this Agreement and any Project Schedule; provided, however, that, except in the case of Highly Sensitive Data, all such information is marked or described in writing as "confidential", "proprietary" or the like. Notwithstanding the foregoing, Confidential Information shall not include Joint Project Results or Joint Inventions, which shall be subject to Section 7.7.
  - 1.30. "Contract Laboratories" has the meaning set forth in Section 4.6.
- 1.31. "<u>Control</u>" or "<u>Controlled</u>" means, with respect to any Intellectual Property, item of information or other intangible right, possession of the right, whether directly or indirectly, and whether by

ownership, license or otherwise, to grant the other Party access, a license or sublicense, as provided for herein, without violating the terms of any written agreement with any Third Party, [...\*\*\*...].

- 1.32. "<u>Cutoff Value</u>" means, with respect to the Blueprint Product and any Ventana Assay, any proposed or established cutoff value(s) for use in scoring results including that serves as thresholds for determining positive and negative results.
  - 1.33. "Deliverables" means the data or Materials to be provided by either Party in connection with a particular Project.
- 1.34. "<u>Development Activities</u>" means the Activities consisting of or directed to development, optimization, validation or clinical testing of, or obtaining Regulatory Approval for, the Blueprint Product or the Ventana Assay, to be performed by either Party under a particular Project Schedule; <u>provided</u>, <u>however</u>, that in the case of Blueprint with regard to any Clinical Trial it carries out under a Project Schedule, Development Activities shall be deemed to include only those aspects of such Clinical Trial relating to the use of any Ventana Assay or the validation of any Ventana Assay for use with the Blueprint Product.
- 1.35. "<u>Diagnostics Field</u>" means *in vitro* testing for research use, or exploratory use, or as a clinical diagnostic for use in the diagnosis or on-going evaluation of a disease or medical condition, including the prediction or monitoring of a response to a therapeutic agent, selection for therapy and also use as an *in vitro* diagnostic.
- 1.36. "<u>Disclosing Party</u>" means, with respect to Confidential Information and Materials, the Party providing such Confidential Information or Materials to the other Party.
  - 1.37. "<u>Dispute</u>" has the meaning set forth in Section 15.1.
  - 1.38. "<u>Divisional Affiliate</u>" means, with respect to:
  - 1.38.1. Ventana, (i) those Affiliates that are not engaged in the Pharmaceutical Field, or (ii) other Affiliates whose services Ventana requires to perform its obligations hereunder, provided that in the case of any Affiliate covered by clause (ii), Ventana shall be subject to the covenant set forth in Section 16.3.1. Notwithstanding part (ii) of this Section 1.38.1, neither Genentech, Roche's pharmaceutical group nor Chugai shall be considered Ventana's Divisional Affiliates under this Agreement.
  - 1.38.2. Blueprint, (i) those Affiliates that are not engaged in the provision of services in the Diagnostic Field, or (ii) other Affiliates whose services Blueprint requires to perform its obligations hereunder, provided that in the case of any Affiliate covered by clause (ii), Blueprint shall be subject to the covenant set forth in Section 16.3.2.
  - 1.38.3. For purposes of this Section 1.38 and also Section 16.3: (i) the provision of diagnostic products or services by Ventana (or its Affiliates) to a Person in the Pharmaceutical Field shall not be construed as being engaged in the Pharmaceutical Field, and (ii) Blueprint's (or its Affiliates') research and development activities in the Diagnostic Field, obtaining of products and services from a Person in the Diagnostic Field, or promoting an Assay for use with its therapeutic products, shall not be construed as being engaged in the Diagnostic Field.
- 1.39. "<u>Drug Development Failure</u>" means that Blueprint has: (i) discontinued development of the Blueprint Compound in the applicable Indication for any reason (<u>e.g.</u>, as a result of safety, efficacy or other technical issues, as a result of intellectual property issues or in the event that Blueprint reasonably determines that further development or commercialization of the Blueprint Product is not commercially reasonable), and (ii) if applicable, withdrawn or will withdraw at an appropriate time relative to the ongoing clinical trials any applicable INDs and/or clinical trial applications for the applicable Indication with respect to the Blueprint Product.
  - 1.40. "Drug Specific Assay Matters" means the following matters: (i) the Cutoff Value(s); and

- (ii) those aspects of the fourth module of the PMA to the extent related to the safety or efficacy of the Blueprint Product.
- 1.41. "<u>EEA</u>" means the European Economic Area as its membership may be constituted from time to time, and any successor thereto, and which, as of the Effective Date, is comprised of the members of the European Union together with Iceland, Liechtenstein and Norway.
  - 1.42. "Effective Date" has the meaning set forth in the first paragraph of this Agreement.
- 1.43. "European Union" means the European Union as its membership may be constituted from time to time, and any successor thereto, and which, as of the Effective Date, consists of Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, and that certain portion of Cyprus included in such organization.
  - 1.44. "FDA" means the United States Food and Drug Administration and any successor agency.
  - 1.45. "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as amended.
  - 1.46. "Force Majeure Event" has the meaning set forth in Section 16.5.
- 1.47. "<u>Foundation</u>" means Foundation Medicine, Inc., with offices located at 150 Second Street, Cambridge, MA 02141, USA, and its Subsidiaries, but excluding in any event Spring or any of its Subsidiaries.
- 1.48. "<u>Genentech</u>" means Genentech, Inc., with offices located at 1 DNA Way, South San Francisco, CA 94080, USA, and its Subsidiaries, but excluding in any event Spring or any of its Subsidiaries.
- 1.49. "<u>Generic Leftover Materials</u>" are Materials that: (i) are not attributable to, or associated with, the Disclosing Party, and (ii) need not be used by the Receiving Party to satisfy the purpose for which the Disclosing Party disclosed the Materials.
  - 1.50. "Highly Sensitive Data" has the meaning set forth in Section 7.2.
- 1.51. "<u>Hybridoma</u>" means a hybridoma or cell line that expresses an antibody necessary for production or use of an Assay, and all Know-How therewith, relating to the use of such hybridoma.
  - 1.52. "Indemnitee" has the meaning set forth in Section 14.3.
  - 1.53. "<u>Indemnitor</u>" has the meaning set forth in Section 14.3.
  - 1.54. "Independent Development" has the meaning set forth in Section 11.2.
- 1.55. "<u>Indication</u>" means any disease or condition that a product can be used to treat or prevent, which use is the subject of a Regulatory Approval.
- 1.56. "<u>Intellectual Property</u>" means all intellectual property rights, including rights to Patents, Know-How, utility models, registered designs, design rights, copyrights, copyright registrations and trade secrets, and similar intellectual property rights; <u>provided</u>, <u>however</u>, that "Intellectual Property" shall not, unless clearly indicated to the contrary, include names, logos, trademarks, trade dress and service marks.
- 1.57. "Invention" shall mean any inventions or discoveries, whether or not patentable, first conceived or reduced to practice by employees or agents of either Party or its Divisional Affiliates or jointly by employees or agents of both Parties or their Divisional Affiliates in the course of Development Activities performed under any Project Schedule, together with all Patents (including applications) claiming or covering such inventions or discoveries and all other intellectual property rights with respect thereto.
  - 1.58. "IRB" means an Institutional Review Board, independent ethics committee, or any equivalent authority.

- 1.59. "IVD" or "in vitro diagnostic" means: (i) in the United States, an Assay intended for use in the disease prognosis or treatment selection / prediction, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae, as more fully defined in 21 C.F.R. § 800 et seq., including so-called complementary diagnostics (e.g., those used to identify patients whose Biomarker status is associated with a changed therapeutic response), companion diagnostics for a pharmaceutical product as defined in FDA's "Draft Guidance for Industry and Food and Drug Administration Staff In Vitro Companion Diagnostic Devices", (ii) in the European Union, an in vitro diagnostic medical device as defined in the European directive 98/79/EC, and (iii) any similar definitions set by Regulatory Authorities in Markets outside of the United States and the European Union.
  - 1.60. "Joint Invention" has the meaning set forth in Section 8.4.
  - 1.61. "Joint Project Patents" has the meaning set forth in Section 8.7.2.
  - 1.62. "Joint Project Results" has the meaning set forth in Section 8.2.
- 1.63. "JSC", "JCC", and "JPC" or "Joint Steering Committee", "Joint Development Committee", "Joint Commercialization Committee" and "Joint Patent Committee" have their respective meanings set forth in Sections 10.2.1, 10.3.1, 10.4.1 and 10.5.1.
- 1.64. "Know-How" means any information, improvements, practices, formulae, trade secrets, techniques, procedures, information regarding marketing, pricing, distribution, cost, sales or methods, manufacturing procedures and specifications, and test data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information); provided, however, that Know-How does not include Patents or Highly Sensitive Data.
- 1.65. "<u>Labeling</u>" (i) in the United States, the Product Insert that conforms to 21 CFR Part 201.57 for the Blueprint Product and proposed or approved Instructions For Use for the Ventana IVD that conforms to 21 CFR 801 that is approved by FDA or included in any Regulatory Documentation; (ii) outside the United States, Product inserts that conform to similar analogous standards of Regulatory Authorities.
- 1.66. "<u>Laboratory Developed Test</u>" means an in vitro diagnostic test that is designed, validated, and performed within a single laboratory and otherwise complies with FDA's guidance with respect to LDTs.
  - 1.67. "Liabilities" has the meaning set forth in Section 14.1.
  - 1.68. "Markets" means the countries set forth and designated as such in a Project Schedule.
- 1.69. "<u>Materials</u>" means Samples, biological materials, compounds, reagents, and supplies that one Party delivers or causes to be delivered to the other Party in connection with a Project.
- 1.70. "Milestone" means a milestone event specified in a Project Schedule that triggers a payment obligation on the part of Blueprint.
- 1.71. "<u>Package Instructions</u>" means instructions and/or restrictions placed on Materials, including, as applicable, Labeling on Materials that have received Regulatory Approval.
- 1.72. "<u>Party</u>" means Blueprint or Ventana as the context requires and "<u>Parties</u>" means both Blueprint and Ventana; <u>provided</u>, <u>however</u>, if consented to by both Parties in writing, a Party's Divisional Affiliate may execute a Project Schedule that is subject to the terms and conditions of this Agreement; and <u>provided</u>, <u>further</u>, that the rights and obligations of a Party (or, if applicable, such Party's Divisional Affiliate) shall apply only with respect to those Project Schedules that have been executed by such Party or Divisional Affiliate.
- 1.73. "<u>Patent</u>" means any existing or future: (i) national, regional or international patent or patent application in any jurisdiction (including any provisional, divisional, continuation, continuation-in-part,

non-provisional, converted provisional, or continued prosecution application, any utility model, petty patent, design patent or certificate of invention), (ii) any extension, restoration, revalidation, reissue, re-examination and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications, and (iii) any ex-U.S. equivalents corresponding to any of the foregoing.

- 1.74. "<u>Person</u>" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.
- 1.75. "<u>Pharmaceutical Field</u>" means the discovery, development, manufacture, use, or sale of biological or chemical substances for the medical cure, treatment, or prevention of diseases or conditions in human beings.
- 1.76. "<u>PMA</u>" means: (i) a U.S. pre-market approval application for a Class III medical device, including all information submitted with or incorporated by reference, or (ii) any analogous application to those set forth in (i) that is filed with the relevant Regulatory Authority in a country or region in the Markets, including any supplemental applications.
- 1.77. "<u>PMA Laboratory Developed Test</u>" means a Laboratory Developed Test for which a PMA is submitted and approved by the relevant Regulatory Authority.
- 1.78. "Project" means a project in one or more of the following areas: (i) Biomarker identification and validation, (ii) prototype development of a Ventana Assay, (iii) companion diagnostic proof of concept, (iv) *in vitro* diagnostic development, (v) development of the Ventana Assay for use in Clinical Trials, (vi) pivotal trial support, or (vii) PMA submission; which project ultimately may result in the creation or Regulatory Approval of a Ventana IVD under this Agreement.
- 1.79. "<u>Project Results</u>" means data, reports, Deliverables, and any other Know-How developed or produced in the course of Development Activities performed under any Project Schedule; excluding Inventions.
- 1.80. "<u>Project Schedule</u>" means an attachment to this Agreement, as described in Section 2.2 below, containing a list of Activities, Deliverables and other terms applicable to a Project.
  - 1.81. "Publication" has the meaning set forth in Section 7.6.
- 1.82. "Qualified Assignee" means, at the time of Blueprint's notice under Section 16.1.2 or 16.1.3, either: (i) an Affiliate of Ventana, or (ii) a Third Party that meets each of the following qualifications: (a) it has either assets or a market capitalization equal to or greater than [...\*\*\*...], (b) it is not in the business of manufacturing or selling instruments or reagents to Third Parties for use in in vitro diagnostic immunohistochemistry assays, and (c) it is not threatening to engage in litigation with Ventana, it is not then engaged in litigation with Ventana, and it has not engaged in litigation with Ventana during the prior five (5) years.
  - 1.83. "Reach-Through Licenses" has the meaning set forth in Section 4.4.1.
- 1.84. "<u>Receiving Party</u>" means, with respect to Confidential Information and Materials, the Party receiving such Confidential Information or Materials from the other Party or its agents.
- 1.85. "Regulatory Approval" means with respect to a regulatory jurisdiction, any and all approvals, clearances, product or establishment licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacture, use, storage, import, export, transport, or Commercialization of a product in such jurisdiction, including, where applicable, (i) pricing and reimbursement approval in such regulatory jurisdiction, (ii) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), and (iii) Labeling approval. With regard to an

- IVD, Regulatory Approval includes FDA approval of a PMA (or PMA supplement, as applicable), or as applicable FDA clearance of a 510(k) notification or FDA grant of a de novo petition for reclassification, for the IVD, the issue of a CE marking declaration of conformity by or on behalf of the manufacturer of the device in the EEA and similar approvals of Regulatory Authorities in other jurisdictions in the Markets; with regard to the Blueprint Product, NDA or BLA approval granted by the FDA, and similar approvals of Regulatory Authorities in other jurisdictions in the Markets or supplementary approvals by Regulatory Authorities.
- 1.86. "<u>Regulatory Authority</u>" means, as applicable, the FDA, the European Medicines Agency, or any other analogous regulatory authority or agency in a country or region in the Markets.
- 1.87. "Regulatory Documentation" means all: (i) submissions (including all INDs, Drug Approval Applications, IDEs, 510(k)s, de novo determinations, HDEs and PMAs), registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), including all adverse event files and complaint files, in each case ((i) and (ii)) relating to a Blueprint Product or Ventana IVD.
  - 1.88. "Replacement Diagnostic Solution" has the meaning set forth in Section 5.9.3.
  - 1.89. "Roche" means F. Hoffman-La Roche Ltd.
- 1.90. "RUO Product" means a product developed under a Ventana/Blueprint Project Schedule to be offered for sale on a "research use only" basis, including an antibody or a product comprising an antibody.
- 1.91. "Samples" means, to the extent that a Party delivers or causes to be delivered to the other Party hereunder: (i) human tissue samples, whether in blocks, slides, fresh or otherwise, (ii) human patient blood samples, clinical isolate, bodily fluids, cells, organs, and human-derived waste or other similar specimen samples, and (iii) any data or information associated with such Samples; provided, however, that xenografts not identifiable as coming from a particular natural person (e.g., xenografts used as controls) shall not be included in this definition of Samples.
  - 1.92. "Sample Requirements" has the meaning set forth in Section 3.2.1.
- 1.93. "Scoring Algorithm" means any algorithm developed by or on behalf of employees or agents of either Party or its Divisional Affiliates or jointly by or on behalf of employees or agents of both Parties or their Divisional Affiliates in the course of Development Activities performed under any Project Schedule that is used to determine the expression level of one or more Biomarkers in patients or subjects. As used herein, "Scoring Algorithm" shall include any improvement or modification to an existing algorithm.
  - 1.94. "Senior Officers" has the meaning set forth in Section 15.1.
- 1.95. "Specific Diagnostic Intellectual Property" means, on a Biomarker-by Biomarker-basis: (i) a Hybridoma Controlled by Blueprint which produces a Biomarker-specific antibody or a probe (or other molecule useful for imaging and/or quantifying a Biomarker) needed by Ventana to produce a Ventana Assay under a Project, (ii) Patents Controlled by Blueprint that could be asserted to prevent making, using or selling a Ventana Assay under a Project, or (iii) both (i) and (ii).
- 1.96. "<u>Spring</u>" means Spring Bioscience Corporation with offices at 4300 Hacienda Drive, Pleasanton, CA 94588 USA, a Subsidiary of Ventana.
  - 1.97. "Subsidiary" means any Affiliate of a Party that is directly or indirectly controlled by such Party.
  - 1.98. "<u>Term</u>" has the meaning set forth in Section 12.1.

- 1.99. "<u>Territory</u>" means worldwide.
- 1.100. "<u>Third Party</u>" means any individual or entity other than Ventana, its Divisional Affiliates, Blueprint, or Blueprint's Divisional Affiliates; for the avoidance of doubt, Genentech, Roche's pharmaceutical group and Chugai each are deemed to be Third Parties to this Agreement.
  - 1.101. "Third Party Claims" has the meaning set forth in Section 14.1.
  - 1.102. "Third Party Intellectual Property" has the meaning set forth in Section 4.2.
- 1.103. "<u>Trademark Rights</u>" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.
  - 1.104. "<u>Undisclosed Specific Diagnostic Intellectual Property</u>" has the meaning set forth in Section 4.3.
  - 1.105. "Ventana Assay" means an Assay developed by Ventana under a Project.
- 1.106. "<u>Ventana Assay Performance Data</u>" means all data, information, results and reports pertaining specifically to the technical performance and analytical validity of the Ventana Assay, including any such data generated during technical performance verification studies, method comparison for clinical utility demonstration, and clinical reproducibility studies. Ventana Assay Performance Data does not include Biomarker Data.
  - 1.107. "Ventana Indemnitee" has the meaning set forth in Section 14.2.
  - 1.108. "Ventana Inventions" has the meaning set forth in Section 8.4.
- 1.109. "<u>Ventana IVD</u>" means a Ventana Assay (including any investigational or prototype versions thereof) that is developed or Commercialized by Ventana into an IVD for use with the Blueprint Product under a Project.
- 1.110. "<u>Ventana Platform Technology</u>" means those technologies Controlled by Ventana in the Diagnostic Field that do not necessarily relate to the individual Assay, antibodies or Biomarkers described in a Project Schedule, (<u>e.g.</u>, hardware, detection chemistry, computer software programs for image analysis of biological systems, immunohistochemistry, *in situ* hybridization, automated anatomic pathology systems, Assays, diagnostic Assay development expertise, diagnostic test kits including secondary antibodies (but excluding Biomarker-specific antibodies), statistical methodologies and other formulae and analytical techniques), excluding any Biomarker Data.
- 1.111. "<u>Ventana Platform Technology Improvements</u>" means any improvement to the Ventana Platform Technology utilized under any Project Schedule, which improvement was first conceived or reduced to practice or made by or on behalf of employees or agents of either Party or its Divisional Affiliates or jointly by or on behalf of employees or agents of both Parties or their Divisional Affiliates in the course of Development Activities performed under any Project Schedule.
  - 1.112. "Ventana Project Results" has the meaning set forth in Section 8.2.
- 1.113. "<u>Ventana Trademark Rights</u>" means any Trademark Rights used by Ventana or its Affiliates in connection with the commercialization of a Ventana Assay (other than the Trademark Rights or corporate names Controlled by Blueprint and its Affiliates) that are Controlled by Ventana or its Affiliates as of the Effective Date or at any time during the Term.
- 1.114. <u>Other Definitional And Interpretative Provisions</u>. References herein to days means calendar days. The words "hereof", "herein" and "hereunder" and words of like import used in this

Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. Any capitalized term used in any Project Schedule but not otherwise defined therein shall have the meaning as defined in this Agreement. Any singular term in this Agreement shall be deemed to include the plural, any plural term the singular and the word "or" is used in the inclusive sense (and/or), whether or not the convention "and/or" is used in some places but not others. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. Ambiguities, if any, in this Agreement will not be construed against either Party, irrespective of which Party may be deemed to have authored the ambiguous provision. This Agreement will be fairly interpreted in accordance with its terms and without any strict construction in favor of or against either Party. In this Agreement, unless otherwise specified, the Project Schedules and other attachments hereto form part of the operative provision of this Agreement and references to "this Agreement" shall include references to the Project Schedules and such attachments, whether or not Project Schedules are expressly referenced.

#### 2. PROJECTS

- 2.1. <u>Responsibility</u>. As further specified in this Agreement and each Project Schedule, Blueprint shall be responsible for development and Commercialization of the Blueprint Compound and Ventana shall be responsible for development and Commercialization of the Ventana Assay. Except to the extent that such an action would violate its obligations under this Agreement or a Project Schedule, Blueprint shall have final discretion with respect to all matters regarding the Blueprint Compound and Ventana shall have final discretion with respect to all matters regarding the Ventana Assay. The Parties shall coordinate their respective Development Activities through the Joint Steering Committee, or the Joint Development Committee, as applicable.
- 2.2. <u>Project Schedules, Generally.</u> This Agreement governs all Projects undertaken at the times and locations specified in the Project Schedule in relation to each Project. Ventana shall undertake the Activities and provide the Deliverables set forth in, and for which Ventana has been allocated responsibility under, the relevant Project Schedule with the standards of care and skill to be reasonably expected in the Diagnostics Field, including adherence to applicable cGCP and cGMP practices. Blueprint shall undertake the Activities and provide the Deliverables set forth in, and for which Blueprint has been allocated responsibility under, the relevant Project Schedule with the standards of care and skill to be reasonably expected in the Pharmaceutical Field, including adherence to applicable cGCP and cGMP practices. Blueprint shall, at its own expense, ensure that any Clinical Trial involving the use of the Ventana IVD hereunder includes all necessary IRB approvals for the Blueprint Product and reimburse Ventana for the costs of all necessary IRB approvals for the Ventana IVD.
- 2.3. <u>Negotiation of Project Schedules</u>. During the period commencing on the Effective Date and continuing until the fifth (5th) anniversary thereafter, the Parties may negotiate in good faith to adopt one or more Project Schedules under this Agreement. The specific details of each Project conducted by the Parties under this Agreement shall be negotiated separately and specified in a written Project Schedule to be agreed upon and executed by both Parties. Each Project Schedule will describe the scope of Activities, Deliverables, Project time lines and compensation terms. Once executed by both Parties, each Project Schedule shall be incorporated in its entirety into this Agreement. Each time that the Parties agree that a new Project should be added to and come within the scope of this Agreement, the Parties shall prepare a new Project Schedule for such Project. Subject to the covenants of good faith and reasonableness (including those in Section 2.4), nothing herein shall create an express or implied obligation on the part of either Party to execute any particular Project Schedule.
- 2.4. <u>Scope Changes</u>. Each time that the Parties agree that the Activities or Deliverables should be amended or additional Activities or Deliverables should be added to and come within the scope of a

Project under this Agreement, the Parties shall prepare and execute a revised version of the Project Schedule for such Project. Upon a request to extend the scope of any Project to further Indications (i.e., detection of the antigen in different tissues) or to include additional Markets, Ventana shall: (i) not unreasonably withhold its consent to such extension, and (ii) reasonably discuss with Blueprint in good faith the necessary amendments to the respective Project Schedule. The revised Project Schedule shall have added to it a description of such new or amended Activities, provisions regarding the financial consideration (if any), and other details regarding the new or amended Activities. Ventana shall not vary from the Activities and Deliverables set out in the original Project Schedule until the Parties have agreed to do so in writing.

2.5. <u>Agreement Precedence</u>. Terms or conditions on a Project Schedule that differ from those in this Agreement take precedence over the terms and conditions in the Agreement only with respect to that particular Project Schedule, and only where the Project Schedule sets forth those terms and conditions in the Agreement that are intended to be superseded or modified for purposes of such Project Schedule.

## 3. MATERIALS AND RECORDS

3.1. <u>Materials Delivery</u>. As more specifically provided in each Project Schedule, Blueprint shall provide to Ventana the Materials specified in such Project Schedule as a responsibility of Blueprint, free of charge. If after Blueprint provides such Materials, it is determined that they do not conform to their descriptions or are not suitable for the Activities under the Project Schedule, then Blueprint shall: (i) provide new or replacement Materials or, if that is not possible, propose and discuss with Ventana in good faith an alternative, and (ii) subject to written agreement between the Parties, adjust the Project Schedule, fees and/or costs as necessary to account for any delay caused by non-conforming Materials.

#### 3.2. <u>Samples</u>.

- 3.2.1. <u>Sample Requirements</u>. Each Party acknowledges that certain of the Materials transferred hereunder may consist of Samples that are derived or collected from human subjects. Each Party further acknowledges that the transfer of Samples is a highly sensitive matter, and therefore, each Party shall ensure that all Samples transferred by or on behalf of such Party to the other Party under this Agreement shall have been collected, processed, de-identified, tracked, stored, transported, manipulated and destroyed in a manner appropriate to ensure compliance with: (i) the terms and conditions of this Agreement, (ii) any applicable requirements of an IRB, and (iii) all Applicable Laws and ethical standards, including privacy and patient confidentiality laws (collectively, (i), (ii) and (iii) are referred to as "<u>Sample Requirements</u>") in connection with the collection of the Samples.
- 3.2.2. <u>Treatment of Samples</u>. With respect to any Samples provided by or on behalf of a Party to the other Party hereunder, the providing Party shall have developed and followed such Party's documented policies and procedures with respect to the protection of the autonomy and confidentiality of the human subjects from whom the Samples were collected in compliance with the Sample Requirements. If collection of the Samples was subject to informed consent or required authorization, the Disclosing Party shall ensure that the scope of such informed consent or authorization is consistent with the transfer of (and the other Party's permitted use of) the Samples (and any accompanying data) is permitted by this Agreement and is not prohibited by Applicable Law. All Samples delivered under this Agreement shall be labelled clearly as required by any Sample Requirements.
- 3.2.3. <u>Special Case for Certain Countries</u>. In the event that (i) Applicable Law prohibits the export of Samples from a particular country or jurisdiction and (ii) Ventana cannot with Commercially Reasonable Efforts provide (or, with the prior written consent of Blueprint, contract with) a laboratory to test such Samples within such country or jurisdiction, the Parties shall work in good faith to discuss and implement an alternative for testing such Samples pursuant to the goals of the applicable Project Schedule.

3.2.4. <u>Identifiable Healthcare Information</u>. The providing Party shall not, without first obtaining the other Party's prior written consent, deliver to the other Party personally identifiable healthcare information or data relating to patients or subjects, in connection with the Samples or otherwise.

#### 3.3. <u>Use Restrictions</u>.

- 3.3.1. <u>Permissible Uses</u>. Each Receiving Party shall handle, store and use the Materials provided to it by or on behalf of the other Party in accordance with Applicable Laws, the relevant informed consent (to the extent the terms of such consent have been disclosed in writing to the Receiving Party), any applicable documentation, reasonable handling procedures, applicable common scientific standards of care, and the Disclosing Party's written instructions. Each Receiving Party may use the Materials (other than the Generic Leftover Materials) of the Disclosing Party only in connection with the Activities described in the applicable Project Schedule and for no other purpose.
- Restrictions; Respect For Package Instructions. Materials whose Package Instructions prohibit transfer to Third Parties shall not be transferred by the Receiving Party to Third Parties without the other Party's written consent. Subject to the foregoing, none of the Materials provided by or on behalf of one Party to the other Party hereunder or pursuant to any Project Schedule shall be transferred by a Receiving Party to any Third Parties except as: (i) otherwise agreed by the Parties in writing, and (ii) to Contract Laboratories or (sub)contractors who are legally bound to treat the Materials in a manner consistent Receiving Party's obligations hereunder. The Receiving Party shall not use the Materials of the Disclosing Party for testing in or treatment of human subjects except to the extent described in the applicable Project Schedule. The Receiving Party understands and agrees that the Materials may be experimental in nature the Receiving Party shall be solely responsible for any property damage, personal injury or death attributable to the use, storage or handling of the Materials of the Disclosing Party in a manner proscribed by either the Package Instructions or generally recognized scientific standards; provided that nothing in this Section 3.3.2 is intended or shall be construed to limit a Party's indemnification obligations under Article 14 in the case of personal injury or death caused by the use or administration of the Ventana IVD or the Blueprint Product. To the extent that the Disclosing Party includes with any Materials (including, for example, the Blueprint Product, the Blueprint Compound, Ventana Assay or Ventana IVD) specific Package Instructions (including, for example, package inserts or legends reading "For Research Use Only" or "For Investigational Use Only"), the Receiving Party shall only use such Materials in accordance with its accompanying Package Instructions.
- 3.4. <u>Documents Required for Activities</u>. Each Party will, upon request, timely provide the other Party with reasonable access to documents and records in its possession (or that it controls) related to the Ventana IVD or Blueprint Product that are reasonably necessary or useful for the performance by the requesting Party of each Project under this Agreement. This shall include: (i) Blueprint providing Ventana with reasonable access to its protocols (including forms of patient consents) for any Clinical Trial involving the use of the Ventana IVD and Blueprint Confidential Information and documentation relating to the Blueprint Product if and to the extent reasonably necessary to enable Ventana to perform the Activities included in the Project Schedule, and (ii) Ventana providing Blueprint with reasonable access to Ventana Confidential Information and documentation relating to the Ventana IVD if and to the extent reasonably necessary to enable Blueprint to perform the Activities included in the Project Schedule.

#### 4. THIRD PARTY INTERACTIONS

## 4.1. Subcontractors.

4.1.1. <u>Generally</u>. Any involvement of Third Party contractors by either Party for a

material portion of the Activities for which it is responsible requires the prior written consent of the other Party, such consent not to be unreasonably withheld. The foregoing shall not be construed as: (i) preventing either Party from (a) using individual consultants, (b) subcontracting those minor portions of the Activities that it would customarily subcontract in the ordinary course of business, (c) subcontracting to Divisional Affiliates, or (ii) preventing Blueprint from subcontracting drug development activities that are either substantially unrelated to Ventana (e.g., API manufacture, supply chain contracts), otherwise addressed hereunder (e.g., Contract Laboratories in accordance with Section 4.6) or that are customarily subcontracted by companies in the Pharmaceutical Field (e.g., contracting with generally reputable contract research organizations and clinical sites and investigators). Prior written consent shall not be required in the cases (i) through (ii), above.

- 4.1.2. <u>Confidentiality and Assignment of IP</u>. To the extent that a Party utilizes Third Party contractors or Divisional Affiliates to perform tasks within the scope of a Project, such Party shall ensure all such Third Party contractors and Divisional Affiliates: (i) are obligated to treat the other Party's Confidential Information in accordance with the provisions of Article 7, and (ii) are subject to obligations to assign or license Inventions and other work product resulting from such contracted services in accordance with the provisions of Article 8. Each Party shall be solely responsible for the acts, performance and compensation of its respective Third Party contractors.
- 4.2. <u>Third Party Intellectual Property</u>. Subject to Section 4.4, with respect to any Ventana IVD, Ventana shall be responsible, at its own cost and expense, for obtaining and maintaining any licenses or other rights to access or use any Intellectual Property Controlled by a Third Party that, in the absence of a license, would be infringed by Ventana's development, manufacture, use or Commercialization of such Ventana IVD pursuant to this Agreement ("<u>Third Party Intellectual Property</u>"). Such license obtained by Ventana shall cover Ventana's development, manufacture, use and Commercialization of the Ventana IVD in connection with the stratification or selection of patients for treatment with the Blueprint Product and development of the Ventana IVD (as an *in vitro*, complementary or companion diagnostic) with the Blueprint Product.
- 4.3. <u>Specific Diagnostic Intellectual Property.</u> Prior to executing any Project Schedule hereunder, Blueprint shall make good faith efforts to disclose to Ventana the existence of any Specific Diagnostic Intellectual Property, in which case the Parties may (but are not obligated to) negotiate a commercially reasonable, separate, non-exclusive license agreement providing Ventana with access to such Materials or Patent Rights for use in an Assay, it being understood that such Assay may support both Blueprint's and Third Parties' pharmaceutical products. The Parties acknowledge and agree that those portions of Specific Diagnostic Intellectual Property which Blueprint sublicenses (as opposed to licenses) to Ventana shall be subject to restrictions and conditions imposed by Blueprint's licensors. [...\*\*\*...].

## 4.4. Reach-Through Licenses.

4.4.1. Reach-Through Licenses Defined. Notwithstanding Section 4.2, in the event that any such in-license by Ventana of Third Party Intellectual Property (other than Third Party Intellectual Property that could block the use, manufacture or sale of Ventana Platform Technology) would require Ventana to undertake an expense greater than [... \*\*\*...] in any one calendar year for the right to use or practice such Third Party Intellectual Property to develop, manufacture, use or Commercialize a Ventana IVD for the applicable Indication(s), [... \*\*\*...]; provided that in no event shall Blueprint be obligated to contribute to or offset any license fees or other amounts paid or due to such Third Party to the extent reasonably allocable to the development, manufacture or commercialization of any Ventana Assay for use with any product other than the Blueprint Product (including any therapeutic product of any Affiliate or Third Party). Licenses negotiated between Ventana and any such Third Party under this Section 4.4 (for which Blueprint has an obligation to negotiate with respect to a contribution to offset such expense) shall be referred to as ("Reach-Through Licenses").

- 4.4.2. <u>Pre-Existing Reach-Through Licenses</u>. Prior to executing a Project Schedule, the performance of which Ventana in good faith knows would cause it to seek an economic contribution under an existing Reach-Through Licenses with a Third Party, Ventana shall disclose to Blueprint the financial terms of such Reach-Through License to Blueprint and the amount of any contribution by Blueprint with respect thereto shall be agreed by the Parties in the applicable Project Schedule. In no event shall Blueprint have an obligation to offset the expense of any such existing Reach-Through License prior to execution of the Project Schedule.
- 4.4.3. <u>Future or Unknown Reach-Through Licenses</u>. From time to time, one or both of the Parties may become aware of a potential Reach-Through License which was not known prior to execution of the applicable Project Schedule. In such case, Ventana shall regularly inform Blueprint about the necessity and the negotiation status of Reach-Through License and shall consult with Blueprint regarding the content of the negotiation drafts of agreements for such Reach-Through Licenses. Ventana shall reasonably take into account any comments from Blueprint on the terms of the license agreements that are applicable to all Reach-Through Licenses for the development and Commercialization of Blueprint Products and shall seek Blueprint's approval of such terms before executing agreements for Reach-Through Licenses.
- 4.5. Other Licenses; Cooperation. For the avoidance of doubt, Blueprint shall be solely responsible, at its own expense, for obtaining and maintaining any licenses or other rights to access or use any Third Party Intellectual Property (other than as described in Section 4.2 and Section 4.4) that is necessary for the development, manufacture, use or Commercialization of any Blueprint Product. Each Party agrees to cooperate reasonably with the other Party to assist the other Party's acquisition of any licenses that it is obligated to obtain pursuant to this Section 4.5; provided, however, that such cooperation shall not (except as set forth in Section 4.4) include the undertaking of any financial obligations such as the payment of royalties, milestones or the like.
- Contract Laboratories. The Parties may use Third Party contract laboratories for the performance of certain services such as Samples testing pursuant to a Project Schedule ("Contract Laboratories"). Blueprint and Ventana shall cooperate reasonably on a case-by-case basis when contracting with such Contract Laboratories. Ventana shall have the right to select Third Party Contract Laboratories for use in activities directed to demonstrating analytical validation of the Ventana Assay (including intra-laboratory reproducibility), in each case, with the prior written consent of Blueprint, such consent not to be unreasonably withheld, conditioned or delayed. In the absence of an agreement under a Project Schedule to the contrary, however, Blueprint shall be responsible and authorized to select and contract with the Contract Laboratories that it has engaged to assess the clinical utility of the Ventana IVD, subject to Ventana's prior written consent, not to be unreasonably withheld, conditioned or delayed. Blueprint and Ventana shall endeavor to ensure that the Contract Laboratories are properly certified to do the clinical utility work according to the applicable Project Schedule for the Project and this Agreement. Ventana shall be solely responsible for the manufacture and supply of the Ventana IVD to the Contract Laboratories for clinical utility testing and for sufficient educating and training the Contract Laboratories personnel as necessary for conducting the clinical utility testing. Ventana also shall be responsible for ensuring that each such Contract Laboratory has or is provided the necessary equipment (including any upgrades) needed to perform the Ventana IVD; provided, however, that such equipment shall be provided on terms to be agreed upon between Ventana and the Contract Laboratories that are consistent with the standard terms currently being offered by Ventana to its other Third Party customers for such equipment. If a Contract Laboratory and Ventana are unable to enter into and perform under an agreement that is consistent with Ventana's standard terms, then the Parties shall select an alternate Contract Laboratory (which selection shall be subject to the terms of this Section 4.6).

#### 4.7. <u>Regulatory Matters</u>.

4.7.1. <u>In General</u>. Subject to Section 4.7.2 and each applicable Project Schedule,

Ventana shall be responsible for preparing, obtaining and maintaining Regulatory Approvals for the Ventana IVD; Blueprint shall, at its discretion, be responsible for preparing, obtaining and maintaining Regulatory Approvals, if any, for the Blueprint Product. Ventana shall ensure that the Ventana IVD developed in a Project complies with all Applicable Laws. Ventana shall use Commercially Reasonable Efforts to ensure that the Ventana IVD receives Regulatory Approval in the time specified in the applicable Project Schedule. The Parties shall cooperate and assist each other reasonably in the Regulatory Approval process and reasonably coordinate and align their Regulatory Approval filings, or equivalents, and Activities pertaining thereto as far as necessary in connection with Ventana's obtaining and maintaining Regulatory Approvals for the Ventana IVD for use with the Blueprint Product. For the avoidance of doubt, each Party acknowledges that Ventana's obligation to seek Regulatory Approvals in countries or territories other than the Markets identified in a Project Schedule shall be subject to additional costs for matters such as regulatory filing fees, preparation of regulatory filings and, if necessary, support for Clinical Trials to be negotiated in good faith pursuant to Section 2.4. If Ventana fails or refuses despite Ventana's use of Commercially Reasonable Efforts, to seek or obtain or maintain Regulatory Approvals for the Ventana IVD in any country in any Market then the Parties shall negotiate in good faith to select and agree upon and implement, a Replacement Diagnostic Solution(s) that is reasonably acceptable to the Parties in the impacted Market or Markets.

- 4.7.2. <u>Coordination on Regulatory Submissions for Ventana IVDs</u>. Ventana shall provide Blueprint with an opportunity to review and comment on all filings that are required to be made to obtain or maintain Regulatory Approval of any Ventana IVD to the extent that such filing involves any Drug Specific Assay Matter or any material discussion of the Blueprint Product that has not been the subject of a prior opportunity for review and comment by Blueprint. Ventana shall consider in good faith Blueprint's comments with respect thereto to the extent relating to any Blueprint Product and, additionally, any Drug Specific Assay Matter shall be further subject to Section 10.6. To the extent legally permissible, Ventana shall provide Blueprint with an opportunity to attend any scheduled meeting with a Regulatory Authority regarding obtaining or maintaining Regulatory Approval of any Ventana IVD for use with the Blueprint Product solely to the extent such meeting includes (or is reasonably anticipated to include) consideration of any Drug Specific Assay Matter or any other material discussion of the Blueprint Product or use of such Ventana IVD specifically in connection with the Blueprint Product.
- 4.7.3. <u>Right of Reference to Ventana</u>. Blueprint shall, and shall ensure that its Divisional Affiliates shall, upon request, provide Ventana with any appropriate letters or other similar documentation necessary to authorize such Person to cross-reference and rely (on a non-exclusive basis) upon the contents of any of Blueprint's or its Affiliates' Regulatory Documentation and Regulatory Approvals for the Blueprint Product, for the purposes of the filing, obtaining and maintaining of Regulatory Approvals for any Ventana IVD for use with the Blueprint Product in the Markets; <u>provided</u>, <u>however</u>, that, for clarity, Blueprint's obligations shall not require Blueprint or its Divisional Affiliates to provide to Ventana such letters, documentation or authorization for the purpose of supporting approval of any Ventana Assay for use with any product other than the Blueprint Product.
- 4.7.4. <u>Right of Reference to Blueprint</u>. Ventana shall, and shall ensure that its Divisional Affiliates shall, upon request provide Blueprint (and Blueprint's designated Affiliates and (sub)licensees) with any appropriate letters or other similar documentation necessary to authorize such Person to cross-reference and rely (on a non-exclusive basis) upon the contents of any of Ventana's or its Divisional Affiliates' Regulatory Documentation and Regulatory Approvals for any Ventana IVD for use with the Blueprint Product, for the purposes of the filing, obtaining and maintaining of Regulatory Approvals for the Blueprint Product for use in conjunction with such Ventana IVD(s) in the Markets.

- 4.7.5. <u>Rights In Regulatory Documentation</u>. As between the Parties, each Party shall retain sole all right, title and interest in and to its Regulatory Documentation, and except for the limited right of reference specified in Sections 4.7.3 and 4.7.4, nothing herein shall be construed as transferring, or otherwise granting, expressly or by implication, to the other Party any rights in or to such Regulatory Documentation.
- 4.8. <u>Covenants of Ventana Concerning Highly Sensitive Data/Documentation of Blueprint</u>. Ventana covenants to Blueprint that Ventana and its Divisional Affiliates shall not, directly or indirectly, provide Clinical Outcomes Data, Regulatory Documentation of Blueprint or other Highly Sensitive Data of Blueprint, to any Third Party (other than Regulatory Authorities as permitted in Section 4.7), or permit any Third Party access to, or the opportunity to attend meetings (or portions thereof) with Regulatory Authorities specifically regarding any Ventana Assay for use specifically with the Blueprint Product. Without limitation to the foregoing, Ventana covenants to Blueprint that Ventana and its Divisional Affiliates shall not, directly or indirectly, with respect to any Clinical Outcomes Data, Regulatory Documentation of Blueprint or other Highly Sensitive Data of Blueprint: (i) submit or resubmit such data or documentation to any Regulatory Authority, (ii) rely on any such data or documentation in any submission to any Regulatory Authority by specifically referencing it, or (iii) provide to any Third Party any such data or documentation, in each case of (i), (ii) and (iii) above, for the purpose of obtaining or maintaining Regulatory Approval for any Indication for use of any Assay (including a Ventana Assay) with any therapeutic product other than the Blueprint Product.

#### 5. COMMERCIALIZATION

- 5.1. General Principles. The Parties agree that the ultimate goal of each Project conducted under this Agreement is the Commercialization of a Ventana IVD used in connection with the Blueprint Product, and Ventana acknowledges that availability of such Ventana IVD as a companion diagnostic might be a condition for obtaining a Regulatory Approval for a Blueprint Product. Upon notice from Blueprint, the Parties shall negotiate in good faith a Project Schedule to further govern Commercialization of the Ventana IVD. The Parties shall cooperate on the following principles: (i) the determination of whether and to which extent and in what countries the Blueprint Product shall be Commercialized shall be within Blueprint's sole discretion, (ii) [...\*\*\*...]: (a) neither Party shall be obligated to undertake any action that it believes in good faith is unlawful, or which exposes it to regulatory or legal risks (e.g., infringement of Third Party Intellectual Property rights, non-compliance with export or corruption laws, etc.) in excess of those which it customarily assumes, (b) subject to clause (a), a goal of the Parties shall be to ensure that after Regulatory Approval the Ventana IVD can be sold in each such Market by Ventana's Divisional Affiliates through the use of Commercially Reasonable Efforts. If a commercially reasonable plan for Commercializing the Ventana IVD in a given Market is not possible despite Ventana's use of Commercially Reasonable Efforts, or Ventana otherwise fails to Commercialize the Ventana IVD in any country in any Market, then the Parties shall negotiate in good faith to select and agree upon and implement, a Replacement Diagnostic Solution(s) that is reasonably acceptable to the Parties in the impacted Market or Markets.
- 5.2. <u>Joint Commercialization Efforts</u>. Under the direction and oversight of the JCC, and to the extent provided pursuant to any Project Schedule, Blueprint and Ventana will use Commercially Reasonable Efforts to collaborate on efforts to Commercialize the Ventana IVD and the Blueprint Product. Blueprint and its Divisional Affiliates may encourage use of the Ventana IVD (where legally permitted and in accordance with Ventana's policies and guidelines) in connection with efforts to Commercialize the Blueprint Products related to the Ventana IVD.
- 5.3. <u>Ventana Obligations</u>. Upon Regulatory Approval of the Ventana IVD in each Market, Ventana (or its Divisional Affiliates, as applicable) shall use Commercially Reasonable Efforts, at their expense, to Commercialize the Ventana IVD in such Markets in accordance with the Project Schedule.
  - 5.4. <u>Blueprint Obligations</u>. Upon Regulatory Approval of the Blueprint Product in each Market,

the Commercialization by Blueprint and its Divisional Affiliates (and any Third Parties involved in marketing and selling the Blueprint Product) of such Blueprint Product in such Market shall be at its and their sole expense and discretion. As permitted by Applicable Laws, Blueprint and its Divisional Affiliates (and any Third Parties involved in marketing and selling the Blueprint Product) shall have the right to reference testing with the Ventana IVD (where legally permitted and in accordance with Ventana's applicable policies and guidelines that are disclosed to Blueprint reasonably in advance in writing) to the target customer segment.

- 5.5. <u>Coordination</u>. Under the direction and oversight of the JCC, and at their own respective costs, each of the Parties will (as considered reasonable by each Party, in its sole discretion, and to the extent legally allowed and in accordance with the Parties' promotional policies and guidelines) discuss scientific support, marketing strategies and sales force initiatives and [... \*\*\*...], including identification of Markets, alignment of package inserts, instructions for use, data sheets, marketing collateral and materials, Publications, training reimbursement strategies, support of investigator initiated studies, sharing of market research information and use of advisory boards/key opinion leaders. As it becomes available or known to Blueprint, Blueprint shall provide Ventana with information concerning its launch plans and its anticipated release timelines for the Blueprint Product.
- 5.6. <u>Commercialization Plan</u>. Under the direction and oversight of the JCC, the Parties will work cooperatively to develop one or more commercialization plans for each Ventana IVD for which Regulatory Approval for use with the Blueprint Product has been obtained or is expected (each being a "<u>Commercialization Plan</u>"). Each Commercialization Plan shall include a description of those Commercialization activities to be conducted by Ventana in support of the launch of and the Commercialization of the Ventana IVD pursuant to and subject to this Agreement, deliverables and projected timelines for completion of activities/delivery of deliverables and, if any, [...\*\*\*...]. Each Commercialization Plan shall be subject to the written approval of the Parties and shall include provisions for the supply of the Ventana IVD in sufficient quantities in the countries in the Markets.

## 5.7. <u>Trademarks and Labeling</u>.

- 5.7.1. <u>Ventana References to Blueprint</u>. Ventana shall ensure that its, and its Divisional Affiliates', references to Blueprint (and any product, trademark, logo or trade name of Blueprint or any of its Affiliates) in connection with the Ventana IVD or the Commercialization activities (including any use in any Labeling, Package Instructions, the Ventana IVD description, technical information, instructions for use, promotional material, advertising and other information and messaging to be included with the Ventana IVD or otherwise to be provided by Ventana to potential purchasers or users of the Ventana IVD) shall comply with Section 9.4.
- 5.7.2. <u>Blueprint References to Ventana</u>. Blueprint shall ensure that its, and its Divisional Affiliates', references to Ventana (and any product, trademark, logo or trade name of Ventana or any of its Affiliates) in connection with the Blueprint Product or the Commercialization activities (including any use in any Labeling, Package Instructions, the Blueprint Product description, technical information, instructions for use, promotional material, advertising and other information and messaging to be included with the Blueprint Product or otherwise to be provided by Blueprint to potential purchasers or users of the Blueprint Product) shall comply with Section 9.5.
- 5.8. <u>Manufacture and Supply</u>. Ventana shall be solely responsible for the manufacture of the Ventana IVD in compliance with cGMP requirements, as applicable. Until commercial launch of a Ventana IVD, Ventana shall ensure that adequate supplies of the Ventana IVDs (or prototypes), are made available to any Contract Laboratories and any Clinical Trial sites in accordance with Ventana's generally applicable commercial terms and any forecast, order, payment, delivery and shipment terms mutually agreed between the Parties in good faith negotiations unless already set forth in the Project Schedule. Subject to receiving sufficient notice from Blueprint, Ventana shall use its Commercially Reasonable Efforts to ensure that it

maintains sufficient inventories of the Ventana IVD as is necessary for the conduct of the Clinical Trials and to support the launch of the respective Blueprint Product. Ventana shall be responsible for the transfer of the Ventana IVD or the prototypes thereof to the Contract Laboratories involved in the Clinical Trials. If Ventana fails to make available adequate supplies of the Ventana IVD to laboratories in a Market in violation of this Section 5.8, then Ventana shall provide, and the Parties shall negotiate in good faith to select and agree upon and implement, one or more Replacement Diagnostic Solution with respect to the applicable Ventana IVD.

#### 5.9. <u>Supply Failures</u>.

5.9.1. <u>Generally</u>. For Ventana IVDs (or investigational use only (IUO)/investigational device exemption (IDE) prototypes of Ventana IVDs that have passed the design lock stage gate), if Ventana fails or refuses despite Ventana's use of Commercially Reasonable Efforts, to develop, manufacture, supply, have distributed or otherwise make commercially available or adequately meet the development needs or the commercial demand for the Ventana IVD (or such IUO/IDE prototypes of the Ventana IVD) as agreed in a Project Schedule in the Markets, or if Ventana is otherwise required to provide a Replacement Diagnostic Solution under this Agreement, then upon Blueprint's notice to Ventana, the Parties shall negotiate in good faith to select and agree upon and implement, a Replacement Diagnostic Solution(s) that is reasonably acceptable to the Parties in the impacted Market or Markets.

5.9.2. [...\*\*\*...]

Replacement Diagnostic Solution. A "Replacement Diagnostic Solution" as defined under this Section 5.9.3. 5.9.3 is an alternative arrangement consisting of one or more of the following: (i) an arrangement (to be facilitated by Ventana acting in good faith) whereby Blueprint may distribute the Ventana IVD in a country or countries in the relevant Markets and have the right to purchase from Ventana or its Divisional Affiliates the necessary quantities of Ventana IVD at a commercially reasonable price, (ii) an arrangement whereby a Third Party may distribute the Ventana IVD in a country or countries in the relevant Markets, (iii) an arrangement to transport tissue samples to countries in the relevant Markets where the Ventana IVD is available, (iv) a licensing arrangement whereby Blueprint may use, make, have made, sell, offer for sale, import or otherwise exploit the Ventana IVD or an alternative product to the Ventana IVD for use with the Blueprint Product in a country or countries, (v) [...\*\*\*...], (vi) supplying the antibodies, reagents (except for those reagents that are part of the Ventana proprietary detection systems) and the Know-How that may be useful or necessary for Blueprint or a Third Party to develop an alternative product to the Ventana IVD, including in such quantities as reasonably required by Blueprint for development and Commercialization purposes, and providing such assistance as is reasonably requested by Blueprint, (vii) enabling a Laboratory Developed Test at a mutually acceptable laboratory (to the extent such alternative arrangement would meet Blueprint's needs consistent with Applicable Law), (viii) enabling a PMA Laboratory Developed Test at a mutually acceptable laboratory (to the extent such alternative arrangement would meet Blueprint's needs consistent with Applicable Law), or (ix) [...\*\*\*...], or (x) such other mutually agreeable arrangement to help support sales of the Blueprint Product, with the ultimate goal of ensuring that diagnostic testing using the Ventana IVD in connection with the Blueprint Product is (or remains) available in the countries in the relevant Markets as reasonably practicable. In the case of each Replacement Diagnostic Solution, Ventana shall grant to Blueprint and, if agreed by the Parties, to one or more Third Parties, the necessary licenses to implement such Replacement Diagnostic Solution under Intellectual Property Controlled by Ventana, and Ventana or its Divisional Affiliates shall reasonably assist Blueprint in obtaining the requisite services and/or materials (including, as applicable, Biomarker-specific antibodies for use in an alternative product to the Ventana IVD in quantities that enable Blueprint to meet the demands in the relevant country(es) in the relevant Market(s)) from distributors, Affiliates of Ventana or Third Parties needed for the Replacement

Diagnostic Solution. The Parties acknowledge and agree that any Intellectual Property which Ventana sublicenses (as opposed to licenses) under this Section 5.9.3 to Blueprint shall be subject to restrictions and conditions imposed by Ventana's licensors.

- 5.9.4. Antibody Supply Agreement. If, at any time, Blueprint desires to enter into a supply agreement with Spring or another applicable Subsidiary of Ventana with respect to supply of any Biomarker-specific antibody used in a Ventana IVD, then Ventana shall use reasonable efforts to facilitate Blueprint's negotiation of such agreement with Spring or other applicable Subsidiary on commercially reasonable terms, provided that Ventana and Blueprint agree that such supply agreement shall not require Spring (or the other applicable Subsidiary) to sell and deliver such antibody supply pursuant to such supply agreement except in circumstances where Ventana's obligation to provide to Blueprint a Replacement Diagnostic Solution pursuant to this Agreement has been triggered or in other circumstances expressly agreed in such supply agreement.
- 5.10. RUO Product. In the event that Ventana or Blueprint believes it advantageous to release an RUO Product, the JDC will discuss whether or not to make such RUO Product available. If the Parties agree through the JDC to make such RUO Product available, then the Parties will cooperate to work with Ventana's Affiliate, Spring, or another Third Party, to develop, manufacture and commercialize such RUO Product. Each Party shall ensure that Confidential Information Controlled by the other Party regarding the potential content, use, results and details of such RUO Product will be discussed and approved by the JDC before being publicly communicated. If Ventana or Blueprint believes such RUO Product would be detrimental to its business strategy, such considerations shall be discussed between the Parties and a good faith approach shall be mutually agreed upon by the JDC. The foregoing shall not be construed as requiring Ventana or Spring to obtain Blueprint's permission to develop and commercialize any RUO Product, provided that if any such RUO Product contains the same antibody as any Ventana Assay developed under any Project Schedule, then Blueprint shall not be associated with such product. Neither Ventana, Spring nor any of Ventana's Affiliates shall use any Highly Sensitive Data, or any Materials provided by Blueprint, in connection with such RUO Product without Blueprint's prior written consent. Each Party shall ensure that in no event shall an RUO Product include, or be described or portrayed as an IVD.
- 5.11. Access. Authorized representatives of Blueprint shall have the right to access Ventana's facilities used in the performance of Activities and to inspect the records that relate to the accuracy of Third Party expenses described in Section 6.2, and/or the performance of the Project Schedules under this Agreement. Unless otherwise agreed by the Parties, such access and inspection shall be: (i) on reasonable prior notice, (ii) during Ventana's regular business hours, (iii) not unreasonably disruptive to Ventana's business operations, (iv) reasonable in scope and duration, (v) not unduly burdensome to Ventana's personnel, (vi) not more than once per year (except if for cause or circumstances reasonably warrant), and (vii) subject to Ventana's generally applicable confidentiality, security and safety procedures for Third Party auditors (which procedures shall not be inconsistent with the terms of this Agreement).

#### 6. PAYMENT

6.1. <u>Fees and Invoices</u>. Blueprint shall pay Ventana in accordance with the fee/payment provisions set forth in the applicable Project Schedule and payments are made in USD by wire transfer to a bank account specified by Ventana in writing. Following the end of each quarter, Ventana shall submit to Blueprint an itemized invoice for the fees and milestones payable in respect of that quarter to the following e-mail address:

Blueprint ap@blueprintmedicines.com
Purchase order (PO) number of the respective Project in the reference line.
Name of invoice requisitioner.

Blueprint shall pay such invoices within thirty (30) days of receipt of the invoice.

- 6.2. <u>Reimbursable Expenses</u>. In addition to the fees payable under Section 6.1, Blueprint shall reimburse all reasonable out of pocket travel expenses validly incurred and itemized by Ventana in performing the Activities in the amounts set forth in the applicable Project Schedule or otherwise only and to the extent approved in advance by Blueprint in its sole discretion.
- 6.3. <u>Sunshine Act Reporting</u>. Each Party shall report any reportable payments or transfers of value that it makes to covered recipients pursuant to §6002 of the Affordable Care Act of 2010, and other similar laws in connection with Activities under this Agreement.
- 6.4. <u>Taxes</u>. The amounts payable by Blueprint to Ventana pursuant to this Agreement (each, a "<u>Payment</u>") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 6.4, Ventana shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by Blueprint) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Blueprint shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold.
- 6.5. <u>Late Payments</u>. If Blueprint fails to pay any undisputed amount specified in this Agreement on or before date it is due, the amount owed will bear interest at the Citibank, NA base lending rate plus [...\*\*\*...] from such date until paid; <u>provided</u>, <u>however</u>, that if this interest rate is held to be unlawful or unenforceable for any reason, the interest rate will be the lesser of (i) the Citibank, NA base lending rate plus [...\*\*\*...] and (ii) the maximum rate allowed by Applicable Laws at the time payment is due.
- 6.6. <u>Fee Adjustments</u>. In the event that any Third Party in the Pharmaceutical Field works with Ventana to develop or commercialize an Assay for the same Biomarker as any Biomarker that is included in a Ventana Assay under this Agreement, then the Parties may negotiate to adjust the fees/payment provisions under any of the affected Project Schedule(s) or Section 6.1, or the expenses reimbursable pursuant to Section 6.2, which adjustments shall only become effective upon the mutual written agreement of both Parties.

#### 7. CONFIDENTIALITY

#### 7.1. Confidential Information.

- 7.1.1. Generally. Except in connection with the Activities or with the performance of this Agreement, including the permitted use in filings for Regulatory Approval, or as otherwise permitted by either this Agreement or the Disclosing Party, the Receiving Party shall, during the Term and for a period of five (5) years thereafter: (i) not use any Confidential Information of the Disclosing Party, (ii) maintain the Disclosing Party's Confidential Information in confidence using the same degree of care that the Receiving Party uses for its own Confidential Information, but in no event using less than reasonable care, and (iii) not disclose or transfer any Confidential Information of the Disclosing Party (or any materials which contain such Confidential Information), to any Third Party; provided, however, that disclosure shall be permitted to the Receiving Party's directors, officers, employees, agents or advisors (including attorneys, accountants and members of such Party's standing Scientific Advisory Board) and permitted sub-contractors (and those of its Divisional Affiliates) who reasonably require such Confidential Information for the purposes hereof and who (except in the case of attorneys) are bound by obligations of non-use and confidentiality with respect to such Confidential Information no less stringent than those set forth in this Section 7.1.
- 7.1.2. <u>Disclosures to Certain Third Parties</u>. The Receiving Party shall be permitted to disclose Confidential Information to bona fide potential or actual (x) development or

commercialization partners or licensees for the Blueprint Product (or, for clarity, any combination therapy including the Blueprint Product or Blueprint Compound) and sources of debt or equity financing for the Receiving Party, (y) accountants, consultants, bankers, and financial advisors, and (z) parties to a merger, acquisition or similar transaction involving the Receiving Party (including attorneys, accountants, consultants, bankers or financial advisors to any party covered by clauses (x)-(z)), in each case, who reasonably require such Confidential Information (including as part of their due diligence investigations) and who are informed of the confidential nature of such information and this Agreement and (except in the case of attorneys) are bound by obligations of non-use and confidentiality with respect to such Confidential Information substantially similar to the Receiving Party's obligations hereunder; <u>provided</u>, <u>however</u>, that notwithstanding the foregoing and subject to Section 7.1.1, with respect to Confidential Information comprising the terms of this Agreement or any financial terms contained in any Project Schedule, except to the extent permitted pursuant to Section 7.4 or 7.5, neither Party may disclose such Confidential Information to a Third Party without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed.

## 7.2. <u>Highly Sensitive Data</u>.

- 7.2.1. <u>Defined</u>. As used herein, "<u>Highly Sensitive Data</u>" means, regardless of whether it is marked as confidential or not: (i) confidential and proprietary data and information consisting of clinical outcomes of the Compound (including Clinical Outcomes Data), (ii) personally identifiable information (<u>e.g.</u>, Annotated Data) with respect to or from subjects in Clinical Trials or individual donors from whom Samples were derived, and (iii) to the extent related to the Blueprint Product, all confidential and proprietary data and information: (a) supplied to Ventana by Blueprint, (b) generated in any Clinical Trial of a Blueprint Product, (c) generated by the Contract Laboratories in the course of any Project under this Agreement, (d) Cutoff Value(s) for the Ventana IVD, or (e) related to Commercialization; <u>provided</u>, <u>however</u>, that in the case of (iii), in no event shall Highly Sensitive Data be deemed to include information pertaining to Ventana Platform Technology or Ventana Assay Performance Data. Highly Sensitive Data shall be deemed to be the Confidential Information of Blueprint.
- 7.2.2. <u>Use and Disclosure</u>. Ventana shall maintain Highly Sensitive Data in strict confidence in accordance with Section 7.1 above, and shall use coded identifiers for such Highly Sensitive Data for additional security. Ventana's obligations with respect to Highly Sensitive Data described clauses (i) and (ii) of Section 7.2.1 shall continue for a minimum period of twenty (20) years after the Term, and thereafter in perpetuity unless such Highly Sensitive Data has been destroyed. In addition to the obligations set forth in Section 7.1, Ventana shall not disclose any of Blueprint's Highly Sensitive Data to any Third Party (other than Third Party contractors in accordance with Section 4.1), nor shall Ventana disclose any of Blueprint's Highly Sensitive Data to employees, agents or subcontractors of Chugai, Genentech, Inc., or any employees, agents or subcontractors of Ventana's Affiliates if such persons are engaged in or involved with the discovery, development or commercialization of pharmaceutical products.
- 7.2.3. <u>Special Cases.</u> Notwithstanding the foregoing in this Section 7.2: (i) Project Results constituting or relating to Cutoff Value(s) for the Ventana IVD for use in conjunction with the Blueprint Product shall be deemed the Confidential Information of Blueprint unless and until such information is made public by Blueprint or as a result of Labeling approval by a Regulatory Authority, and (ii) upon prior notice to Blueprint, Ventana shall have the right to disclose to Regulatory Authorities Highly Sensitive Data consisting of the aggregated incidence of a particular Biomarker in a particular intended use if requested by such Regulatory Authority.
- 7.3. <u>Non-Confidential Information</u>. The obligations set forth in Section 7.1 and 7.2 shall not apply to any information that: (i) was possessed by the Receiving Party or any of its Affiliates prior to

disclosure or development under this Agreement, (ii) was developed by the Receiving Party or any of its Affiliates independently from disclosure or development under this Agreement, (iii) is now or later becomes publicly available other than by breach of this Agreement by Receiving Party or any of its Affiliates, or (iv) is available to the Receiving Party or any of its Affiliates from a Third Party that is not legally prohibited from disclosing such information. Notwithstanding the foregoing, clauses (i) and (ii) of this Section 7.3 shall not operate to relieve Ventana of any of its obligations with respect to Highly Sensitive Data of Blueprint or, to the extent that they constitute or relate to any Cutoff Value for any Ventana IVD for use with a Blueprint Product, Project Results.

- 7.4. Compelled Disclosure; Other Corporate Communications. The Receiving Party may disclose Confidential Information of the Disclosing Party pursuant to applicable judicial or governmental law, regulation, request or order. In such case the Receiving Party either shall ensure that a protective order to protect the confidentiality of such Confidential Information is in place or, when allowed under Applicable Laws, take reasonable steps to provide the Disclosing Party sufficient prior notice in order to contest such law, regulation or order at the expense of the Disclosing Party. At the Disclosing Party's request and expense, the Receiving Party shall contest such law, regulation or order, such request made in the Disclosing Party's reasonable discretion. In the event the Receiving Party ultimately is required to disclose such Confidential Information then the Receiving Party shall disclose only such portion of the Confidential Information that is required to be disclosed (based on the advice of the Receiving Party's legal counsel) and shall seek, at the Disclosing Party's request and expense, a protective order to protect the confidentiality of such Confidential Information. Without limitation to the foregoing, for the avoidance of doubt, Blueprint shall have the right to include in corporate communications and other public announcements reasonably discrete analysis of Clinical Trial data concerning the use of the Ventana Assay in such Clinical Trials in order to describe a trial design or interpret the trial results; provided that Blueprint shall provide Ventana with prior written notice of any such proposed disclosure related to the Ventana Assay and a reasonable opportunity to review and comment on such proposed disclosure, which comments shall be considered in food faith by Blueprint.
- 7.5. Securities Filings. Notwithstanding any term or condition of this Agreement to the contrary, any Party or its Affiliates may disclose this Agreement, the subject matter hereof or any Party's activities hereunder pursuant to Applicable Law, including the rules and regulations of the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a securities exchange on which its or its Affiliate's securities are listed (or to which an application for listing has been submitted), provided that such Party shall provide the other Party with prior written notice of such proposed disclosure and a reasonable opportunity to review and comment on such proposed disclosure (including, if applicable, a proposed redacted version of this Agreement to request confidential treatment for this Agreement). The other Party shall promptly provide its comments in a reasonable manner in order to allow the Party seeking disclosure to make, file or otherwise submit such disclosure within applicable timelines required by Applicable Law, which comments shall be considered in good faith by the disclosing Party.
- 7.6. <u>Publication</u>. The Parties shall have the right to publish or present data or any portion thereof for their publication objectives (a "<u>Publication</u>") in accordance with this Section 7.6. Blueprint will be responsible for and control the timing and scope of any Publication of Blueprint Project Results. Ventana will be responsible for and control the timing and scope of any Publication of Ventana Project Results. Any Publications of the Joint Project Results must be agreed and approved by both Parties. Blueprint shall not publish or present the Ventana Project Results or any portion thereof for any Publication without Ventana's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), and Ventana shall not publish or present Blueprint Project Results or any portion thereof for any Publication without Blueprint's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). Such Publication shall be subject to the provisions of this Agreement relating to confidentiality and non-disclosure, and shall be consistent with academic standards. At least sixty (60) days prior to submission of a Publication that requires the approval of the other Party, the publishing Party shall submit to the other

Party for review any proposed Publication and the other Party shall review the proposed Publication and provide its comments to the publishing Party no later than thirty (30) days prior to the proposed submission date for the Publication; provided, however, that if such Publication is an abstract the foregoing periods of sixty (60) days and thirty (30) days shall be reduced to ten (10) Business Days and five (5) Business Days, respectively. Upon the other Party's notice to the publishing Party that the other Party reasonably believes that one or more Patent applications should be filed which relate to Project Results owned by the other Party or Joint Project Results prior to any Publication, the publishing Party shall delay the Publication until such Patent application(s) have been filed; provided, that the other Party will cooperate in expeditiously filing any such Patent application(s); and, provided, further, that any such delay of a Publication will not exceed one hundred and eighty (180) days from the date of such notice by the other Party to the publishing Party. If the other Party believes that any Publication contains Confidential Information belonging to the other Party, the other Party will notify the publishing Party, which will remove all references to such Confidential Information prior to publication, presentation or use. Notwithstanding the foregoing, neither Party shall be required to seek the permission of the other Party to repeat any information in a Publication that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 7.6, provided that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable. Each Party acknowledges and agrees that this Section 7.6 is not intended to, and shall not be construed to, limit, restrict or require a Party to limit or restrict the publication or the results of any Clinical Trials by investigators or sites participating in such Clinical Trials, provided that such Party has entered into written agreements with such investigators or sites requiring them to grant such Party (and by extension, the other Party) reasonable and customary rights to review in advance of such publications. Notwithstanding the foregoing, each Party acknowledges and agrees that nothing contained herein shall require either Party to include in its agreements with investigators or sites participating in such Clinical Trials any right of such Party or the other Party to block any publication or presentation (or portion thereof) by such investigators or sites, and the Parties further acknowledge and agree that neither Party shall be in breach of this Section 7.6 as a result of any failure or breach by such sites or investigators in complying with their obligations to the contracting Party with respect to publications (including advance review).

7.7. <u>Confidentiality of Joint Project Results and Joint Project Inventions</u>. Without limitation to anything in this Article 7, notwithstanding that Joint Project Results and Joint Project Inventions are not Confidential Information, each Party shall, for the Term of this Agreement and for twenty (20) years thereafter, treat any Joint Project Results and Joint Inventions in accordance with such Party's reasonable and customary confidentiality practices.

#### 8. INTELLECTUAL PROPERTY OWNERSHIP

- 8.1. <u>Ownership of Background Intellectual Property</u>. Each Party (and its respective Affiliates) shall own all right, title and interest in and to its (and their) respective Background Intellectual Property. Each Party acknowledges and agrees that, except for the licenses expressly granted in Article 9 below, neither Party (nor their respective Affiliates) shall have any rights to, or licenses under, the other Party's Background Intellectual Property.
- Ownership of Clinical Outcomes Data and Project Results. Blueprint shall own all Clinical Outcomes Data. Ownership of Project Results shall be determined as follows: (i) Blueprint shall, as between the Parties, own all Project Results that: (a) constitute Clinical Outcomes Data or (b) otherwise relate solely to the Blueprint Product or any other therapeutic product used in combination with the Blueprint Product, including the composition, use, method of use or method of manufacture of the Blueprint Product or any other therapeutic product used in combination with the Blueprint Product ("Blueprint Project Results"), (ii) Ventana shall own all Project Results that: (a) constitute Ventana Assay Performance Data (excluding any data with respect to the Cutoff Value(s) for the Ventana IVD for use in conjunction with the Blueprint Product or any other therapeutic product used in combination with the Blueprint Product), or (b) otherwise relate solely to the Ventana Assay or any Ventana Platform Technology Improvement ("Ventana Project Results"), and (iii) all other Project Results, including: (x) Project Results consisting of: (1) Cutoff Values for the Ventana IVD for use in conjunction with the Blueprint Product (or any other therapeutic product used in combination with the Blueprint Product), and (2) Biomarker Data, and (y) Project Results consisting of or relating to the Scoring Algorithm, shall be jointly owned by the Parties ("Joint Project Results"); provided, however, that Cutoff Value(s) for use with the Blueprint Product (or any other therapeutic product used in combination with the Blueprint Product) shall be subject to Section 7.2. Subject to the licenses granted in Article 9 and rights of reference granted in Section 4.7, each Party shall have the right to Exploit the Joint Project Results without a duty of seeking consent or accounting to the other Party; provided that each Receiving Party shall, for the Term of this Agreement and for [...\*\*\*...] thereafter, treat any Joint Project Results and Joint Inventions as the confidential information of such Receiving Party and shall refrain from disclosure of such Joint Project Results and Joint Inventions to Third Parties except to

the extent that disclosure thereof is in accordance with such Receiving Party's reasonable and customary practice (including, as appropriate and customary, pursuant to confidentiality agreements with Third Party recipients).

- 8.3. Transfer of Project Results. Ventana shall use reasonable efforts to promptly provide to Blueprint all Project Results covered by Section 8.2 (i) (and hereby assigns, and shall cause its subcontractors permitted under Section 4.1 to so assign, all of its and their right, title, and interest in such Project Results) to Blueprint. Blueprint shall use reasonable efforts to promptly provide to Ventana all Project Results covered by Section 8.2 (ii) (and hereby assigns, and shall cause its subcontractors permitted under Section 4.1 to so assign, all of its and their right, title, and interest in such Project Results) to Ventana. Acting under the oversight of the JPT or JSC as applicable, each Party: (i) shall use reasonable efforts to promptly provide to the other Party all Joint Project Results that constitute Deliverables under any Project Schedule or that are otherwise reasonably requested by the other Party, and (ii) hereby assigns to the other Party, and shall cause its Divisional Affiliates who perform Development Activities to so assign, an equal joint interest in and to Joint Project Results, in each case as is necessary to fully effect the ownership provided for in Section 8.2. The Parties agree, upon request by the other Party and at the other Party's cost and expense, to promptly execute any and all documents reasonably necessary or appropriate to memorialize, effect or perfect the assignments under this Section 8.3 throughout the Territory.
- 8.4. Ownership of Inventions. Acting under the oversight of the JPT or JSC as applicable, the Parties shall promptly notify each other in confidence of any Inventions. Ownership of Inventions shall be determined by the following provisions: (i) Blueprint shall, as between the Parties, own all Inventions (regardless of inventorship) that (a) arise out of Clinical Outcomes Data, and/or (b) relate solely to the Blueprint Compound or any other therapeutic product, including the composition, use, method of use or method of manufacture of the Blueprint Product or other therapeutic product ("Blueprint Inventions"), (ii) Ventana shall own all Inventions (regardless of inventorship) that relate solely to the Ventana Assay or to any Ventana Platform Technology Improvement ("Ventana Inventions"); and (iii) all Inventions comprised or consisting of the Scoring Algorithm for any Ventana Assay (including Cutoff Value(s) for the Ventana Assay) developed under or in connection with a Project and all other Inventions (i.e., Inventions other than those covered by clause (i) or clause (ii)) (regardless of inventorship), including all other Inventions relating to the Diagnostic Field, shall be jointly owned by the Parties ("Joint Inventions"). Subject to the licenses granted in Article 9 and the rights of reference granted in Section 4.7, each Party shall have the right to (and the right to license its interest therein to Affiliates and Third Parties to) use, make, have made, offer for sale, sell and import goods and services claimed by the Joint Inventions without a duty of seeking consent or accounting to the other Party.
- 8.5. <u>Transfer of Inventions</u>. Where applicable under Section 8.4, the Parties agree to and do hereby assign, and shall cause their respective Subsidiaries and Divisional Affiliates who perform Development Activities under this Agreement or any Project Schedule to so assign, any and all right, title, and interest in such Inventions to the other Party, in each case as is necessary to fully effect the ownership provided for in Section 8.4. The Parties agree, upon request by the other Party and at the other Party's cost and expense, to promptly execute any and all documents deemed necessary or appropriate by the other Party to memorialize, effect or perfect the assignments under this Section 8.4 throughout the Territory.
- 8.6. <u>Background Patents</u>. Ventana shall have the right, but no obligation, to prosecute and maintain, and to control, enforce, and defend worldwide, at its own expense, Ventana Background Intellectual Property. Blueprint shall have the right, but no obligation, to prosecute and maintain, and to control, enforce, and defend worldwide, at its own expense, Blueprint Background Intellectual Property.

## 8.7. <u>Prosecution and Enforcement of Project Patents</u>.

- 8.7.1. <u>Prosecution of Blueprint Project Patents and Ventana Project Patents</u>. Blueprint shall have the right, but no obligation, to prosecute and maintain any Patents claiming any Blueprint Inventions and Ventana shall have the right, but no obligation, to prosecute and maintain any Patents claiming any Ventana Inventions.
- 8.7.2. <u>Prosecution of Joint Project Patents</u>. In the case of any Patents claiming Joint Inventions ("<u>Joint Project Patents</u>"), Blueprint shall have the first right, but not the obligation, at its sole cost and expense, using counsel agreeable to the JPC, to prosecute and maintain any Joint Project Patents. Blueprint will supply Ventana with an advance copy of any Joint Project Patent and any documents relevant and material to the filing, prosecution and maintenance of such Joint Project Patent, and will consider in good faith any comments thereon made by Ventana.

Blueprint will promptly provide copies of any papers related to the filing, prosecution and maintenance of each Joint Project Patent for Ventana's files, including a copy of the Joint Project Patent as filed together with notice of its filing date and serial number. If Blueprint elects not to prepare and file, or to abandon during prosecution, any Joint Project Patent, it will so inform Ventana in writing and, upon written notice to Blueprint, Ventana may, in its sole discretion, prepare, file and/or prosecute such Joint Project Patent at its own cost and expense. The Parties agree to cooperate to execute all necessary and lawful papers and instruments, to make all rightful oaths and declarations and to provide reasonable consultation and assistance as may be necessary in the preparation, prosecution, maintenance, and enforcement of any Joint Project Patents.

8.8. Patent Term Restoration. The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 102(c) (pre-AIA 35 U.S.C. 103(c)) for United States Patents. The Parties shall cooperate with each other, including to provide necessary information and assistance as the other Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to the Joint Project Patents and any other Patents claiming Inventions. In the event that elections with respect to obtaining such patent term restoration are to be made, Blueprint shall have the right to make the election and Ventana agrees to abide by such election.

## 9. LICENSES

- 9.1. <u>Blueprint Generic Assay License to Ventana</u>. Blueprint hereby grants Ventana a perpetual, irrevocable, royalty-free, non-exclusive license in the Territory under Blueprint Background Intellectual Property and, subject to Section 4.3, the Undisclosed Specific Diagnostic Intellectual Property, to the extent reasonably necessary to make, have made, use, sell, offer for sale, import and otherwise Commercialize the Ventana Assay in the Diagnostic Field in accordance with this Agreement. The license granted in this Section 9.1 is not sublicensable, except to Ventana's Divisional Affiliates and any Third Party engaged in the development, manufacture or Commercialization of the Ventana Assay. For clarity, nothing contained in this Section 9.1 is intended or shall be construed to grant to Ventana or its Affiliates any license to use, make, have made, sell, offer for sale, import or otherwise exploit any Blueprint Product.
- 9.2. <u>Blueprint Product Specific License to Ventana</u>. Blueprint hereby grants Ventana a royalty-free, non-exclusive license in the Territory under any Specific Diagnostic Intellectual Property, the Blueprint Inventions, the Blueprint Project Results and Blueprint's interests in any Joint Inventions and Joint Project Results to the extent reasonably necessary to make, have made, use, sell, offer for sale, import and otherwise Commercialize the Ventana IVD with the Blueprint Product in the Diagnostic Field during the Term in accordance with this Agreement. The license granted in this Section 9.2 is not sublicensable, except to Ventana's Divisional Affiliates and any Third Party engaged in the development, manufacture or Commercialization of the Ventana IVD. For clarity, nothing contained in this Section 9.2 is intended or shall be construed to grant to Ventana or its Affiliates any license to use, make, have made, sell, offer for sale, import or otherwise exploit any Blueprint Product.
- 9.3. <u>Ventana License to Blueprint</u>. Ventana hereby grants to Blueprint a royalty-free, non-exclusive license in the Territory under: (i) Ventana's Know-How and Ventana's interests in any Joint Inventions and Joint Results to the extent reasonably necessary to make, have made, use, sell, offer for sale, import and otherwise Commercialize the Blueprint Product (including for use with any Assay) irrevocably and in perpetuity in accordance with this Agreement, and (ii) Ventana's Background Intellectual Property, the Ventana Inventions and the Ventana Project Results to the extent reasonably necessary to make, have made, use, sell, offer for sale, import and otherwise Commercialize the Blueprint Product with the Ventana

IVD during the Term in accordance with this Agreement. The license granted in this Section 9.3 is not sublicensable, except to Blueprint's Divisional Affiliates and any Third Party engaged in the development, manufacture or Commercialization of the Blueprint Product. For clarity, and except in connection with the Commercialization of the Blueprint Product, nothing contained in this Section 9.3 is intended or shall be construed to grant to Blueprint or its Affiliates any license to use, make, have made, sell, offer for sale, import or otherwise exploit any Ventana Assay or Ventana Platform Technology.

- 9.4. <u>Blueprint Trademark License to Ventana</u>. Blueprint, on behalf of itself and its Affiliates, hereby grants to Ventana and its Divisional Affiliates, a non-exclusive, perpetual (except as set forth in the termination section of this Agreement), royalty-free right and license to use the Blueprint Trademark Rights and corporate names of Blueprint and its Affiliates for use in performance of development Activities under a Project Schedule and the Commercialization of a Ventana IVD in conjunction or for use with, or referring to, the Blueprint Product, in each case, in the Markets; <u>provided</u>, <u>however</u>, that Ventana shall: (i) use the Blueprint Trademark Rights and corporate names of Blueprint and its Affiliates in a manner consistent with the standards provided in writing by Blueprint from time to time and that do not otherwise diminish the value of or dilute such marks and corporate names, (ii) upon request, from time to time, provide samples of the Package Instructions, packaging, Labeling, advertising or promotional materials that use such Blueprint Trademark Rights or corporate names, and (iii) promptly notify Blueprint if it becomes aware of actual or possible infringement of Blueprint Trademark Rights in connection with any Ventana Assay or the activities contemplated under this Agreement.
- 9.5. <u>Ventana Trademark License to Blueprint</u>. Ventana, on behalf of itself and its Affiliates, hereby grants to Blueprint and its Divisional Affiliates a non-exclusive, perpetual (except as set forth in the termination section of this Agreement), royalty-free right and license to use the Ventana Trademark Rights and corporate names of Ventana and its Affiliates, if applicable, for use in performance of development Activities under a Project Schedule and the Commercialization of the Blueprint Product in conjunction or for use with, or referring to, any Ventana IVD intended for use with the Blueprint Product, in each case, in the Markets; <u>provided</u>, <u>however</u>, that Blueprint shall: (i) use the Ventana Trademark Rights and corporate names of Ventana and its Affiliates in a manner consistent with the standards provided in writing by Ventana from time to time and that do not otherwise diminish the value of or dilute such marks and corporate names, (ii) upon request, from time to time, provide samples of the Package Instructions, packaging, Labeling, advertising or promotional materials that use such Ventana Trademark Rights or corporate names, and (iii) promptly notify Ventana if it becomes aware of actual or possible infringement of Ventana Trademark Rights in connection with the Blueprint Product or the activities contemplated under this Agreement.
- 9.6. <u>No Other Rights; No Implied Licenses</u>. Only the licenses and other rights expressly granted by one Party to the other Party under terms of this Agreement are of any legal force or effect. No other licenses or other rights are granted, conveyed or created (whether by implication, estoppel or otherwise).

#### 10. MANAGEMENT

#### 10.1. <u>Committees; Generally.</u>

- 10.1.1. <u>Membership and Decisions</u>. Each Party shall only appoint as representatives to a Committee those of its employees who have appropriate experience, knowledge, and ongoing familiarity with the Projects in their then-current phases. Each Party shall be free to replace such representatives to a Committee with a new representative, upon prior written notice to the other Party. Unless set forth to the contrary by the JSC, decisions of (including approval by) each Committee shall be by consensus, with each Party having one (1) vote.
- 10.1.2. <u>Meetings</u>. The JSC shall meet (either in person, telephonically or via video conference) not less than twice per year or at such other frequency as agreed by the respective JSC members; other Committees shall meet as directed by the JSC. Additional representatives of the Parties may from time to time be invited to attend Committee meetings, subject to the other Party's prior consent which shall not be unreasonably withheld, conditioned or delayed. On a meeting by meeting basis, choice of the meeting location shall alternate between the Parties and the chair of each Committee shall alternate between a representative of Blueprint and a representative of Ventana. Each Party shall bear its own expenses related to the attendance of meetings by its representatives.
- 10.1.3. <u>Management and Administration</u>. The Parties shall alternate recording minutes of the meetings and draft minutes of the meetings of each Committee, which will be generated and circulated to its members within ten

(10) Business Days following each meeting and finalized by the applicable Committee promptly thereafter.

#### 10.2. <u>Joint Steering Committee</u>.

- 10.2.1. <u>Membership and Powers</u>. Within thirty (30) days after the Effective Date, the Parties shall form a joint steering committee ("<u>Joint Steering Committee</u>" or "<u>JSC</u>") to facilitate the efficient and orderly transfer of information and coordination of processes related to the development, Regulatory Approval and Commercialization of the Blueprint Products and the Ventana IVDs that are the subject of this Agreement. The initial members of the JSC shall be: (a) the LifeCycle Leader of the Companion Diagnostic Lifecycle and the Head of CDx Partnering representing Ventana, and (b) comprised of the Vice President of Translational Medicine and the Chief Business Officer representing Blueprint.
- 10.2.2. Responsibilities. The role and responsibilities and decision-making authority of the JSC is to generally manage and optimize the collaboration between the Parties on Projects in accordance with this Agreement and each applicable Project Schedule. The JSC's responsibilities shall include the following functions: (i) facilitating the transfer of information and data required hereunder, (ii) facilitating the cooperation of the Parties, when requested, to provide the information and support required to be provided by a Party hereunder, (iii) facilitating coordinated interpretation of clinical data as reasonably necessary in connection with the performance of a Project Schedule, (iv) discussing freedom to operate in relation to any Ventana IVD, (v) coordination of planned marketing activities as required under any Commercialization Plan, (vi) forming additional Committees as the Parties may agree, (vii) resolving disputes escalated by any other Committees, and (viii) taking such other actions as may be specifically allocated to the JSC by the Parties from time to time. In the event that the JSC is unable to resolve a dispute arising hereunder, then, subject to Section 10.6, such dispute shall be escalated to the Parties' Senior Officers pursuant to Section 15.1.

#### 10.3. <u>Joint Development Committee</u>.

- 10.3.1. <u>General</u>. Upon the request of either Party, the JSC shall form a joint development committee (a "<u>Joint Development Committee</u>" or "<u>JDC</u>") for each Project. The JDC shall have the role and responsibilities and decision-making authority as set forth below. Blueprint shall reimburse Ventana for the travel and related costs for Ventana's representatives for such meetings; <u>provided</u>, that (i) such reasonable out-of-pocket travel and related costs have been approved in advance by the JDC, and (ii) such representatives of Ventana have adhered to applicable company travel guidelines as agreed upon by the JSC.
- 10.3.2. <u>Responsibilities</u>. The JDC shall be responsible for reviewing and reporting on the progress of each Project, and ensuring that each Project proceeds according to the timelines set forth in the applicable Project Schedule. The JDC shall be informed of, and each Party shall reasonably and in good faith consider the other Party's views on the following decisions prior to submission of the relevant documents to Regulatory Authorities or finalization of such decisions:

(i) approval of the requirements for the Ventana IVD; (ii) selection of the primary antibody (as applicable) for the Ventana IVD and any standards for the Ventana IVD; (iii) the Labeling (including the "Intended Use" statement to be submitted in a PMA) to be submitted in a Regulatory Submission or otherwise to be presented to a Regulatory Authority for the Ventana IVD; (iv) the decision regarding the type of approval application to be developed and filed for Regulatory Approval for the Ventana IVD (e.g., in the U.S., the decision whether the Ventana IVD will be developed for Regulatory Approval under a PMA or a 510(k)); (v) selection of any Scoring Algorithm with respect to the Ventana IVD; and (vi) the decision whether a particular RUO Product should be developed and launched.

#### 10.4. Joint Commercialization Committee.

- 10.4.1. <u>General</u>. Upon request by either Party, the Parties shall form a joint commercialization committee (the "<u>Joint Commercialization Committee</u>" or "<u>JCC</u>") comprised of three (3) representatives of each Party, to be designated by each Party in its sole discretion. The JCC shall have at least one representative responsible for Commercialization from each Party. The JCC shall be responsible for planning and coordinating the activities of the Parties with respect to the Commercialization of the Ventana IVD with the objective of assuring that: (i) the Ventana IVD is Commercialized in a manner that supports diagnostic testing for the Blueprint Product, and (ii) the Ventana IVD is commercially available and being supplied to support diagnostic testing for the Blueprint Product in all countries of the Markets in sufficient quantities.
- 10.4.2. <u>Responsibilities</u>. Unless otherwise agreed to in writing by the Parties, the responsibilities of the JCC shall include the following activities: (i) to discuss, coordinate and make efforts to align the launch, marketing and Commercialization of the Ventana IVD and the Blueprint Product, including the exchange of information on forecasted demand of the Ventana IVD for use with the Blueprint Product; (ii) to discuss and coordinate Ventana's activities supporting the Commercialization of the Ventana IVD, such as sales training (including, at Ventana's discretion, training for Blueprint sales representatives), promotion, customer service, support and education activities; (iii) to discuss and coordinate possible activities with respect to quality assurance plans (including training and monitoring programs for the Ventana IVD); (iv) to discuss and resolve issues concerning shelf-supply and emergency stocks of Ventana IVD; and (v) such other activities as mutually agreed between the Parties from time to time. The Parties acknowledge and agree that the JCC shall not have any powers to make decisions with respect to Ventana's development and Commercialization of the Ventana Assay in relation to the use of such Ventana Assay with Third Party products (including products that may be competitive to the Blueprint Product).

#### 10.5. <u>Joint Patent Committee</u>.

- 10.5.1. <u>General</u>. Upon request by either Party, the Parties shall form a joint patent committee (the "<u>Joint Patent Committee</u>" or "<u>JPC</u>") comprised of one or more representatives of each Party, to be designated by each Party in its sole discretion; <u>provided</u>, that at least one representative is a licensed patent attorney or patent agent.
- 10.5.2. Responsibilities. The JPC shall be responsible for planning and coordinating the activities of the Parties with respect to matters involving Joint Inventions and Joint Project Patents as follows: (a) allocating responsibility for prosecution of applications for Joint Project Patents, (b) providing the Parties with copies of material communications submitted to, and received from, any Patent authority regarding Joint Inventions, (c) providing drafts of any material filings or responses to be made to such Patent authorities a reasonable amount of time in advance of submitting such filings or responses so that the Parties may have an opportunity to review and comment, (d) ensuring that Joint Project Patents are not abandoned or not maintained without proper coordination, (e) conferring regarding Third Party infringement of any Joint Project Patents, misappropriation or misuse of any Joint Know-How that is subject to this Agreement, (f) conferring regarding Third Party Claims contesting the validity or enforceability of any Joint Project Patents, and (g) enforcing Joint Project Patents.
- 10.6. <u>Committee Decision-Making and Related Restrictions</u>. As further specified in this Agreement and each Project Schedule, Blueprint shall have final decision making authority with respect to all matters regarding the Blueprint Product and with respect to Drug Specific Assay Matters, and Ventana shall have final decision making authority with respect to all matters regarding the Ventana IVD (other than Drug Specific Assay Matters). Neither Ventana nor any Committee shall have any authority over the conduct of any Clinical Trial or, in each case, any protocol therefor for a Blueprint Product. No Committee shall have the power or authority to amend the terms and conditions of this Agreement.

#### 11. NON-EXCLUSIVITY; INDEPENDENCE AND NON-INTERFERENCE

- 11.1. <u>Non-Exclusive Relationship</u>. The Parties' relationship hereunder is non-exclusive. Ventana may enter into arrangements whether or not similar to those described in this Agreement with Third Parties (including its Affiliates); Blueprint also may enter into arrangements whether or not similar to those described in this Agreement with Third Parties (including its Affiliates). Nothing in this Agreement will be construed as restricting either Party's ability to acquire, license, develop, manufacture or distribute for itself, or have others acquire, license, develop, manufacture or distribute for such Party, similar technology performing the same or similar functions as the technology contemplated by this Agreement, or to market and distribute such similar technology in addition to, or in lieu of, the technology contemplated by this Agreement; <u>provided</u>, that such Party complies with all provisions herein.
- 11.2. <u>Independent Development Efforts</u>. The Parties acknowledge and agree that Blueprint, Ventana and their respective Affiliates will retain the right to perform independent development, including as further outlined in this Section 11.2. As used herein, the term "<u>Independent Development</u>" shall mean the undertaking of development work; provided, that such work is: (i) not prohibited by this Agreement, and (ii) undertaken without the unpermitted aid, application or use of any of the other Party's Background Intellectual Property or Inventions.
  - 11.2.1. <u>Independent Development by Blueprint</u>. Blueprint and its Affiliates have and shall retain ownership of all rights, title, and interest in and to the Blueprint Compound and are free to conduct Independent Development involving the use of the Blueprint Compound for any purpose (whether alone or in combination with any other product or service) and in collaboration with any Third Party. The foregoing shall include Blueprint's rights to independently utilize diagnostic tests (including *in vitro*, complementary or companion diagnostic products), other than or in addition to the Ventana IVD in connection with the development or Commercialization of the Blueprint Compound or any other compound, whether alone or in collaboration with Third Parties.
  - 11.2.2. <u>Independent Development by Ventana</u>. Ventana or its Affiliates have and shall retain ownership of all rights, title, and interest in and to the Ventana Assay and are free to conduct Independent Development involving the use of the Ventana Assay or the Ventana Platform Technology for any purpose (whether alone or in combination with any other product or service) and in collaboration with any Third Party. The foregoing shall include Ventana's rights to independently develop, utilize, or Commercialize the Ventana Assay, the Ventana Platform Technology and other diagnostic tests and platforms (including *in vitro*, complementary or companion diagnostic products), whether alone or in collaboration with Third Parties, for use either alone or in conjunction with the development or Commercialization of any pharmaceutical products other than the Blueprint Product, provided that in no event shall Ventana have any right to use or disclose any Clinical Outcomes Data, Regulatory Documentation of Blueprint or other Highly Sensitive Data of Blueprint for such purpose.

11.3. [...\*\*\*...]

#### 12. TERM AND TERMINATION

12.1. <u>Term.</u> The term of this Agreement will commence upon the Effective Date, and shall continue until terminated in accordance with this Article 12 (the "<u>Term</u>"). If all Projects hereunder have been terminated in accordance with this Article 12, then either Party may terminate this Agreement for its business convenience upon thirty (30) days' prior written notice to the other Party.

## 12.2. <u>Termination For Cause</u>.

12.2.1. <u>Termination Rights</u>. Either Blueprint or Ventana may terminate this Agreement or any Project Schedule immediately by written notice to the other Party, in the event that the other Party has failed to cure its material breach of this Agreement (or the respective Project Schedule) within sixty (60) days of its receipt of notice of such breach; <u>provided</u>, <u>however</u>, that a termination of the entire Agreement (as compared with a Project Schedule) shall only take place if the breach is material with respect to this Agreement as a whole or of a material provision of all of the Project Schedules. Either Blueprint or Ventana also may terminate this Agreement (and any or all Project Schedules) immediately by written notice to the other Party, if the other Party becomes insolvent, makes or has made

an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against it (except for involuntary bankruptcies which are dismissed within ninety (90) days) or has a receiver or trustee appointed for substantially all of its property. Regardless of which Party terminates under this Section 12.2.1, Ventana shall cease performing all work not necessary for the orderly close-out of the applicable Activities and for fulfillment of any regulatory requirements.

- 12.2.2. <u>Effect of Termination by Blueprint for Cause</u>. In the event of termination by Blueprint pursuant to Section 12.2.1, in addition to any other remedies Blueprint may have under Applicable Laws, if requested by Blueprint, the Parties shall promptly meet to prepare a close-out Project Schedule and Ventana also shall use Commercially Reasonable Efforts to conclude or transfer such Project(s), as instructed by Blueprint, as expeditiously as reasonably possible. With respect solely to the Blueprint Products being developed or Commercialized under the terminated Project(s), upon Blueprint's notice, Ventana shall provide and the Parties shall negotiate in good faith to select and agree upon and implement, one or more Replacement Diagnostic Solutions that are reasonably acceptable to Blueprint.
- 12.2.3. <u>Effect of Termination by Ventana for Cause</u>. In the event of termination by Ventana pursuant to Section 12.2.1, in addition to any other remedies Ventana may have under Applicable Laws, Blueprint shall pay Ventana any outstanding amounts due in accordance with this Agreement prior to or in connection with such termination.

## 12.3. <u>Termination by Blueprint Other Than for Cause</u>.

- 12.3.1. <u>Other Blueprint Termination Rights</u>. Blueprint may terminate any individual Project Schedule upon: (i) thirty (30) days' prior written notice to Ventana in the event of a Drug Development Failure, and (ii) thirty (30) days' prior written notice at any time and for any (or no) reason.
- 12.3.2. <u>Effect of Blueprint Termination</u>. In the event of a termination by Blueprint under this Section 12.3, with regard to the terminated Project(s): (i) Ventana shall cease performing all work not necessary for the orderly close-out of the applicable Activities, (ii) Ventana shall wind down such Project(s) in accordance with all regulatory requirements, and (iii) Blueprint shall pay Ventana all amounts due for Activities performed prior to the date of termination and on account of winding up such Project. If the Ventana Assay has entered Ventana's design control and Blueprint terminates an individual Project Schedule under part (ii) of Section 12.3.1, then [...\*\*\*...].

### 12.4. <u>Termination by Ventana Other Than for Cause</u>.

Other Ventana Termination Rights. Any Project hereunder may be terminated by Ventana on an intended use by intended use basis, upon thirty (30) days' written notice (except that in the case of clause (iii)(d), one hundred and eighty (180) days' written notice shall be required with respect to any Market for which Regulatory Approval has been obtained for a Ventana IVD) if: (i) Blueprint either does not provide reasonable assurance that it intends that the Labeling proposed for the Ventana IVD will reference the Blueprint Product, or Blueprint files for Regulatory Approval of the Blueprint Product without requesting that Ventana also file for Regulatory Approval of the Ventana IVD with Labeling that references the Blueprint Product, (ii) prior to design lock for the Ventana IVD, proceeding with the Project would require [...\*\*\*...] alterations to Ventana's Platform Technology and Ventana would be unable to implement such alterations with Commercially Reasonable Efforts, or (iii) despite the exercise of Commercially Reasonable Efforts by Ventana or its Divisional Affiliates, as applicable: (a) Ventana is not able to obtain a Third-Party license pursuant to Section 4.2 or Section 4.4 for the respective Project, (b) the further development of the Ventana IVD under the respective Project is not [...\*\*\*...] feasible despite the exercise of Commercially Reasonable Efforts, which reasons were not reasonably anticipated as of the Effective Date, (c) there are regulatory barriers that preclude the commercially reasonable development of the Ventana IVD, which barriers were not reasonably anticipated as of the Effective Date, or (d) Ventana can demonstrate that [...\*\*\*...] of the Ventana IVD in such Market will not [...\*\*\*...] the Commercialization of the Ventana IVD in such Market by a Ventana Divisional Affiliate. In the case of termination pursuant to clause (a), (c) or (d) of this Section 12.4.1, Ventana shall have the right to exercise any such termination right only on a Market-by-Market basis with respect to the applicable Market(s).

- 12.4.2. Effect of Ventana Termination. In the event of a termination by Ventana under Section 12.3.1, with regard to the terminated Project Schedule(s): (i) the Parties shall promptly meet to prepare a close-out Project Schedule, (ii) Ventana shall cease performing all work not necessary for the orderly close-out of the applicable Activities or for the fulfillment of any regulatory requirements, (iii) Ventana shall use Commercially Reasonable Efforts to conclude or transfer such Project(s), as instructed by Blueprint, as expeditiously as reasonably possible and in accordance with all regulatory requirements, and (iv) Blueprint shall pay Ventana any outstanding amounts due for Activities performed prior to or in connection with such termination. Without limitation of the last sentence of Section 12.4.1, in the event Ventana terminates an individual Project under parts (ii) or (iii) of Section 12.4.1, then solely with respect to any Blueprint Product that is the subject of the terminated Project(s), at Blueprint's request, the Parties shall negotiate in good faith to select and agree upon and implement one or more Replacement Diagnostic Solutions with respect to the applicable country(ies) in the Markets that are reasonably acceptable to both Parties.
- 12.5. Return of Materials and Confidential Information. At the earlier of completion or termination of a particular Project (or this Agreement as a whole), and except as otherwise permitted herein, each Party shall destroy or return at the other Party's expense and election, Project-related Materials (other than Generic Leftover Materials) and Confidential Information of the other Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information: (i) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing licenses or other rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes, and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes.
- 12.6. <u>Non-Exhaustive Remedy</u>. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more Project Schedules)) in accordance with the provisions hereof shall not be construed as an election of remedies in lieu of those remedies that might otherwise be available under or in connection with this Agreement.
- 12.7. <u>Survival</u>. Termination or expiration of this Agreement will not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation arising hereunder. Sections 3.2.2, 3.2.4, 3.3, 4.1.2, 4.2, 4.7.3, 4.7.4, 4.7.5, 4.8, 5.1 (last sentence only), 5.9.1, 5.9.3, and 5.9.4 (but only to the extent that at the time of such termination or expiration Ventana is obligated to provide a Replacement Diagnostic Solution to Blueprint), 5.10, 5.11, 6.1 and 6.2 (in each case solely as applicable to payment obligations that have accrued prior to the effective date of such termination or expiration), 6.3, 6.4, 6.5, 7 (subject in the case of Sections 7.1.1 and 7.2.2 to the relevant periods stated therein, as applicable), 8, 9.1 (including the third sentence of Section 4.3 to the extent necessary to give effect thereto), 9.3 (but only with respect to the grant set forth in part (i)), 9.6, 12, 13.4, 14, 15 and 16 shall

survive any termination or expiration of this Agreement, as the case may be.

#### 13. WARRANTIES AND DISCLAIMERS

- 13.1. <u>General Warranties</u>. Each Party hereby represents and warrants to the other Party as of the Effective Date that: (i) it is a corporation duly organized, validly existing, and in good standing under Applicable Laws, (ii) it has obtained all necessary consents, approvals and authorizations of all Regulatory Authorities (both inside and outside the Markets) and other Persons required to be obtained by it in connection with this Agreement, (iii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part, (iv) it has, to the best of its knowledge, the right to grant the applicable rights and licenses provided for under this Agreement, (v) all Samples that it provides to the other Party hereunder shall comply with the applicable Sample Requirements, and (vi) it shall perform its obligations and exercise its rights under this Agreement in compliance with Applicable Law.
- 13.2. <u>No Inconsistent Agreements</u>. Each of Ventana and Blueprint further hereby represents, warrants and covenants to the other Party that during the Term it will not grant or convey to any Third Party any right, license or interest in any Intellectual Property that is, or would become, inconsistent with the rights and licenses expressly granted to the other Party under this Agreement.
- 13.3. <u>No Debarment Nor Prohibited Payments</u>. Each Party hereby certifies that it will not and has not employed or otherwise used in any capacity the services of any Persons debarred under Title 21 United States Code Section 335a in performing any Activities under this Agreement. Each Party further represents and warrants that in connection with the subject matter of this Agreement: (i) none of its employees, agents, officers or directors is a Foreign Official as defined in the U.S. Foreign Corrupt Practices Act, (ii) it will not make, accept or request any payment, either directly or indirectly, of money or other assets to any Third Party where such payment would constitute violation of any Applicable Laws, including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010, (iii) regardless of legality, it shall neither make, accept nor request any such payment for the purpose of improperly influencing the decisions or actions of any Third Party, (iv) it shall report any suspected or actual violation of this Section 13.3 to the other Party upon becoming aware of the same.
- 13.4. <u>Disclaimers</u>. EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 13, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES TO THE OTHER PARTY HEREUNDER, EXPRESS, IMPLIED, OR STATUTORY, AND EACH PARTY HEREBY DISCLAIMS ANY AND ALL OTHER WARRANTIES OR REPRESENTATIONS, EXPRESS, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHTS.

#### 14. INDEMNIFICATION AND LIMITATIONS ON LIABILITY

14.1. <u>Indemnification by Ventana</u>. Ventana shall defend, indemnify and hold each of Blueprint, its Affiliates and their respective directors, officers, employees and agents, together with the successors and assigns of any of the foregoing (each, a "<u>Blueprint Indemnitee</u>") harmless from and against any and all claims, suits, actions, demands or judgments made by a Third Party (collectively, "<u>Third Party Claims</u>") and any and all resultant liabilities, damages, settlements, penalties, fines, costs or expenses (including reasonable attorneys' fees) ("<u>Liabilities</u>") to the extent that such Third Party Claims and Liabilities arise out of, or in connection with this Agreement and: (i) a Ventana Indemnitee's gross negligence or willful misconduct, (ii) a Ventana Indemnitee's violation of Applicable Laws, (iii) the breach by Ventana of any of its representations and warranties or obligations under this Agreement, (iv) personal injury or death caused by the use or administration of the Ventana IVD hereunder; <u>provided</u>, <u>however</u>, that Ventana's obligations under this Section 14.1 shall be excused to the extent that such Third Party Claims or Liabilities

arise out of (a) a Blueprint Indemnitee's gross negligence or willful misconduct, (b) a Blueprint Indemnitee's violation of Applicable Laws, or (c) the breach by Blueprint of any of its representations, warranties or obligations under this Agreement.

- 14.2. <u>Indemnification by Blueprint</u>. Blueprint shall defend, indemnify and hold each of Ventana, its Affiliates, and their respective directors, officers, employees and agents, together with the successors and assigns of any of the foregoing (each, a "<u>Ventana Indemnitee</u>") harmless from and against any and all Third Party Claims and any and all resultant Liabilities, to the extent that such Third Party Claims and Liabilities arise, out of, or in connection with this Agreement, and: (i) a Blueprint Indemnitee's gross negligence or willful misconduct, (ii) a Blueprint Indemnitee's violation of Applicable Laws, (iii) the breach by Blueprint of any of its representations and warranties or obligations under this Agreement, and (iv) personal injury or death caused by the use or administration of a Blueprint Product, and (v) medical malpractice occurring in connection with any Clinical Trials of a Blueprint Product; <u>provided</u>, <u>however</u>, that Blueprint's obligations under this Section 14.2 shall be excused to the extent that such Third Party Claims or Liabilities arise out of (a) a Ventana Indemnitee's gross negligence or willful misconduct, (b) a Ventana Indemnitee's violation of Applicable Laws, or (c) the breach by Ventana of any of its representations, warranties or obligations under this Agreement.
- 14.3. <u>Procedure.</u> A Party seeking indemnification under Section 14.1 or Section 14.2 (an "<u>Indemnitee</u>"), shall notify the other Party (the "<u>Indemnitor</u>") upon becoming aware of any Third Party Claim that may be subject to indemnification under this Section 14. Failure to provide such notice shall not constitute a waiver or release of the Indemnitee's rights to indemnification, except to the extent that such delay or failure materially prejudices the Indemnitor. The Indemnitee shall cooperate reasonably with the Indemnitor and its legal representatives in connection with the investigation and defense of any Third Party Claim or Liability covered by this Section 14. Neither Party may enter into any settlement, consent judgment or other voluntary final disposition of any Third Party Claim or Liability for which an Indemnitee seeks indemnification hereunder without the prior written consent of the other Party, if such settlement would: (i) impose any monetary obligation on the other Party or any of its Affiliates, (ii) constitute an admission of guilt or wrong-doing by the other Party or any of its Affiliates, or (iii) require the other Party or any of its Affiliates to submit to an injunction or otherwise limit the other Party's or any of its Affiliates' rights under this Agreement.
- 14.4. <u>Limitation of Damages</u>. EXCEPT IN THE EVENT OF THE GROSS NEGLIGENCE, INTENTIONAL BREACH OR FRAUD OF A PARTY, OR A PARTY'S WILLFUL AND ONGOING BREACH OF ITS OBLIGATIONS UNDER ARTICLE 7, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, MULTIPLE OR OTHER SIMILAR DAMAGES (INCLUDING ANY CLAIMS FOR LOST PROFITS OR REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT. EXCEPT FOR LIABILITIES ARISING OUT OF THIRD PARTY CLAIMS UNDER SECTIONS 14.1 OR 14.2 (WHICH LIABILITIES, REGARDLESS OF THEIR CHARACTERIZATION BY SUCH THIRD PARTY, SHALL BE CONSIDERED DIRECT DAMAGES HEREUNDER), [...\*\*\*...].
- 14.5. <u>Insurance</u>. During the Term and until the last Project conducted under this Agreement, each Party shall maintain reasonable and customary liability insurance under this Agreement, or the equivalent amount in self-insurance. It is expressly understood that this requirement does not, in any way, represent that the types and minimum limits of insurance specified herein are sufficient or adequate to protect a Party's interests or liability.

#### 15. DISPUTE RESOLUTION

15.1. <u>Resolution of Disputes by Senior Officers</u>. Any unresolved disagreement or dispute ("<u>Dispute</u>") arising at the JSC or otherwise shall be referred to the Parties' respective senior officers

designated below (the "Senior Officers"), or their respective designees, for resolution through good faith negotiations over a period of up to thirty (30) days. To the extent that a Party's Senior Officer delegates his/her responsibility for resolution of a Dispute to another officer of such Party, such Party shall ensure that the designee has all necessary and appropriate authority to fully resolve the Dispute on behalf of such Party. No such Senior Officer shall be a Party's representative on the JSC or any other Committee hereunder. Such Senior Officers are as follows:

For Blueprint: Chief Executive Officer

For Ventana: The individual to whom Ventana's most senior JSC member reports.

15.2. <u>Arbitration</u>. Except for those matters for which a Party has final decision-making pursuant to Section 10.6 and as set forth in Section 15.8, any Dispute between the Parties arising in connection with this Agreement or their performance hereunder not resolved pursuant to Section 15.1 shall be finally resolved through binding arbitration. The arbitration shall be conducted pursuant to the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association ("<u>AAA</u>") and the provisions of this Section 15.2.

- 15.3. Arbitration Panel. The arbitration shall be conducted by a panel of three (3) arbitrators. Within thirty (30) days after the initiation of the arbitration, each Party will nominate one individual to act as an arbitrator, and the two arbitrators so named will then jointly appoint the third arbitrator within thirty (30) days of their appointment, who will serve as chairperson of the arbitration panel. All three (3) arbitrators must be independent Third Parties having at least ten (10) years of dispute resolution experience (including judicial experience) or legal or business experience in the biotechnology, pharmaceutical or diagnostics industry. If any Party fails to timely nominate its arbitrator, or if the arbitrators selected by the Parties cannot agree on the individual to be named as chairperson within such thirty (30) day period, the AAA will make the necessary appointments for such arbitrator(s) or the chairperson. Once appointed by a Party, such Party will have no ex parte communication with its appointed arbitrator.
- 15.4. <u>Location and Proceedings</u>. The place of arbitration will be in Wilmington, Delaware or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrators have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The decisions of the arbitrators shall be final and binding on the Parties and shall not be subject to appeal.
- 15.5. <u>Limitation on Awards</u>. Except as permitted in Section 14.4, the arbitrators shall have no authority to award any punitive, exemplary, consequential, indirect, special or other similar damages. Each Party shall bear its own costs and expenses (including attorneys' fees and expert or consulting fees) incurred in connection with the arbitration. The Parties shall equally (50:50) share the arbitrator's fees and any other administrative costs and expenses associated with the arbitration.
- 15.6. <u>Confidentiality.</u> Neither Party, nor any of the arbitrators, shall be permitted to disclose the existence, content or results of any arbitration proceedings pursuant to this Article 15, without the prior written consent of both Parties.
- 15.7. <u>Governing Law</u>. The formation, existence, performance, validity and all aspects of this Agreement shall be governed by and construed in all respects in accordance with the laws of the State of Delaware, U.S., excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.
- 15.8. <u>Intellectual Property Disputes</u>. Notwithstanding anything herein to the contrary, any and all issues regarding the scope, inventorship, construction, validity, enforceability or ownership of the Background Intellectual Property of each Party, the Blueprint Inventions, the Ventana Inventions and the Joint Inventions shall be determined in a court of competent jurisdiction under the local patents laws of the

jurisdictions having issued the Intellectual Property in question.

#### 16. MISCELLANEOUS

# 16.1. Assignment.

- 16.1.1. Permitted Assignments. Neither Party has the right to assign its rights or obligations under this Agreement without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed); provided, however, that (i) either Party may assign this Agreement and all of its rights and obligations hereunder, without such consent, to a person that acquires all or a majority of the shares or assets of such Party (or the business or assets to which this Agreement pertains) whether by merger, consolidation, reorganization, acquisition, sale, license or otherwise, and (ii) each Party may assign this Agreement and all of its rights and obligations hereunder, without such consent, to a Divisional Affiliate if the assigning Party remains liable and responsible for the performance and observance of all of the Divisional Affiliate's duties and obligations hereunder. Any assignment not in accordance with this Section 16.1 shall be void.
- 16.1.2. Assignment of One or More Project Schedules. In the event that Blueprint or its Affiliates have agreed in writing with a Third Party to exclusively license (or otherwise sell, transfer or divest) Blueprint's or its Affiliates' rights in a Blueprint Compound or a Blueprint Product to a Third Party, either in their entirety or with respect to one or more Markets, and Blueprint desires in connection therewith to assign to a Third Party any Project Schedule and its rights in connection therewith, without limitation to Section 16.1.1, Blueprint shall have the right to assign such Project Schedule to such Third Party pursuant to this Section 16.1.2 as follows: (i) in the case of any such Third Party that does not constitute a Qualified Assignee, only with the written consent of Ventana, not to be unreasonably withheld or delayed; (ii) in the case of any such Third Party that does constitute a Qualified Assignee, upon notice to Ventana without any requirement that Ventana provide consent.
- 16.1.3. <u>Assignments to Qualified Assignees</u>. If Blueprint and a Third Party who is a Qualified Assignee consent, and (i) if such Qualified Assignee has executed a companion diagnostic collaboration agreement with Ventana in the five (5) years prior to such time, then Ventana shall offer to novate the Project Schedules applicable to such Blueprint Compound or Blueprint Product to such Qualified Assignee under the terms of such companion diagnostic collaboration agreement between Ventana and the Qualified Assignee, and (ii) if such Qualified Assignee has not executed a companion diagnostic collaboration agreement with Ventana in the five (5) years prior to such time, then Ventana shall offer to novate the Project Schedules applicable to such Blueprint Compound or Blueprint Product to such Qualified Assignee under the terms of a companion diagnostic collaboration agreement with such Qualified Assignee on terms and conditions that are substantially similar to those contained herein, but in no event less favorable to such Qualified Assignee than Ventana's then-current template master collaboration agreement for companion diagnostics.
- 16.1.4. <u>Rights to Intellectual Property of a Permitted Assignee</u>. The rights to Intellectual Property, data and materials: (i) controlled by a Third Party permitted assignee of a Party or any Person that is an affiliate of such Third Party immediately prior to such assignment, which Intellectual Property, data and materials were controlled by such assignee or any such affiliate (and not such Party) immediately prior to such assignment (other than as a result of a license or other grant of rights by such Party or its Affiliates to, or for the benefit of, such Third Party or such affiliate); or (ii) controlled by a Third Party that acquires all or a majority of the shares or assets of such Party (or the business or assets to which this Agreement pertains) whether by merger, consolidation, reorganization, acquisition, sale, license or otherwise, after the Effective Date, or by any Person that is an affiliate of such Third Party immediately prior to such acquisition,

which Information, materials and intellectual property were controlled by such Third Party or any such affiliate (and not such Party) immediately prior to such acquisition (other than as a result of a license or other grant of rights by such Party or its Affiliates to, or for the benefit of, such Third Party or such affiliate), in each case ((i) and (ii)), shall be automatically excluded from the rights licensed or granted to the other Party under this Agreement; provided, that in each case ((i) and (ii)), that such exclusion shall not continue to apply with respect to such Intellectual Property, data or materials to the extent that such Party uses, practices or incorporates such Intellectual Property, data or materials in its development Activities under a Project Schedule after such assignment or acquisition. Unless otherwise agreed by the Parties, for purposes of any Project Schedule, the exclusion set forth in this Section 16.1.4 shall not apply to Intellectual Property, data and materials controlled by any Third Party that becomes a Qualified Assignee with respect to such Project Schedule pursuant to Section 16.1.2 or 16.1.3.

16.2. <u>Counterparts</u>. This Agreement and any Project Schedule hereunder may be signed in two (2) or more counterparts (electronic transmission of scanned signatures included), each of which shall be deemed an original, but all of which shall constitute one and the same instrument. After electronic transmission of scanned signatures the Parties shall, upon either Party's request, execute and exchange documents with original signatures.

#### 16.3. <u>Covenant Regarding Divisional Affiliates</u>.

- 16.3.1. <u>Ventana Covenant</u>. Ventana hereby covenants to Blueprint that in the event that Ventana requires the services of any Affiliate covered by clause (ii) of the definition of a Ventana "Divisional Affiliate" to perform Ventana's obligations under this Agreement, Ventana shall ensure that any employee or agent of such Divisional Affiliate that is engaged in the Pharmaceutical Field does not access Blueprint's Confidential Information held by Ventana.
- 16.3.2. <u>Blueprint Covenant</u>. Blueprint hereby covenants to Ventana that in the event that Blueprint requires the services of any Affiliate covered by clause (ii) of the definition of a Blueprint "Divisional Affiliate" to perform Blueprint's obligations under this Agreement, Blueprint shall ensure that any employee or agent of such Divisional Affiliate that is engaged in the Diagnostic Field does not access Ventana's Confidential Information held by Blueprint.
- 16.4. Entire Agreement. This Agreement sets out the entire agreement and understanding between the Parties regarding the subject matter of this Agreement and supersedes all prior discussions, arrangements and agreements, whether oral or in writing or which may be inferred from the conduct of the Parties. That certain Services Agreement by and between the Parties effective May 27, 2015 is hereby terminated and superseded by mutual agreement; provided, however, that any Confidential Information exchanged thereunder (and any Confidential Information exchanged under that certain Mutual Non-Disclosure Agreement for Pharmaceutical Related Diagnostics by and between the Parties effective as of the 27th day of January, 2014) shall be subject to Article 7 of this Agreement, and provided, further, that that certain Exhibit A, effective as of August 3, 2015 to that Services Agreement shall be deemed to be a Project Schedule subject to this Agreement, which Project Schedule is hereby ratified and affirmed by the Parties in its entirety.
- 16.5. <u>Force Majeure</u>. Neither Party shall be liable for failure or delay in performance under this Agreement due to force majeure causes such as an act of God, strike, lockout or other labor dispute, civil commotion, sabotage, fire, flood, explosion, acts of any government, any other similar causes not within the reasonable control of the Party affected (a "<u>Force Majeure Event</u>"). In the event either Party is unable to perform any of its obligations hereunder due to a Force Majeure Event, such non-performing Party shall promptly notify the other Party. Performance hereunder shall be promptly resumed after the applicable Force Majeure Event has been remedied. If the Force Majeure Event lasts for more than sixty (60) days, the other Party may terminate this Agreement or any Project Schedule by written notice to the non-performing Party, and for purposes of consequences of termination, solely clauses (i) and (ii) only of Section

- 16.6. <u>Notice</u>. All notices under this Agreement shall be in writing and shall be sent by registered or certified mail, postage prepaid, or by overnight courier service, to the attention of the general counsel at the addresses of the respective Parties set forth in the first paragraph of this Agreement or to such other address as the Party to whom notice is to be given may have provided to the other Party. Such notice shall be deemed to have been given (i) as of the date delivered if such notice is delivered by hand, or (ii) on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service.
  - 16.7. <u>Relationship of the Parties</u>. The relationship of the Parties is that of independent contractors.
- 16.8. <u>No Third Party Beneficiaries</u>. No provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any person or entity other than the Parties hereto and their respective successors and assigns.
- 16.9. <u>Use of Parties' Names</u>. The Parties will agree upon an initial form of press release regarding their execution and entering into this Agreement, and which is intended to be issued on or promptly after the Effective Date as mutually agreed to by the Parties. Thereafter, neither Party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement which uses the other Party's name, symbols, or trademarks without the other Party's prior written approval.
- 16.10. <u>Validity/Severability</u>. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision which shall remain in full force and effect.
- 16.11. Waiver; Modification of Agreement; Non-Exhaustion of Remedies. No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

[Signatures appear on subsequent page]

In witness whereof, Ventana and Blueprint, intending to be legally bound, have executed this Agreement as of the Effective Date by their respective duly authorized representatives.

Blueprint Medicir	nes Corporation
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# Ventana Medical Systems, Inc.

By: <u>/s/ Jeffrey Albers</u> By: <u>/s/ Douglas Ward</u>

Name: Jeffrey Albers Name: Douglas Ward

Title: President and CEO Title: VP & Life Cycle Leader, CDx

[Signature Page to Master Collaboration Agreement]

# DEVELOP A PREMARKET APPROVAL (PMA) READY AUTOMATED IHC IUO ENROLLMENT ASSAY FOR FGF19

### **Project Snapshot:**

<b>Company:</b> Blueprint Medicines Corporation	Intended Use(s): Hepatocellular carcinoma ("HCC")
Drug: BLU-554	Pharmaceutical Class: Small molecule
Signaling Pathway: FGFR4	Assay Target(s): FGF19
Assay Needed: FGF19 IHC	PMA to be submitted for: FGF19 IUO IHC

Capitalized terms used in this Project Schedule and defined in the Master Collaboration Agreement between the Parties dated as of March 1, 2016 (the "Collaboration Agreement") shall have the meanings ascribed therein.

Effective Date: March 1, 2016

### **Scope of Work Summary**

### 1. IUO Development Stage

- a. Goal: to prepare an analytically validated, Investigational Use Only Assay using the [...\*\*\*...] antibody, the Benchmark ULTRA platform and OptiView detection and verified to the United States' FDA specifications that may be used to select patients in registrational trial(s) of BLU-554 in hepatocellular carcinoma ("HCC").
- b. Anticipated Timeline [...\*\*\*...] for HCC (the "Intended Use"). Ventana will use commercially reasonable efforts to have Ventana IUO ready for BLU-554 pivotal Clinical Trials. In the event the Ventana IUO will not be ready, a Joint Project Team will identify contingencies to select patients for such trials such as incorporating the Ventana CAP CLIA Lab.
- c. Estimated Fees to Blueprint for the Intended Use: [...\*\*\*...] (excluding passed through¹ and optional costs as described further, and assuming Blueprint has elected to [...\*\*\*...])

# 2. Clinical Development Stage and Product Registration

- a. Goals: (i) to use the Ventana IUO to determine patient eligibility in Clinical Trials of BLU-554, and collect data from those trials to demonstrate clinical utility of the Assay for FDA approval; (ii) conduct Inter-laboratory-Reproducibility study, a diagnostic clinical study needed for FDA submission; (iii) to seek product approval and/or registration with global regulatory authorities.
- b. Anticipated Timeline: dependent on Blueprint's clinical development plan
- c. Markets: Based on this plan, Ventana is expected to seek registration for the Ventana IUO in the United States and countries that recognize the CE/ IVD self- registration process (including, but not limited to, [... \*\*\*...]). For clarity, [...\*\*\*...] do not permit self- declaration and require studies that are not in the scope of this Project Schedule, unless added by mutual agreement under a new Project Schedule. Unless otherwise agreed by the Parties in writing, for purposes of the Agreement and this Project Schedule, "Markets" means the United States and countries that recognize the CE/ IVD self- registration process (including, but not limited to, [...\*\*\*...]).

1

<sup>&</sup>lt;sup>1</sup> Generally, tissue acquisition pass through costs [...\*\*\*...].

d. Estimated Cost to Blueprint for the Intended Use: [...\*\*\*...] (excluding passed through costs).

#### 3. Commercialization

a. Goal is to prepare for market launch in the Markets listed above. Timelines and, if any, a budget/cost estimate to be detailed in separate Commercialization Plan and/or Project Schedule as outlined in Collaboration Agreement.

#### **Detailed Scope of Work and Budget**

### Stage 1: IUO Development Stage

At the initiation of Stage 1, Blueprint and Ventana will agree to develop an IUO for BLU-554 in HCC. A Joint Project Team (JPT) will be created, comprised of functional subject matter expert representatives of each party. The leaders of the Joint Project Team will be a CDx Project Leader from Ventana and Project Manager from Blueprint. Matters before the JPT will be decided by consensus.

The final Ventana IUO will consist of three key components:

- 1) An assay system that is optimized and analytically validated for the Intended Use,
- 2) An optimized interpretation guide with validated Cutoff Value(s) for patient selection, and
- 3) A validated cGMP manufacturing process for production of test kit reagents.

The Ventana IUO will be developed under full design control as per Ventana's Product Development Process ("PDP"), and will be developed through stage gates known as Early Concept ("EC"), Design Goals ("DG"), Design Input ("DI"), and Design Output ("DO"). The activities and key deliverables are outlined in tables to this document. Formal Design Reviews ("FDR") occur at the end of each stage as governed by the PDP, and summary PowerPoint presentations required will be shared with Blueprint as the key Deliverables for each stage gate, including where expressly listed for each Phase of the Project below, and for each such PowerPoint presentation the JPT shall agree upon the level of detail to be included. Supporting information and data will also be shared upon agreement by the respective Parties' Project Leaders on the Joint Project Team. The JPT shall also coordinate and approve Ventana's advancement to each subsequent Phase of this Project Schedule (and it is anticipated and agreed that such approval/advancement could occur in parallel with or prior to the completion of the preceding Phase(s)). A portfolio committee within Ventana governs the PDP and assigns dedicated resources to projects, and Ventana will ensure that the Ventana members of the Joint Project Team are appropriately allocated and dedicated to the project.

The manufacturing of critical raw material, the anti-FGF19 antibody, clone [...\*\*\*...], will be manufactured by a Divisional Affiliate of Ventana, Spring BioScience Corporation, in Pleasanton, CA, using previously determined manufacturing processes.

Once [...\*\*\*...] lots of critical raw material have been produced and are available for development studies, the Assay will be analytically validated using OptiView detection and on the Benchmark ULTRA platform. A scoring/ interpretation system, developed in part through the use of the prototype FGF19 Assay previously used in the Ventana CAP/ CLIA lab, will be optimized, and Cutoff Value(s) selected for patient selection will be verified. The scoring system development and Cutoff Value(s) selection will be a joint effort, relying on each Party's biostatisticians to analyze patient outcomes and FGF19 expression levels from earlier trials. Ventana will verify that the Assay can reproducibly identify patients above and below the selected Cutoff Value(s).

Following scoring optimization and Cutoff Value(s) verifications, Ventana will produce necessary training materials for study pathologists, and will verify control tissues and instructions for laboratories to use to complete the enrollment Assay system. Verification studies including FDA-required preclinical studies designed to understand the impact of tissue sample variability on Assay performance will also be completed prior to the start of the registrational Clinical Trial.

Ventana will prepare a pre-submission briefing package, and submit to FDA, to align with FDA on the development strategy for the product. If needed, Ventana will prepare and seek a Significant Risk Determination ("SRD") from the FDA,

hold a joint meeting with FDA (with Blueprint participating as needed), and prepare and receive an Investigational Device-Exemption (IDE) for the Ventana Assay to be used for the selection of patients for inclusion in Clinical Trials evaluating BLU-554. Ventana will then receive the IDE in accordance with FDA pre-IDE feedback and 21CFR812 requirements.

IUO Development will be initiated for HCC as the Intended Use. This Project Schedule does not include a second Intended Use. If a second Intended Use is needed a separate Project Schedule will be developed.

#### 1.0 Design Control Overview and Stage Gates (EC, DG, DI, DO)

### 1.1 Projection Initiation/Early Concept Phase (EC)

The key objectives of the Early Concept phase are:

- 1. Resource allocation, including creation of Ventana Project Team. Ventana Project Team should consist of, but not be limited to, personnel from the following functions: Project Management, Development, Pathology, Marketing, Regulatory, Clinical, Quality, and Statistics ("Ventana Project Team")
- 2. Complete freedom to operate (FTO) and intellectual property (IP) analysis
- 3. If needed, antibody transfer and initiation of antibody manufacturing at Ventana

Phase 1.0 Summary:

1.0 Project I	1.0 Project Initiation/Early Concept Phase Activities, Deliverables, and Milestones		
Milestone	Activities and Deliverables		Milestone Fee and Payment Terms
Resource Allocation	-	o be shared for the following, when	[***]
Freedom to Operate Analysis	☐ Ventana-Blueprint Teleconference or Face to Face meeting to discuss IP/FTO legal assessment		[***]
Third Party License Agreement	TBD, if necessary, pending results of FTO analysis		TBD if needed
Antibody Production	☐ Spring to optimize and scale antibody production ☐ If needed, Spring to manufacture three lots for development studies		N/A
Anticipated Timelines	[***]	<b>Estimated Cost for Phase</b>	[***]

### 1.1 Analysis Phase - Design Goal (DG) Stage Gate

The key objectives of the design goal phase are:

- 1. Determine the feasibility of an IUO Assay that supports the Intended Use
- 2. Identify the risks and develop a risk mitigation plan
- 3. Set the Design Goals
- 4. Source and qualify tissues in the Intended Use to support the feasibility and verification studies.
- 5. Formal project initiation by Ventana Marketing to develop launch plan and by Ventana Regulatory to develop regulatory strategy.

Phase 1.1 Summary:

1.1 Analysis Phase Activities, Deliverables, and Milestones			
Milestone	Activities and Deliverable	s	Milestone Fee and Payment Terms
Project Kickoff		schedule first JPT meeting to build n goals & project governance, and review eam meetings	N/A
Sourcing for Analysis Phase	analysis phase, including but not l o Primary and metastatic tissues o Pharma arrays	S	[***]
Establish Technology Feasibility	instrument system using OptiView	n of antibody on a BenchMark ULTRA DAB IHC detection kit elopment/validation data toward new assay	N/A
Completion of IUO Assay Technology Feasibility (DG)	Review: o Technology Feasibility report o Design History File o Design Goals Document o Draft Global Launch Plan and	JO Assay Technology Feasibility has been	[***]
Anticipated Timeline for Phase	[***]	Estimated Cost for Phase (excluding pass through costs)	[***]

# 1.2 Planning and Product Feasibility Phase – Design Input (DI) Stage Gate

The key objectives of the design input phase are:

- 1. Develop and optimize conditions for the Ventana IUO
- 2. Identify control tissue and complete feasibility testing
- 3. Develop a preliminary scoring algorithm for the interpretation guide
- 4. Regulatory: Pre-IDE submission to FDA

1.2 Planning and Product Feasibility Phase Activities, Deliverables, and Milestones		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
Sourcing for Planning and Product Feasibility Phase	☐ Ventana to identify and acquire materials needed for Planning and Product Feasibility Phase, including but not limited to the following:  o Primary and metastatic tissues for the Intended Use o Multi-tissue blocks for Tour of Body/Tour of Tumor (TOT/TOB) studies o Pharma arrays o Cell lines for development	[***]
Antibody Assay Development and Optimization	□ Antibody Assay Development and Optimization may include as needed:  o Tissue screening and MTBs  o Working titer  o Diluent screen  o Pretreatment screen (Antigen retrieval methods Protease)  o Antibody incubation time  o OptiView DAB detection  o Official Titer  o Accelerated Stability  o Intended Use Case Staining (50 pos and 50 neg per Intended Use  □ TOT/TOB Studies summaries into Product & Process Feasibility Report	N/A
Tissue Control Identification	<ul> <li>☐ Formatting:         <ul> <li>o FFPE Tissue Control</li> <li>o Cut Sections on glass slides</li> </ul> </li> <li>☐ Feasibility Testing:         <ul> <li>o Optimization on BenchMark ULTRA</li> <li>o Lot to lot or case to case reproducibility as needed and determined at the JPT level to optimization across instrument systems.</li> <li>o Failure Mode Testing</li> </ul> </li> </ul>	N/A
Preliminary Scoring Algorithm Development	<ul> <li>☐ Studies to be summarized in Product &amp; Process Feasibility Report</li> <li>☐ Define positive/negative Cutoff Value(s) using following:         <ul> <li>o Patient case review using clinical samples and outcomes data to establish a Cutoff Value</li> <li>o Pre-Method comparison to approved test method.</li> <li>o Input from pathologist with expertise in Intended Use.</li> </ul> </li> </ul>	N/A
Significant Risk Determination (SRD) and IDE as needed	☐ If needed, prepare and submit SRD to FDA, determine the need for IDE. ☐ Ventana to prepare IDE documentation as determined at the JPT Prepare and file IDE if needed	N/A
Completion of IUO Assay Development Feasibility (DI)	□ Ventana to generate the following internal deliverables for Formal Design Review:     ○ Product & Process Feasibility Report     ○ Product Requirements Document     ○ Trace Matrix     ○ Design & Development Plan     ○ Design Transfer Plan     ○ Customer Requirements Document	[***]
Anticipated Timeline for Phase	PowerPoint summary of internal deliverable contents to Blueprint  [***]  Estimated Cost for Phase (excluding pass through costs)	[***]

# 1.3 Design and Development Phase – Design Output (DO) Stage Gate

The key objectives of the Design Output phase are:

- 1. Optimization and validation of the interpretation guide
- 2. Full design verification studies for the locked Ventana IUO

- 3. GMP Manufacturing process validation for test kit reagents and control tissue; timing of process validation flexible depending on Project timeline
- 4. Production and labeling of test kits ready to use in clinical stage
- 5. Regulatory: data to support SRD (if needed) and IDE submission to FDA

Phase 1.3 Summary:

1.3 Design and Development Phase Activities, Deliverables, and Milestones		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
Sourcing for Design and Development Phase	<ul> <li>Ventana to identify and acquire mutually agreed upon materials needed for Design and Development Phase, including but not limited to the following:</li> <li>Primary and metastatic tissues for the Intended Use</li> <li>Pharma arrays</li> <li>Cell lines for control slide development</li> </ul>	[***]
Optimization/ Verification of Scoring System	<ul> <li>Deliver final Interpretation Guide</li> <li>Provide written notice that Final Interpretation Guide is available</li> <li>Provide a copy of Final Interpretation Guide</li> </ul>	[***]
Manufacture IUO Assay and Process Validation	<ul> <li>□ Manufacturing process validation plan</li> <li>□ PowerPoint summary outlining process validation and manufacturability plans</li> <li>□ Generation of IUO label for test kit</li> <li>□ Orderable IUO kits available</li> </ul>	[***]
Design Verification Studies	<ul> <li>□ All Design Verification Studies performed as a system</li> <li>□ Parameters: Formulation of antibody must be locked and instrument protocol selections must be determined prior to initiation of studies</li> <li>□ Requirements: 150 positive and 150 negative tissues for Intended Use; scoring algorithm and Interpretation Guide are available</li> <li>□ Studies to support IUO build in operations include:         <ul> <li>□ Design lot(s) formulation − lot to lot equivalency established</li> <li>□ Accelerated stability − assign IUO build expiration dating</li> <li>□ Immunoreactivity − Normal and neoplastic tissue screen</li> <li>□ Repeatability/Reproducibility − Intra-day repeatability, Inter-day, and Intraplatform reproducibility to establish Assay precision</li> <li>□ Pre-analytical studies include:</li> <li>□ Ischemia study</li> <li>□ Fixation study</li> <li>□ Tissue thickness (2 to 7 micron sections)</li> <li>□ Stability Studies include:</li> <li>□ Reagent real time stability testing</li> <li>□ Cut slide stability − for antigen stability in FFPE sections provided in IUO package insert, provided to clinical sites</li> <li>□ Reader precision studies include:</li> <li>□ Inter-reader/Intra-reader precision</li> <li>□ Assay migration − platform compatibility to support CE/IVD launch</li> <li>□ Reproducibility and Robustness − multiple lots of antibody combined with multiple lots of detection across multiple instrument platforms and cases</li> <li>□ Design lot to IUO lot equivalency</li> <li>□ Failure Mode testing/Protocol limitations</li> <li>□ Antibody Characterization studies include</li> <li>□ Western blot</li> <li>□ Peptide inhibition</li> <li>□ Immunoprecipitation</li> <li>□ PowerPoint summaries of Design Verification studies wi</li></ul></li></ul>	N/A

1.3 Design and Development Phase Activities, Deliverables, and Milestones		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
Completion of IUO Assay Verification (DO)	<ul> <li>□ Ventana to generate following internal Deliverables for Formal Design Review:         <ul> <li>o Design Verification Reports</li> <li>□ PowerPoint summary of internal deliverables to Blueprint</li> <li>□ Written notice that IUO Assay Verification has been completed</li> </ul> </li> </ul>	[***]
Anticipated Timeline for Phase	[***] Estimated Cost for Phase (excluding pass through costs)	[***]

#### 1.4 Submission Phase

The key objective is to receive IDE designation of IUO assay

Phase 1.4 Summary:

1.4 Submission Phase Activities, Deliverables, and Milestones		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
Pre-Submission Briefing Packet and, if needed, Significant Risk Determination (SRD) and if needed, IDE preparation	<ul> <li>□ Ventana to create pre-submission briefing packet</li> <li>□ If needed, Ventana to prepare SRD documentation, submit to FDA to determine risk level</li> <li>□ If required, Ventana will hold joint meeting with FDA, (Blueprint will participate, as needed)</li> <li>□ If needed, Ventana to prepare and deliver, IDE documentation as determined by the FDA</li> <li>□ If needed, Ventana to prepare, seek, and receive IDE from FDA for Ventana Assay to be used in patient selection for trial inclusion</li> </ul>	[***]
Anticipated Timeline for Phase	[***] Estimated Cost for Phase	[***]

Stage 2: Clinical Development Stage and Product Registration

The Ventana IUO will be transferred to commercial laboratories and used as an enrollment Assay for global Clinical Trials of BLU-554 in HCC. For clarity, while the Ventana CAP/CLIA laboratory is qualified to be a testing lab for pivotal studies, it is Ventana's recommendation that the Ventana IUO be transferred to a commercial laboratory(ies) other than Ventana's CAP/CLIA certified laboratory for use in registrational Clinical Trials. If the Ventana IUO is not ready to be transferred to commercial laboratories for the start of an BLU-554 pivotal study, Blueprint and Ventana will negotiate in good faith the terms of separate Project Schedules (i) for patient screening using the prototype Ventana Assay at Ventana's CAP/CLIA laboratory and (ii) any resulting bridging studies that are required for the Ventana Assay to gain Regulatory Approval.

The Ventana IUO will be transferred and validated at those labs, and the lab pathologists trained and qualified by Ventana prior to enrollment for those pivotal Clinical Trials. A diagnostic clinical trial protocol will be written and a clinical site initiation visit ("SIV") will be completed at the start of each Clinical Trial, to ensure proper data capture and operations to support the clinical development of the IUO. Following Clinical Trial start and throughout the duration of the enrollment portion of the Clinical Trial, Ventana will monitor the performance of the testing lab, collecting data for the PMA submission.

In addition to the Clinical Trials involving BLU-554, a separate inter-laboratory reproducibility study (ILR) will be designed and completed ("ILR"). The ILR is a purely diagnostic Clinical Trial that does not need BLU-554 treated patients or samples. The Clinical Trial is designed and executed solely by Ventana and the data are required for a PMA application.

Near the end of the BLU-554 registrational Clinical Trial(s), Ventana will submit a modular PMA application to the FDA. Modules 1, 2, and 3 are focused primarily on the analytical performance of the Ventana Assay and the system components, and Module 4 brings in the clinical utility data to BLU-554. In addition and if needed, Ventana will prepare and submit necessary document to the Roche Diagnostics Germany Regulatory group, which will determine whether Roche may self-declare conformity to CE rules for companion diagnostics. Following declaration of conformity, Ventana may register the assay as a CDx in countries where Blueprint intends to launch BLU-554.

# 2.0 Set-Up and Use of IUO Assay In Clinical Trials

The key objectives of the phase are:

- 1. Enable patient selection in relevant Clinical Trials
- 2. Collect Assay performance data to support future regulatory filings

Phase 2.0 Summary:

2.0 Set-Up and Use of IUO Assay In Clinical Trials		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
Clinical Site Initiation Visit and Assay Transfer	<ul> <li>□ Lab selection is at Blueprint's discretion; Ventana will provide input on lab selection and contracting upon request</li> <li>□ Ventana, Blueprint, and laboratory(ies) will work together on Data Analysis Plan (i.e., establish data collection processes and database format), and Communication Plan</li> <li>□ Ventana to perform preliminary Audits, as necessary</li> <li>□ Ventana to provide Pathologist/reader training and proficiency</li> <li>□ Ventana to lead Site and Study Initiation and Ventana IUO transfer at a minimum of [***]</li> <li>□ Ventana to prepare Lab Readiness Report; Blueprint will be able to review report.</li> <li>□ Note: Fees listed are for sites in the USA and EU only. For sites outside the USA and EU, the Parties agree to negotiate in good faith in order to accommodate additional travels costs if any</li> </ul>	[***]
First Patient Screened Milestone	□ Ventana to provide written notice that first patient has been screened using the Ventana IUO for potential enrollment into a Clinical Trial evaluating BLU-554     □ Milestone to be paid one time per Intended Use	[***]
Clinical Site Monitoring	☐ Quarterly monitoring of laboratories by Ventana ☐ Activities will include Data Quality Assurance and Audits, as necessary ☐ Written quarterly updates will be provided to Blueprint ☐ Monitoring will cease upon final patient screen result ☐ Note: Fees listed are for sites in the USA and EU only. For sites outside the USA and EU, the Parties agree to negotiate in good faith in order to accommodate additional travels costs if any	[***]
IUO Kit Manufacturing	<ul> <li>[***] of IUO kits transferred from Ventana manufacturing to Ventana clinical group; the exact number will be determined at the Joint Project Team level and depends on the number of slides as described in clinical protocol</li> <li>Transfer to Clinical Operations Group for use in Clinical Trials</li> <li>Standard Ventana unit is [***]</li> </ul>	[***]

# 2.1 Inter-laboratory Reproducibility Study

The key objectives of the phase are:

- 1. Identify qualifying labs to participate.
- 2. Train labs on Ventana IUO
- 3. Perform FDA required inter-laboratory study and include data in appropriate submissions

Phase 2.1 Summary:

2.1 Inter-laboratory Reproducibility Study		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
Tissue Acquisition and Qualification	Ventana to identify and acquire tissues needed for ILR study	[***]
ILR Study	<ul> <li>□ Ventana solely responsible for conducting ILR study</li> <li>□ Intended Use Cohort Generation</li> <li>□ Data collection from multiple pivotal lab sites</li> <li>□ Analysis to demonstrate concordance of Ventana IUO performance across multiple labs/customer sites</li> <li>□ Ventana will summarize findings in ILR Report, which will be made available to Blueprint</li> </ul>	[***]

# 2.2 IVD Registration and Launch

The key objectives of the phase are:

1. To gain approval and launch IVD

Phase 2.2 Summary:

2.2 IVD Registration and Launch		
Milestone	Activities and Deliverables	Milestone Fee and Payment Terms
PMA Submission Preparation	<ul> <li>☐ In coordination with Blueprint, Ventana will prepare PMA Modules 1-4</li> <li>☐ Assume modular submission will be performed by Ventana</li> </ul>	[***]
PMA Submission User Fees	Final modules submission	[***]
CE/IVD Predictive Registration	Declaration of Conformity obtained by Ventana	[***]
	Commercial Readiness Review conducted by Ventana to ensure training of operations, support and sales personnel are complete or scheduled	
Launch Decision	Formal Design Review, LCM Governance approval of Launch Decision	[***]
	PowerPoint deliverable summarizing Commercial Readiness Review and Formal Design Review	
	Written notice of Launch Decision to Blueprint	
FDA Approval Milestone	☐ Notice of PMA Approval from FDA	[***]

# Termination of this Project Schedule under Section 12.3.1 of the Collaboration Agreement

In the event that Blueprint terminates this Project Schedule pursuant to part (ii) of Section 12.3.1 of the Collaboration Agreement, then Blueprint shall pay, as applicable, a termination fee to Ventana within thirty (30) days after receipt of an invoice therefor, the amount of which termination fee shall be determined as follows:

Termination Gate	Termination Gate Trigger	Termination Fee
1	If Blueprint serves notice of termination at any time after the initiation of the Design and Development Phase (Phase 1.3), but prior to the occurrence of Termination Gate 2	[***]
2	If Blueprint serves notice of termination at any time after the earlier to occur of (i) the initiation of a registrational Clinical Trial, or (ii) notification or designation that an ongoing study will serve as a registrational Clinical Trial ("Termination Gate 2"), but prior to the occurrence of Termination Gate 3	[***]
3	If Blueprint serves notice of termination at any time after the submission of the first PMA ("Termination Gate 3"), but prior to the occurrence of Termination Gate 4	[***]
4	If Blueprint serves notice of termination at any time after receipt of notice of FDA Approval for the PMA ("Termination Gate 4"), but prior to the [***] of such FDA Approval	[***]

### **Optional Studies: Additional Platform Verifications**

The Ventana IUO will first be developed and optimized on the Benchmark ULTRA automated system. The Parties may agree to complete development and platform migration studies to validate the Ventana IUO on additional Ventana platforms (e.g., BenchMark XT or GX). The cost of additional validation would depend on the time at which Blueprint decides to pursue migration, and is outlined in the table below. The timelines to complete those studies would be scoped and agreed to under a new Project Schedule, but would be capped at the costs outlined below if the decision taken in Stage 1. The most efficient time to perform any platform migration studies would be during Stage 1, when resources are most easily leveraged. Ventana and Blueprint will work together to ensure that platform migration studies are initiated at an appropriate time to align IVD approval with the global launch of the Blueprint drug in various countries and regions.

Additional testing on other instrument systems to support an ex-US launch will require enough samples to demonstrate reproducibility testing across multiple instruments (this may be a small sample set of cases including both positives and negatives but a large number of slides). These additional instrument systems would not be included with the PMA.

#### **Optional Studies for Platform Migration**

Activity	Price
Inclusion of Platform Migration to BenchMark XT or GX-	[ *** ]
Decision made prior to (DG)	[***]
Inclusion of Platform Migration to BenchMark XT or GX- Decision	[ *** ]
made after DG but prior to (DO)	["]

# Stage 3: Commercialization Stage

Approximately [...\*\*\*...] prior to the anticipated launch of BLU-554, the Ventana CDx, commercialization planning and launch readiness activities will begin. This will include collaboration between Ventana's and Blueprint's worldwide commercial teams. This includes worldwide registration requirements, including PMA submission in the United States and CE/IVD predictive claim registration in the EU. Further details of commercialization to be covered in separate Project Schedule, as outlined in the Collaboration Agreement.

	Stage 1: IUO Development			
Phase	Milestone	Milestone Fee	Estimated Timing	
1.0	Concept Phase	[***]	[***]	
1.1	Analysis Phase	[***]	[***]	
1,2	Planning and Product Feasibility Phase	[***]	[***]	
1.3	Design and Development Phase	[***]	[***]	
1.4 Submission Phase		[***]	[***]	
	Total	[***]	[***]	

<sup>\*</sup>Note: Assumes [...\*\*\*...].

	Stage 2: Clinical Development Stage and Product Registration			
Phase	Milestone	Milestone Fee	Estimated Timing	
2.0	Clinical Site Initiation Visit and Assay Transfer	[***]	[***]	
2.0	First Patient Screened Milestone	[***]	[***]	
2.0	Clinical Site Monitoring	[***]	[***]	
2.1	Inter-laboratory Reproducibility Study	[***]	[***]	
2.2	PMA Submission Preparation	[***]	[***]	
2.2	CE/IVD Predictive Registration	[***]	[***]	
2.2	Launch Decision	[***]	[***]	
2.2	FDA Approval	[***]	[***]	
	Total	[***]	[***]	

<sup>\*</sup>Note: Assumes [...\*\*\*...].

Where this Project Schedule refers to passed through and other optional costs incurred by Ventana, such costs  $[\dots^{***}\dots]$ .

# **Roles and Responsibilities**

Name	Title	Phone	Address	Email Address
[***]	Senior Manager of	[***]	110 Pine Hill Road	[***]
[	Business Development	[	Southborough, MA	[
[***]	Project Leader	[***]	1910 E Innovation Park Dr	[***]
[	Floject Leader	[	Tucson, AZ 85755	[]
	Associate Director,		38 Sidney Street, Suite 200	
[***]	Business Development	[***]		[***]
	Dusiness Development		Cambridge, MA 02139	
	Min Dunidant		38 Sidney Street, Suite 200	
[***]	Vice President, Translational Medicine	[***]		[***]
	Translational Medicine		Cambridge, MA 02139	

[Signature Page Follows]

**IN WITNESS WHEREOF**, the Parties hereto have caused this Project Schedule to be executed by their duly authorized representatives as of the Effective Date first written above.

Ventana Medical Systems, Inc.

Blueprint Medicines Corporation

By: /s/ Doug Ward By: /s/ Jeffrey Albers

Name: Doug Ward Name: Jeffrey Albers

Title: VP & LCL, CDx Title: President and CEO

[Signature Page to Project Schedule #1]

#### **Project Agreement #2**

A Phase 1 Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of BLU-554 in Patients with Hepatocellular Carcinoma and Cholangiocarcinoma incorporating the Ventana FGF19 IHC Robust Prototype Assay (RPA) for Patient Enrollment.

This Project Schedule #2, effective as of March 11, 2016, is subject to the Master Collaboration Agreement (the "Agreement") effective March 1, 2016, that has been entered into by and between Blueprint Medicines Corporation a corporation formed under the laws of the State of Delaware, with offices located at 38 Sidney Street, Cambridge, MA 02139 ("Blueprint Medicines") and Ventana Medical Systems, Inc., a corporation formed under the laws of the State of Delaware with office located at 1910 E. Innovation Drive, Tucson, AZ 85755 ("Ventana").

Unless otherwise defined herein, capitalized terms used in this Project Schedule #2 shall have the definitions set forth in the Agreement.

By this Project Schedule #2, Blueprint Medicines authorizes Ventana to undertake, in accordance with the terms of the Services Agreement, the laboratory services set forth in this Scope of Work and accompanying Budget and Payment Schedule.

#### Overview:

This Project Schedule #2 pertains to FGF19 immunohistochemistry (IHC) analysis and result reporting for prospective patient tumor tissue samples only obtained during the course of a phase 1 clinical study conducted by Blueprint Medicines (the "Clinical Study"). The Clinical Study is titled "A Phase 1 Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of BLU-554 in Patients with Hepatocellular Carcinoma and Cholangiocarcinoma" (NCT02508467). Patient samples obtained under informed consent approved by a local or central institutional review board/ethics committee will be evaluated using an analytically-validated FGF19 IHC RPA in the Ventana CAP/CLIA laboratory located in Tucson, AZ. The assay is already validated in HCC and cholangiocarcinoma and no further validation is required.

#### **Objectives**

Samples will be evaluated prospectively from this dose-escalation study to determine FGF19 expression using the Ventana FGF19 IHC RPA in the Ventana CAP CLIA lab.

#### **Samples**

It is estimated that up to approximately [...\*\*\*...] will be analyzed during the course of this project; the exact number may vary pending various study-related variables. Samples will be obtained from patients with hepatocellular carcinoma or cholangiocarcinoma. Samples will be provided to Ventana as either formalin-fixed, paraffin-embedded (FFPE) tissue blocks or a set of [...\*\*\*...] sections on positively-charged glass slides (Superfrost Plus) in which case a minimum of [...\*\*\*...] will be provided. Samples will be shipped to Ventana either directly from investigational sites or by a central laboratory (Q² Solutions) contracted by Blueprint Medicines to manage sample logistics. The key contact for this study at Q2 Solutions is [...\*\*\*...], Project Manager, Q2 Solutions, Mobile [...\*\*\*...], Fax + [...\*\*\*...], [...\*\*\*...].

Turn Around Time (TAT) and Logistics for Sample Analysis

TAT is 5 days and by definition starts from the time when the samples are received and accepted (Accessioned) by Translational
Diagnostics Laboratory Services (TDx LS), i.e., DAY 0, until the pathology score is reported to the site or designated party.

If applicable, Blueprint and/or its contracted clinical sites will use the Ventana LabVantage IT System for sample ordering and tracking
as directed at the Project Team Level. Pathology score summaries will be made available to Blueprint or its designee (Chiltern)
immediately following the TAT via Ventana's IT platform.

For cases where a sample cannot be reconciled, Ventana will contact Chiltern International to make a decision regarding whether or not to proceed with analysis of the sample. The Chiltern contact is [...\*\*\*...], Project Manager: [...\*\*\*...], Mobile [...\*\*\*...], Fax: [...\*\*\*...]. Ventana will be responsible for responding to queries generated by Blueprint Medicines or its designee regarding reconciliation of samples during the course of the study. When samples are provided to Ventana as FFPE blocks, unused tissue and slides will be shipped to the central laboratory Q2 Solutions contracted by Blueprint Medicines. Upon notification by Blueprint Medicines, samples provided as slides (including stained and unused slides) will be either be shipped to the central laboratory Q2 Solutions (or an alternative vendor) contracted by Blueprint Medicines or destroyed with documentation of sample disposition retained by Ventana.

#### Final Study Deliverable (Data/Results Reporting)

Final study data will be delivered in an agreed upon file format. An automatically QC'd data file will be generated and uploaded to Blueprint and/or its designees, i.e., Chiltern International as described above. The format and structure of these data will be agreed upon prior to the delivery of these data. If any data parsing or reformatting are required, then subject to Blueprint's prior written approval, additional fees and time to delivery may be incurred. A final clinical study report summarizing the study results and findings (if any) may be provided at additional time and cost and will be delivered on a mutually agreed upon schedule. Additionally all stained slides and copies of captured images will be provided on a mutually agreed upon schedule. Ventana will be responsible for responding to queries generated by Blueprint Medicines or its designee regarding reconciliation of data transfers during the course of the study.

#### **Project Timelines**

The dose-escalation stage of the Clinical Study began in 2015. Approximately [...\*\*\*...] patients will be enrolled in the dose-escalation stage. The dose-escalation stage will require approximately [...\*\*\*...] to be completed. The dose-expansion stage will require approximately [...\*\*\*...] to complete and will enroll [...\*\*\*...] patients. The timeline for enrollment of the study expansion is approximate and dependent on Blueprint's ability to identify and open investigational sites and the availability of potentially eligible patients.

#### **Assay for Clinical Study**

Ventana will be responsible for manufacture of the assay components required for analysis of samples obtained from the Clinical Study. Based upon a forecast provided to Ventana by Blueprint, Ventana will ensure that it maintains sufficient inventories of assay reagents as necessary to complete the Clinical Study. Ventana will also ensure that it has sufficient staff trained on the performance of the assay and will monitor the performance of the assay in connection with the Clinical Study.

#### **Project Management**

Ventana will assign dedicated personnel who will ensure project management and data quality.

#### 2. Budget for Clinical Sample Analysis

All fees are in US dollars.

#### 2.1. Assay Access Fee – FGF19 Assay

Assay Access Fee	Assay	Amount	Payment Due
Access to RPA	FGF19 IHC RPA	Waived	No charge

#### 2.2. Clinical Sample Analysis – Itemized Fixed Costs

Itemized Laboratory	Description of Services	Costs	Estimated Multiplier	Projected Total Cost
Services				
Clinical Study Image	Set-Up of Firewall between	[***]	[***]	[***]
Set-Up	various projects by various			
	sponsors			
Clinical Study Set Up	Initial Clinical Study Setup	[***]	[***]	[***]
Database Management	Database set up, data entry, data	[***]	[***]	[***]
	backup and storage, data			
	transfer to Blueprint and/or			
	Blueprint's clinical research			
	organization (CRO) – per			
	sample; database will be a FDA			
	Part 11 compliant Laboratory			
	Information System			

Itemized Laboratory Services	Description of Services	Costs	Estimated Multiplier	Projected Total Cost
Project Management	Management of study materials (lab manuals, study binders), deliverable milestones, timelines, Quality Control	[***]	[***]	[***]
Reagent New Lot Validation: Ventana Reagents (ex: antibody, probe)	Per Reagent	[***]	[***]	[***]
Significant Risk Determination (SRD)*		[***]	[***]	[***]
Investigational Device Exemption (IDE) - Significant Risk – If Needed		[***]	[***]	[***]
Investigational Device Exemption (IDE) Maintenance – If needed		[***]	[***]	[***]
IRB Submission – Annual Review (per additional year of study if needed)		[***]	[***]	[***]
IRB Submission – Study Maintenance (amendments, closure requests, etc., if needed)		[***]	[***]	[***]
Final Report	Final Report (data analysis of FGF19 in an agreed to format)	[***]	[***]	[***]
Projected Sub Total	,	•		[***]
(excludes "if needed" line	items)			

<sup>\*</sup> Email confirmation from Kelley Wolfe on 30-Nov-2015 Ventana has determined that a SRD is not required.

# 2.3. Sample Analysis – Itemized Laboratory Services and Fees FGF19 Assay

	Estimated # of slides or blocks	Cost per Test	Projected Total
Slide/block accessioning fee	[***]	[***]	[***]
per case			
H&E Stain	[***]	[***]	[***]
H&E Pathology Review	[***]	[***]	[***]
IHC Negative Control (non-	[***]	[***]	[***]
immune IgG) Staining			
IHC Negative Control –	[***]	[***]	[***]
Pathology Score			
FGF19 IHC Staining	[***]	[***]	[***]

Staining and Pathology	Estimated # of slides	or blocks	Cost per Test	Projected Total
Testing Charges				
FGF19 IHC Pathology	[***]	[***]		[***]
Score (Total Percent				
of Positive Tumor Cells)				
Clinical Sample Image –	[***]	[***]		[***]
Scan*				
*Image capture and scan;				
PER STAIN upon request				
only, e.g., just FGF19				
positives				
PROJECTED SUB TOTAL				[***]
				,

### **Total CAP/CLIA Laboratory Cost**

Category	Projected Cost
Assay Access Fee	No Charge
CAP/CLIA Lab Itemized Fixed Costs	\$[***]
Clinical Sample Analysis	\$[***]
Total	\$[***]

Payment Terms: Invoiced monthly after completion of sample analysis. For the avoidance of doubt, Blueprint Medicines will only be charged for the actual, not estimated, services performed as described herein.

All invoices should contain the following information in order for them to be processed efficiently:

П	Invoice Number
Ī	Invoice Date
	Reference to <agreed point="" reference="" to=""></agreed>
	Blueprint Medicines, Purchase Order Number (PO#)
	Blueprint Medicines, Project Number <may be="" redundant=""></may>
	Description of Services with Itemization: Stage and milestone identifications
	Deliverables
	Total Amount Due
	Payee Name and Tax ID Number
	Payment Address
	Name of requisitioner
	Contact person for any invoice questions
Additi	onally, invoices shall be submitted to Blueprint at the following email address: an@bl

voices shall be submitted to Blueprint at the following email address: ap@blueprintmedicines.com.

# All invoices will be paid by Blueprint Medicines as follows:

Credit DDA Name:	Ventana Medical Systems, Inc.
Tax Payer ID#:	[***]
Address:	[***]
Credit Bank:	[***]
Credit Bank address	[***]
Credit ABA:	[***]
Credit: DDA	[***]
Citi SWIFT Code:	[***]

### **Pass Through Expenses**

The following expenses will be billed as needed and agreed by the parties:

<u>Tissue Acquisition:</u> This work does not require tissue acquisition by Ventana.

<u>Other</u>: Any unforeseen project related expenses incurred by Ventana will be discussed in good faith by the Parties and agreed to prior to Ventana submitting to Blueprint invoices due for reimbursement.

### **Roles and Responsibilities:**

Though subject to change based on employment, the initial companies' representatives will be:

Name	Title	Phone & Fax	Address	Email Address
[***]	Senior Director of Business Development	[***]	1910 E. Innovation Park Dr.,	[***]
			Tucson, AZ 85755	
[***]	Senior Manager, Business Development	[***]	110 Pine Hill Road,	[***]
			Southborough, MA 01772	
[***]	Associate Director, Business Development	[***]	38 Sidney Street Cambridge,	[***]
			MA 02139	
[***]	Vice President Translational Medicine	[***]	38 Sidney Street Cambridge,	[***]
			MA 02139	

#### **Scope Changes**

In making changes to this Work Order, the parties will seek a "least burdensome approach" and will, to the extent reasonably practicable in light of such regulatory feedback, minimize the changes in activities and milestone payments under this Work Order.

The Work Order may be executed in one or more counterparts by the parties by signature of a person having authority to bind the party, which may be by facsimile signature, each of which when executed and delivered, by facsimile transmission or by mail delivery, will be an original and all of which will constitute but one and the same Work Order.

IN WITNESS WHEREOF, the parties hereto have caused this Work Order to be executed by their duly authorized officers the day and year written below:

Ventana Medical Systems, Inc.	Blueprint Medicines Corporation	
By: /s/ Doug Ward	By: /s/ Anthony Boral	
Name: Doug Ward	Name: Anthony Boral	
Title: VP & LCL, CDx	Title: Chief Medical Officer	
Date: March 16, 2016	Date: March 22, 2016	

# **Project Schedule #3**

# **FGF19 Microdissection Project**

This Project Schedule #3, effective as of April 8th, 2016, is subject to the Master Collaboration Agreement (the "Agreement") effective March 1,2016, that has been entered into by and between Blueprint Medicines Corporation a corporation formed under the laws of the State of Delaware, with offices located at 38 Sidney Street, Cambridge, MA 02139 ("Blueprint Medicines") and Ventana Medical Systems, Inc., a corporation formed under the laws of the State of Delaware with office located at 1910 E. Innovation Drive, Tucson, AZ 85755 ("Ventana").

Unless otherwise defined herein, capitalized terms used in this Project Schedule #3 shall have the definitions set forth in the Agreement.

By this Project Schedule #3, Blueprint Medicines authorizes Ventana to undertake, in accordance with the terms of the Services Agreement, the laboratory services set forth in this Scope of Work and accompanying Budget and Payment Schedule.

# Overview:

Blueprint Medicines is evaluating the previously developed Ventana FGF19 IHC RPA for use as a potential companion diagnostic in its BLU-554 drug development program.

This Project Schedule #3 pertains to additional analysis into previously identified tissue blocks tested using the Ventana FGF19 IHC RPA for subsequent microdissection performed at Ventana and molecular analysis by RT PCR performed at Blueprint.

Tissue samples and/or subsequent extractions will be shared between the Parties as described below. Activities required of Ventana will be performed in the Ventana Assay Development laboratory located in Tucson, AZ.

Extractions for RNA analysis sent from Ventana to Blueprint will be QC'd to confirm concentrations higher than [... \*\*\*...].

#### **Objectives**

The objective of this Project Schedule #3 is to gain a better understanding of [...\*\*\*...] in tissue samples relevant to Blueprint Medicines clinical development programs.

### Samples

The samples to be interrogated with this Exhibit C have been previously used by Ventana in FGF19 IHC RPA development and have been stored per Ventana internal procedures.

#### **Activities Description**

<u>Tier 1</u>: Obtain sections from [...\*\*\*...] FGFI9 IHC-positive blocks [...\*\*\*...] and [...\*\*\*...] FGFI9 IHC-negative blocks [...\*\*\*...]. Isolate and send RNA to Blueprint to perform FGF19 PCR in-house.

Blocks and slice specifications: [...\*\*\*...] slices / "tissue curls" at [...\*\*\*...] each per tissue block. This should provide enough RNA to conduct PCR [...\*\*\*...].

Product/Service	Description	Price	Units	Total
[***] blocks	on site at Ventana	[***]	[***]	[***]
Curls	[***] curl at [***] microns/block	[***]	[***]	[***]

Product/Service	Description	Price	Units	Total
Sections	H&E, Neg. and F6F19 x 4 blocks	[***]	[***]	[***]
Isolate and quantify RNA	[***]	[***]	[***]	[***]
Isolate and quantify RNA	[***]	[***]	[***]	[***]
Shipping	[***]	[***]	[***]	[***]
H&E Staining	[***]	[***]	[***]	[***]
Neg FGF19 staining	[***]	[***]	[***]	[***]
TOTAL				[***]

<u>Tier 2</u>: [...\*\*\*...] ([...\*\*\*...]% of tissue is positive) & [...\*\*\*...] ([...\*\*\*...]% of tissue is positive) - Positive vs Negative Regions from each. Microdissect out all neoplastic hepatocytes vs. stroma. Isolate and send RNA to Blueprint for FGF19 PCR.)

Product/Service	Description`	Price	Units	Total
Sections	([***] blocks - [***] slides and [***] slides)	[***]	[***]	[***]
FGF19 Staining-[ ***] blocks	[***] slide per block	[***]	[***]	[***]
Annotation per Block	Per Block	[***]	[***]	[***]
Dissection per slide	[***] to [***] (may vary)	[***]	[***]	[***]
Isolate and quantify RNA	Fixed Cost	[***]	[***]	[***]
Isolate and quantify RNA	Per sample ([***]/block)	[***]	[***]	[***]
qRT-PCRQC	Per sample ([***]/block)	[***]	[***]	[***]
TOTAL				[***]

<u>Tier 3</u>: If needed only and agreed upon within project teams, [...\*\*\*...] - Positive Tumor vs Positive Stroma from each. VMSI to provide [...\*\*\*...] unstained glass slides from each of the [...\*\*\*...] tissue blocks mentioned above - this will be for performing ISH.

Product/Service	Description	Price	Units	Total
Sections	([***] blocks - [***] slides and [***] slides)	[***]	[***]	[***]
FGF19 Staining - [***] blocks	[***] slide per block	[***]	[***]	[***]
Annotation per Block	Per Block	[***]	[***]	[***]
Dissection per slide	[***] to [***] (may vary)	[***]	[***]	[***]
Isolate and quantify RNA	Fixed Cost	[***]	[***]	[***]
Isolate and quantify RNA	Per sample ([***]/block)	[***]	[***]	[***]
qRT-PCR QC	Per sample ([***]/block)	[***]	[***]	[***]
TOTAL				[***]

### **Summary**

Tier l	[***]
Tier 2	[***]
Tier 3	[***]
TOTAL	[***]

# Final Study Deliverable (Data/Results Reporting)

Results of sample analyses will be provided to the clinical trial investigator as PDF reports within [...\*\*\*...] business days of receipt at Ventana. Ventana will also provide data/results in electronic form to Blueprint Medicines and/or its designee in the format and frequency (e.g., monthly) agreed upon in a date transfer plan. Ventana will be responsible for responding to queries generated by Blueprint Medicines or its designee regarding reconciliation of data transfers during the course of the study. Ventana will provide a final summary at completion of the clinical study to Blueprint Medicines (or a designee).

# **Project Timelines**

The projected start of this Scope of Work is April 15, 2016 and expected completion date is June 30th, 2016.

### **Assay for Clinical Study**

Ventana will be responsible for manufacture of the assay components required for analysis of samples obtained from the Clinical Study. Based upon a forecast provided to Ventana by Blueprint, Ventana will ensure that it maintains sufficient inventories of assay reagents as necessary to complete conduct of the Clinical Study. Ventana will also ensure that it has sufficient staff trained on the performance of the assay and will monitor the performance of the assay in connection with the Clinical Study.

# **Project Management**

Ventana will assign dedicated personnel who will ensure project management and data quality.

Payment Terms: Invoiced monthly after completion of sample analysis. For the avoidance of doubt, Blueprint Medicines will only be charged for the actual, not estimated, services performed as described herein.

All invoices should contain the following information in order for them to be processed efficiently:

Invoice Number

Invoice Date

Reference to <agreed to reference point>

Blueprint Medicines, Purchase Order Number (PO#)

Blueprint Medicines, Project Number <may be redundant>

Description of Services with Itemization: Stage and milestone identifications

Deliverables

**Total Amount Due** 

Payee Name and Tax ID Number

Payment Address

Name of requisitioner

Contact person for any invoice questions

Additionally, invoices shall be submitted to Blueprint at the following email address: [...\*\*\*...].

# All Invoices will be paid by Blueprint Medicines as follows:

Credit DDA Name:	Ventana Medical Systems, Inc.
Tax Payer ID#:	[***]
Address:	[***]
Credit Bank:	[***]
Credit Bank address	[***]
Credit ABA:	[***]
Credit: DDA	[***]
Citi SWIFT Code:	[***]

# **Pass Through Expenses**

The following expenses will be billed as needed and agreed by the parties:

Tissue Acquisition: This work does not require tissue acquisition by Ventana.

<u>Other</u>: Any unforeseen project related expenses incurred by Ventana will be discussed in good faith by the Parties and agreed to prior to Ventana submitting to Blueprint invoices due for reimbursement.

## **Roles and Responsibilities:**

Though subject to change based on employment, the initial companies' representatives will be:

Name	Tide	Phone & Fax	Address	Email Address
[***]	Senior Director of Business Development	[***]	1910 E. Innovation Park Dr., Tucson, AZ 85755	[***]
[**]	Senior Manager, Business Development	[***]	110 Pine Hill Road Southborough, MA 01772	[***]
[***]	Associate Director, Business Development	[***]	38 Sidney Street Cambridge, MA 02139	[***]
[***]	Vice President Translational Medicine	[***]	38 Sidney Street Cambridge, MA 02139	[***]

# **Scope Changes**

In making changes to this Work Order, the parties will seek a "least burdensome approach" and will, to the extent reasonably practicable in light of such regulatory feedback, minimize the changes in activities and milestone payments under this Work Order.

The Work Order may be executed in one or more counterparts by the parties by signature of a person having authority to bind the party, which may be by facsimile signature, each of which when executed and delivered, by facsimile transmission or by mail delivery, will be an original and all of which will constitute but one and the same Work Order.

IN WITNESS WHEREOF, the parties hereto have caused this Work Order to be executed by their duly authorized officers the day and year written below:

Ventana Medical Systems, Inc.	<b>Blueprint Medicines Corporation</b>
By: /s/ Doug Ward	By: /s/ Jeffrey Albers
Name: Doug Ward	Name: Jeffrey Albers
Title: VP & LCL, CDx	Title: CEO
Date: April 21, 2016	Date: May 6, 2016

\*\*\*Text Omitted and Filed Separately with the Securities and Exchange Commission Confidential Treatment Requested Under 17 C.F.R. Sections 200.80(b)(4) and 230.406

# **Execution Version**

# **Collaboration and License Agreement**

This Agreement is entered into with effect as of the Effective Date (as defined below)

by and between

#### F. Hoffmann-La Roche Ltd

with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("Roche Basel")

and

#### Hoffmann-La Roche Inc.

with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, U.S.A. ("**Roche US**"; Roche Basel and Roche US together referred to as "**Roche**")

on the one hand

and

# **Blueprint Medicines Corporation**

with an office and place of business at 38 Sidney Street, Suite 200, Cambridge, Massachusetts 02139, U.S.A. ("**BPM**") on the other hand.

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#### **Collaboration and License Agreement**

WHEREAS, BPM owns or controls a proprietary uniquely annotated small molecule library addressing the entire kinome, including well-characterized library sub-sets suited for screening purposes, and provides significant chemistry and preclinical development expertise and experience in bringing hits from this library through lead optimization and GLP Tox Studies to Phase I Study in an efficient manner; and

WHEREAS, BPM has proprietary bioinformatics expertise including algorithms for mining of genomic information which supports elucidation of new targets or provides differentiated insights on biology of known targets; and

WHEREAS, Roche has expertise in the research, development, manufacture and commercialization of pharmaceutical products, and owns or controls [...\*\*\*...]; and

WHEREAS, Roche is a leader in the field of cancer immunotherapy clinical development including combination trials; and

WHEREAS, Roche and BPM wish to combine their respective expertise to develop products against three (3) selected targets ([... \*\*\*...], [...\*\*\*...] and [...\*\*\*...]) as well as up to an additional two (2) targets selected from a collaboratively shared screening and target validation effort based on BPM Technology (defined below) and Roche's proprietary assays and know-how in cancer immunotherapy; and

WHEREAS, BPM is willing to grant to Roche rights to opt-into each of these five (5) programs at a defined point in time and to use BPM's intellectual property rights to Exploit Collaboration Compounds, Products and Licensed Products in the Territory for use in the Field (as such terms are respectively defined below), as contemplated herein; and

WHEREAS, Roche and BPM agree that BPM will perform certain activities to Exploit the Collaboration Compounds, Products and Licensed Products for use in the Field (as such terms are respectively defined below).

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

#### 1. Definitions

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

#### 1.1 Affiliate

The term "Affiliate" shall mean, with respect to a Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with such Person. As used in this definition of "Affiliate," the term "control" shall mean the direct or indirect ownership of more than fifty percent

(>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of such Person whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, neither [...\*\*\*...] and/or its subsidiaries (if any) nor [...\*\*\*...] and/or its subsidiaries (if any) shall be deemed as Affiliates of Roche unless Roche provides written notice to BPM of its desire to include [...\*\*\*...] and/or their respective subsidiaries (as applicable) as Affiliate(s) of Roche.

# 1.2 Agreement

The term "Agreement" shall mean this document including any and all appendices and amendments to it as may be added and/or amended from time to time in accordance with the provisions of this Agreement.

# 1.3 Agreement Term

The term "Agreement Term" shall mean the period of time commencing on the Effective Date and, unless this Agreement is terminated sooner as provided in Article 21, expiring on the date when no royalty or other payment obligations under this Agreement are or will become due.

#### 1.4 Allocable Overhead

The term "Allocable Overhead" shall mean costs incurred by a Party or for its account which are attributable to a Party's supervisory or support services / functions, occupancy costs, corporate bonus (to the extent not charged directly to department), and its payroll, information systems, human relations or purchasing functions and which are allocated to company departments based on space occupied or headcount or other activity-based method. Allocable Overhead shall not include any costs attributed to a Party's direct personnel costs or Out of Pocket Costs or to general corporate activities including, by way of example, executive management, investor relations, business development, legal affairs and finance.

#### 1.5 Animal POC

The term "Animal POC" shall mean the demonstration of efficacy of Collaboration Compounds in at least one animal model performed by or on behalf of Roche during Lead Optimization.

#### 1.6 Applicable Law

The term "Applicable Law" shall mean any law, statute, ordinance, code, rule or regulation that has been enacted by a government authority (including without limitation, any Regulatory Authority) and is in force as of the Effective Date or comes into force during the Agreement Term, in each case to the extent that the same is applicable to the Parties' respective rights or the performance by the Parties of their respective obligations under this Agreement.

# 1.7 Backup Compound

The term "Backup Compound" shall mean, on a Collaboration Target-by-Collaboration Target basis, any Collaboration Compound made under the Research Plan for a given Collaboration Target that is intended to replace a more advanced Collaboration Compound in the event development of such more advanced Collaboration Compound is terminated, [...\*\*\*...].

## 1.8 BPM Group

The term "BPM Group" shall mean collectively BPM, its Affiliates and its Sublicensees.

## **1.9 BPM IP**

The term "BPM IP" shall mean (a) Know-How and Patent Rights that BPM and its Affiliates Control (i) as of the Effective Date, and/or (ii) during the Agreement Term to the extent used by BPM or its Affiliates to perform activities under this Agreement (but excluding Supplemental Studies

unless Roche opts-in pursuant to Section 7.2), (b) BPM's interest in any Joint IP, and (c) BPM Sole IP, and in each case ((a) through (c)) that are necessary or useful for the Exploitation of Collaboration Compounds, Products or Licensed Products, but excluding BPM Technology, Collaboration Compound IP and Other Compound IP. The foregoing Patent Rights in the BPM IP shall be listed in Appendix 1.9 of this Agreement and updated from time to time (but failure to list same will not exclude them as BPM IP). For clarity, after any Change of Control of BPM, no Know-How or Patent Rights of any BPM Affiliate that becomes a BPM Affiliate after the Change of Control of BPM shall become "BPM IP" hereunder unless such Know-How or Patent Rights are intentionally used by BPM in BPM's performance of research, development or commercialization activities under this Agreement.

#### 1.10 BPM Net Sales

The term "BPM Net Sales" shall mean the net sales on behalf of BPM and any of its Affiliates or Sublicensees for any Licensed Product sold to Third Parties (other than Sublicensees) in bona fide, arms-length transactions, as determined in accordance with GAAP, less the following deductions: (a) normal trade and cash discounts, (b) amounts repaid or credited by reasons of defects, rejections, recalls or returns, (c) rebates and chargebacks to customers and Third Parties (including Medicare, Medicaid, Managed Healthcare and similar types of rebates), (d) any amounts recorded in gross revenue associated with goods provided to customers for free, (e) amounts provided or credited to customers through coupons and other discount programs, (f) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates, (g) fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information), (h) a fixed deduction of [...\*\*\*...] for direct expenses related to the sales of Licensed Product(s) for distribution and warehousing expenses and uncollectible amounts on previously sold Licensed Products, (i) taxes and any other governmental charges or levies imposed upon or measured by the Exploitation of a Licensed Product (excluding income or franchise taxes) as well as government mandated fees and taxes and other government charges, including any fees, taxes or other charges specifically attributable to a Licensed Product that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body, and (j) other reductions or specifically identifiable amounts deducted for reasons similar to those listed above in accordance with GAAP. For clarity, no deduction may be taken more than once in the calculation of BPM Net Sales.

In the case of any sale or other disposal of a Licensed Product between or among BPM and any of its Affiliates or Sublicensees, for resale, BPM Net Sales shall be calculated only on the value charged or invoiced on the first arm's-length sale thereafter to a Third Party (other than a Sublicensee). In the case of any sale that is not invoiced or is delivered before invoice, BPM Net Sales shall be calculated at the time all the revenue recognition criteria under GAAP are met. Notwithstanding the foregoing, the following will not be included in BPM Net Sales: (i) sales between or among BPM and its Affiliates or Sublicensees (but BPM Net Sales will include sales to the first Third Party (other than a Sublicensee) by BPM or its Affiliates or Sublicensees); (ii) samples of Licensed Product used to promote additional BPM Net Sales, in amounts consistent with normal business practices of BPM or its Affiliates or Sublicensees; and (iii) disposal or use of Licensed Products in Clinical Studies or under compassionate use, patient assistance, named patient use, or test marketing programs or non-registrational studies or other similar programs or studies where the Licensed Product is supplied without charge or at the actual manufacturing cost thereof (without allocation of indirect costs or any mark-up).

With respect to a Combination Product, BPM Net Sales of such Combination Product eligible for royalties shall be adjusted to subtract the Relative Commercial Value of any Other Component of such Combination Product in accordance with Section 12.9.4.

To the extent that BPM or its Affiliates or Sublicensees receives consideration other than or in addition to cash upon the sale of a Licensed Product, or the performance of any services (including preliminary treatments or follow-up treatments) related to such Licensed Product, BPM Net Sales will include the fair market value of such additional consideration.

## 1.11 BPM Patent Rights

The term "BPM Patent Rights" shall mean all Patent Rights contained in the BPM IP.

#### 1.12 BPM Sole IP

The term "BPM Sole IP" shall mean all Patent Rights and Know-How arising from a BPM Invention.

## 1.13 BPM Technology

The term "BPM Technology" shall mean BPM's proprietary library (in the form as of the Effective Date or during the Research and Development Term) and related Patent Rights and Know-How against the kinome and its annotation.

#### 1.14 BPM Territory

The term "BPM Territory" shall mean, with respect to Program 2 and Program 4, the US.

#### 1.15 Business Day

The term "Business Day" shall mean 9:00am to 5:00pm local time on a day other than a Saturday, Sunday or bank or other public or federal holiday in Switzerland or Massachusetts, US.

# 1.16 Calendar Quarter

The term "Calendar Quarter" shall mean each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, and December 31.

## 1.17 Calendar Year

The term "Calendar Year" shall mean the period of time beginning on January 1 and ending December 31, except for the first year which shall begin on the Effective Date and end on December 31.

#### 1.18 CCS Criteria

The term "CCS Criteria" shall mean the criteria set forth in Appendix 1.18 of this Agreement that constitute clinical candidate selection, unless such criteria are modified by the JRC.

# 1.19 Change of Control

The term "Change of Control" shall mean, with respect to a Party: (a) the acquisition (in a transaction or series of related transactions) by any Third Party, together with its Affiliates, of beneficial ownership of fifty percent (50%) or more of the then outstanding securities or combined voting power of such Party, other than acquisitions by employee benefit plans sponsored or maintained by such Party; (b) the consummation of a business combination (including a merger or consolidation) involving such Party with a Third Party, unless, following such business combination, the stockholders of such Party immediately prior to such business combination beneficially own directly or indirectly more than fifty percent (>50%) of the then outstanding securities or combined voting power of the surviving entity or the parent of the surviving entity immediately after such business combination; or (c) the sale or other transfer to a Third Party of

all or substantially all of such Party's and its Affiliates' assets or business relating to the subject matter of the Agreement.

## 1.20 Change of Control Group

The term "Change of Control Group" shall mean with respect to a Party, the person or entity, or group of persons or entities, that is the acquirer of, or a successor to, a Party in connection with a Change of Control, together with affiliates of such persons or entities that are not Affiliates of such Party immediately prior to the completion of such Change of Control of such Party.

#### 1.21 Clinical Study

The term "Clinical Study" shall mean any Phase I Study, Phase II Study, Phase III Study, Pivotal Study, Post-Marketing Study, Supplemental Study or other study in humans to obtain information regarding the product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of the product, as applicable.

# 1.22 CLS Achieved

The term "CLS Achieved" shall mean that a Product contains a Collaboration Compound meeting the CLS Criteria, unless such criteria are modified by the JRC.

#### 1.23 CLS Criteria

The term "CLS Criteria" shall mean the criteria set forth in Appendix 1.23 of this Agreement that constitute clinical lead selection, unless such criteria are modified by the JRC.

### 1.24 Collaboration Compound

The term "Collaboration Compound" shall mean any compound made under the Research Plan for a given Collaboration Target that satisfies the Compound Criteria. A Collaboration Compound includes all salts, polymorphs, metabolites, prodrugs, isomers, enantiomers and stereoisomers of such Collaboration Compound, in each case that satisfies the Compound Criteria.

# 1.25 Collaboration Compound IP

The term "Collaboration Compound IP" shall mean all Patent Rights and Know-How Covering Collaboration Compounds and that is generated by either Party individually or both Parties jointly pursuant to a Research Plan or Phase I Plan.

#### 1.26 Collaboration Target

The term "Collaboration Target" shall mean (i) each of [...\*\*\*...] (Uniprot [...\*\*\*...]), [...\*\*\*...] ([...\*\*\*...] is Uniprot [...
\*\*\*...] and [...\*\*\*...] is Uniprot [...\*\*\*...]) and [...\*\*\*...] (Uniprot [...\*\*\*...]) and (ii) each of the Targets selected from the Pool to pursue in Part 2 or mutually selected by the Parties in Part 2 [...\*\*\*...], for each of (i) and (ii) subject to exchange of such Target pursuant to Sections 4.1.5 or 4.1.6, as applicable. For clarity, the Collaboration Targets shall not include any Excluded Targets, Leftover Targets or Terminated Targets.

#### 1.27 Combination Product

The term "Combination Product" shall mean

(a) a single pharmaceutical formulation (whether co-formulated or administered together via the same administration route) containing as its active ingredients both a Collaboration Compound and one or more other therapeutically or prophylactically active ingredients (each an "Other Component"), or

(b) a combination therapy comprised of a Collaboration Compound and one or more Other Component(s), whether priced and sold in a single package containing such multiple products, packaged separately but sold together for a single price, or sold under separate price points but labeled for use together.

in each case, including all dosage forms, formulations, presentations, and package configurations. Drug delivery vehicles, adjuvants and excipients will not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant or excipient is recognized by the FDA as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7). All references to Products or Licensed Products in this Agreement shall be deemed to include Combination Products.

1.28 [...\*\*\*...]

#### 1.29 Commercially Reasonable Efforts

The term "Commercially Reasonable Efforts" shall mean, with respect to the performance of an obligation under this Agreement, such level of efforts and resources consistent with the efforts Roche or BPM, as applicable, devotes to a similar obligation at the same stage of research, development or commercialization, as applicable, for its own internally developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life, taking into account the existence of other competitive products in the market place or under development, the proprietary position of the product, the regulatory structure involved, the anticipated profitability of the product and other relevant factors. It is understood that such level of efforts or resources may change from time to time based upon changing scientific, business and marketing and return on investment considerations; provided, however, that the payments required to be made by a Party to the other Party pursuant to this Agreement will not be taken into account.

However, Roche (and its Affiliates) does not always seek to market its own products in every country or seek to obtain Regulatory Approval in every country or for every potential Indication. As a result, the exercise of diligence by Roche under this standard is to be determined by judging Roche's efforts in (i) the Major Countries, taken as a whole, and (ii) the Territory excluding the Major Countries, taken as a whole.

## 1.30 Companion Diagnostic

The term "Companion Diagnostic" shall mean any product or service that:

- (a) identifies a person having a disease or condition, or a molecular genotype or phenotype that predisposes a person to such disease or condition, for which a Product or Licensed Product could be used to treat and/or prevent such disease or condition;
- (b) defines the prognosis or monitors the progress of a disease or condition in a person for which a Product or Licensed Product could be used to treat and/or prevent such disease or condition;
- (c) is used to select a therapeutic or prophylactic regimen, wherein at least one (1) potential therapeutic or prophylactic regimen involves a Product or Licensed Product, and where the selected regimen is determined, based on the use of such product or service, to likely be effective and/or to be safe for a person; and/or
- (d) is used to confirm a Product or Licensed Product's biological activity and/or to optimize dosing or the scheduled administration of a Product or Licensed Product.

# 1.31 Composition of Matter Claim

The term "Composition of Matter Claim" shall mean, for a given Licensed Product in a given country of the Territory, a Valid Claim of the Collaboration Compound IP or BPM IP or any Patent Rights owned or in-licensed by Roche or its Affiliates (only in the case of sales of Licensed Product

in the BPM Territory for Program 2 and Program 4) that Covers the composition of matter of the Collaboration Compound that is included in such Licensed Product, in whole or as a component thereof.

#### 1.32 Compound Criteria

The term "Compound Criteria" shall mean the criteria, on a Collaboration Target-by-Collaboration Target basis, that are (i) determined by the JRC, (ii) approved by the Parties, and (iii) documented as part of the applicable Research Plan.

# 1.33 Compulsory Sublicense Compensation

The term "Compulsory Sublicense Compensation" shall mean, for a given country or region, the compensation paid to the Roche Group or the BPM Group (as applicable) by a Third Party (a "Compulsory Sublicensee") under a license or sublicense of any applicable Patent Rights granted to the Compulsory Sublicensee (the "Compulsory Sublicense") through the order, decree or grant of a governmental authority having competent jurisdiction in such country or region, authorizing such Third Party to manufacture, use, sell, offer for sale, import or export a Licensed Product in such country or region.

#### 1.34 Confidential Information

The term "Confidential Information" shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by one Party or its Affiliates ("**Disclosing Party**") to the other Party or its Affiliates ("**Receiving Party**"). Confidential Information shall not include any information, data or know-how that:

- (i) was generally available to the public at the time of disclosure, or becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates,
- (ii) can be evidenced by written records to have been already known to the Receiving Party or its Affiliates prior to its receipt from the Disclosing Party,
- (iii) is obtained by the Receiving Party at any time lawfully from a Third Party under circumstances permitting its use or disclosure.
- (iv) is developed independently by the Receiving Party or its Affiliates as evidenced by written records other than through knowledge of Confidential Information, or
- (v) is approved in writing by the Disclosing Party for release by the Receiving Party.

The terms of this Agreement shall be considered Confidential Information of the Parties.

#### 1.35 Continuation Election Notice

The term "Continuation Election Notice" shall mean the notice BPM provides to Roche under Section 21.3.1 describing (i) BPM's bona fide intention(s) to continue ongoing development and commercialization of Licensed Product(s) and (ii) BPM's request for Roche's continuation of activities during the termination period or transfer of the data, material and information relating to the Licensed Product(s) in accordance with Section 21.3.1.

#### 1.36 Control

The term "Control" shall mean (as an adjective or as a verb including conjugations and variations such as "Controls" "Controlled" or "Controlling") (a) with respect to Patent Rights and/or Know-How, the possession by a Party of the ability to grant a license or sublicense of such Patent Rights and/or Know-How without violating the terms of any agreement or arrangement between such Party and any other party and (b) with respect to proprietary materials, the possession by a Party of the ability to supply such proprietary materials to the other Party as provided herein without violating the terms of any agreement or arrangement between such Party and any other party or

without being obligated to pay any royalties or other consideration therefor, except for that which BPM or its Affiliates in-licenses and under which Roche elects to take a sublicense and agrees to make the associated payments pursuant to Section 2.4 which shall be considered under the Control of BPM or its Affiliates.

#### **1.37** Cover

The term "Cover" shall mean (as an adjective or as a verb including conjugations and variations such as "Covered," "Coverage" or "Covering") that the Exploitation of a given compound, formulation or product would infringe a Valid Claim in the absence of a license under or ownership in the Patent Rights to which such Valid Claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis.

#### 1.38 CRO

The term "CRO" shall mean a contract research organization or a contract manufacturing organization, a list of approved CROs is attached as Appendix 1.38, as such appendix may be amended or restated from time to time in accordance with the terms of this Agreement.

## 1.39 Development Costs

The term "Development Costs" shall mean as to each Collaboration Target in the Field in the Territory, those (i) costs and expenses directly incurred (including personnel costs and Allocable Overhead associated with employees and contractors of a Party) with the performance of any clinical development activities (other than Phase I Studies) for Collaboration Compounds, Products or Licensed Products for such Collaboration Target, (ii) fees charged by Third Party service providers and other Out of Pocket Costs reasonably incurred in connection with the performance of any Clinical Study (other than Phase I Studies) with respect to Collaboration Compounds, Products, Licensed Products, or Companion Diagnostics for such Collaboration Target, and (iii) all costs associated with research or development of Companion Diagnostics, in each case, that are recorded as an expense in accordance with IFRS or GAAP as applicable and consistently applied. In addition, Development Costs shall include (A) the cost of additional studies on the toxicological, pharmacokinetic, metabolic or clinical aspects of such Product or Licensed Product conducted by individual investigators or consultants and (B) expenses for data management, statistical designs and studies, document preparation, and other expenses associated with the clinical testing program for additional studies. For clarity, Development Costs for each Product or Licensed Product shall include (a) manufacturing and supply costs and expenses associated with such Product or Licensed Product, and (b) costs related to preparing the initial regulatory dossier for such Product or Licensed Product. All manufacturing and supply costs and expenses for Roche Clinical Compounds and Roche Marketed Products shall be at Roche's sole expense.

For clarity, Development Costs shall exclude (A) capital expenditures, (B) Phase I Development Costs, and (C) for Program 2 and Program 4, any costs and expenses associated with Supplemental Studies (other than Supplemental Studies that a Party opts-in to pursuant to Section 7.2).

## 1.40 Development Plan

The term "Development Plan" shall mean, for each Program, the plan for the clinical development of Licensed Products for such Program in the Field in the Territory, which plan shall include a budget for each of Program 2 and Program 4 and the planned Clinical Studies for the [...\*\*\*...] Label Pursuits for each of Program 2 and Program 4.

#### 1.41 Effective Date

The term "Effective Date" shall mean March 14, 2016.

#### 1.42 EU

The term "EU" shall mean the European Union and all its then-current member countries.

#### 1.43 Excluded Field

The term "Excluded Field" shall mean [...\*\*\*...].

#### 1.44 Excluded Targets

The term "Excluded Targets" shall mean the Targets listed in Appendix 1.44 of this Agreement.

#### 1.45 Expert

The term "Expert" shall mean a person with no less than ten (10) years of pharmaceutical industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to drug discovery, product development (in the case of Section 2.5.2) or commercialization and/or licensing (in the case of Section 12.9.4) but excluding any current or former employee or consultant of either Party or its Affiliates. Such person shall be fluent in the English language.

# 1.46 Exploit

The term "Exploit" shall mean (including conjugations and variations such as "Exploiting" or "Exploitation") to research, have researched, develop, have developed, register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold and offer for sale and have offered for sale, including all research, development, manufacturing and commercialization activities.

## 1.47 FBMC

The term "FBMC" shall mean the sum of (a) the cost of goods produced, determined in accordance with IFRS or GAAP guidelines as consistently applied by Roche or BPM in the ordinary course of its business, including direct labor, material, payments to Third Parties for costs incurred and product testing costs of Collaboration Compounds, Products or Licensed Products, as well as Allocable Overhead, and (b) any other Out of Pocket Costs borne by Roche or BPM for the packaging, transport, customs clearance, and storage of Collaboration Compounds, Products or Licensed Products (e.g., containers, freight, duties, insurance and warehousing).

#### 1.48 FDA

The term "FDA" shall mean the Food and Drug Administration of the United States of America.

#### 1.49 FDCA

The term "FDCA" shall mean the Food, Drug and Cosmetics Act.

# 1.50 Field

The term "Field" shall mean any use other than the Excluded Field.

# 1.51 Filing

The term "Filing" shall mean the filing of an application by the FDA as defined in the FDCA and applicable regulations, or the equivalent application to the equivalent agency in any other country or group of countries, the official approval of which is required before any lawful commercial sale or marketing of Licensed Products.

#### 1.52 First Commercial Sale

The term "First Commercial Sale" shall mean, on a country-by-country and Licensed Product-by-Licensed Product basis, the first commercial sale of a Licensed Product to a Third Party by the Roche Group or by the BPM Group, as applicable, in such country following the receipt of any Regulatory Approval required for the sale of such Licensed Product in such country, or if no such Regulatory Approval is required, the date of the first commercial sale of a Licensed Product in such country to a Third Party by (i) the Roche Group in such country or (ii) the BPM Group in the BPM Territory, as applicable.

#### 1.53 GAAP

The term "GAAP" shall mean US Generally Acceptable Accounting Principles.

#### 1.54 Generic Product

The term "Generic Product" shall mean, with respect to a particular Licensed Product and on a country-by-country basis, a generic pharmaceutical product that is marketed for sale by a Third Party (not licensed, supplied or otherwise permitted by the Roche Group or the BPM Group) and that: (i) (a) contains the same or substantially the same active ingredient as the Collaboration Compound in such Licensed Product; and (b) is approved for use in such country by a Regulatory Authority through an Abbreviated New Drug Application as defined in the FDCA, and the regulations promulgated thereunder, pursuant to Article 10.1 of Directive 2001/83/EC of the European Parliament and Council of 6 November 2001, or any enabling legislation thereof, or pursuant to any similar abbreviated route of approval in such country; or (ii) (a) contains the same or substantially the same active ingredient as the Collaboration Compound in such Licensed Product; and (b) is approved for use in such country by a Regulatory Authority through a regulatory pathway referencing clinical data first submitted by the Roche Group or the BPM Group for obtaining Regulatory Approval for such Licensed Product.

#### 1.55 Handle

The term "Handle" shall mean preparing, filing, prosecuting (including interference and opposition proceedings) and maintaining (including interferences, reissue, re-examination, pre- and post-grant reviews, inter-parties reviews, derivation proceedings and opposition proceedings, patent term adjustment and extensions (including those arising from Regulatory Approvals), supplementary protection certificates and other similar proceedings), but not with respect to any infringement or other enforcement activities.

#### 1.56 IFRS

The term "IFRS" shall mean International Financial Reporting Standards.

#### 1.57 IND

The term "IND" shall mean an application as defined in the FDCA and applicable regulations promulgated by the FDA, or the equivalent application to the equivalent agency in any other country or group of countries, the filing of which is necessary to commence clinical testing of the Products and/or Licensed Products in humans.

## 1.58 Indication

The term "Indication" shall mean a disease (i) for which the Licensed Product is indicated for treatment and (ii) that is described in the Licensed Product label as required by the Regulatory Approval granted by the applicable Regulatory Authority. [...\*\*\*...].

#### 1.59 Initiation

The term "Initiation" shall mean the date that a human is first dosed with the Product or Licensed Product, as applicable, in a Clinical Study approved by the respective Regulatory Authority.

#### 1.60 Initiation of GLP Tox Study

The term "Initiation of GLP Tox Study" shall mean the date of the approval by the JRC of the final protocol for a study of the relationship between dose and its effects on the exposed animal, where (i) the study is to be conducted in accordance with Good Laboratory Practice standards and (ii) the study has been designed in expectation that the results may support establishment of a safe starting dose of the Product in human clinical studies (a "GLP Tox Study").

## 1.61 Insolvency Event

The term "Insolvency Event" shall mean circumstances under which a Party (i) has a receiver or similar officer appointed over all or a material part of its assets or undertaking; (ii) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); (iii) enters into any composition or arrangement with its creditors (other than relating to a solvent restructuring); (iv) ceases to carry on business; or (v) is unable to pay its debts as they become due in the ordinary course of business.

#### 1.62 Invention

The term "Invention" shall mean an invention that is conceived in connection with any activity carried out pursuant to this Agreement. Under this definition, but subject to Section 16.1, an Invention may be made by employees, consultants or contractors of BPM solely or jointly with a Third Party (a "**BPM Invention**"), by employees, consultants or contractors of the Roche Group solely or jointly with a Third Party (a "**Roche Invention**"), or jointly by employees, consultants or contractors of BPM and employees, consultants or contractors of the Roche Group with or without a Third Party (a "**Joint Invention**").

#### 1.63 JDC

The term "JDC" shall mean the joint development committee that oversees all activities pursuant to the Phase I Plans and all clinical development of Licensed Products by the Parties after exercise of an Option Right, and is described in Section 8.2.

#### 1.64 Joint IP

The term "Joint IP" shall mean all Joint Patent Rights and Joint Know-How.

#### 1.65 Joint Know-How

The term "Joint Know-How" shall mean all Know-How that is conceived jointly by the Parties or their Sublicensees in connection with any activity carried out pursuant to this Agreement. For clarity, Joint Know-How shall include all Know-How within the Biomarker IP.

#### 1.66 Joint Patent Rights

The term "Joint Patent Rights" shall mean all Patent Rights arising from a Joint Invention. For clarity, Joint Patent Rights shall include all Patent Rights within the Biomarker IP.

# 1.67 JOT

The term "JOT" shall mean a joint operating team if established by the JRC under Section 8.4 or the JDC under Section 8.5.

#### 1.68 JRC

The term "JRC" shall mean the joint research committee that oversees all activities under the Research Plans, and is described in Section 8.1.

#### 1.69 Know-How

The term "Know-How" shall mean data, knowledge and information, including materials, samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical data, assays, platforms, formulations, specifications, quality control testing data, that are necessary or useful for the discovery, manufacture, development or commercialization of Products and/or Licensed Products.

#### 1.70 Lead Nomination

The term "Lead Nomination" shall mean the preclinical development activities performed for each Collaboration Target at the beginning of Part 1 and for Collaboration Targets selected in Part 2 after Target Validation with the goal to identify Collaboration Compounds which satisfy the Lead Series Identified Criteria.

## 1.71 Lead Optimization

The term "Lead Optimization" shall mean the preclinical development activities performed for each Collaboration Target following Lead Nomination, with the goal to identify Collaboration Compounds suitable for GLP Tox Studies and meeting CCS Criteria.

## 1.72 Lead Series Identified Criteria

The term "Lead Series Identified Criteria" shall mean the lead series identified criteria set forth in Appendix 1.72 of this Agreement, unless such criteria are modified by the JRC.

#### 1.73 Leftover Targets

The term "Leftover Targets" shall mean those Collaboration Targets for which an Option Right has not been exercised by Roche, including those (i) in the Pool after the JRC's right to replace Collaboration Targets in the Pool has ended pursuant to Section 4.1.6, and/or (ii) that have been replaced with a new Collaboration Target, or for which further preclinical development activities are not pursued under Part 2.

#### 1.74 Library Compound

The term "Library Compound" shall mean any compound included in BPM Technology but excluding any Other Compound or Collaboration Compound.

#### 1.75 Licensed Product

The term "Licensed Product" shall mean a Product to which Roche has exercised its Option Right to the corresponding Collaboration Target. For clarity, a Reversion Product shall not be considered a Licensed Product.

#### 1.76 Major Countries

The term "Major Countries" shall mean [...\*\*\*...].

1.77 [...\*\*\*...]

# 1.78 MTD

The term "MTD" shall mean, for each Collaboration Target, the dose and schedule that will be used for the Product [...\*\*\*...] in the expansion part of the first Phase I Study or in the first Phase II Study, if no expansion is planned for the first Phase I Study. The MTD may be the maximum

tolerated dose, as defined in the Phase I Study protocol for each Collaboration Target, or it may be a lower dose. The MTD for each Collaboration Target will be confirmed by the JDC.

#### 1.79 NDA

The term "NDA" shall mean a new drug application, including all necessary documents, data, and other information concerning a Licensed Product, required for Regulatory Approval of the Licensed Product as a pharmaceutical product by the FDA or an equivalent application to the equivalent agency in any other country or group of countries (*e.g.* the marketing authorization application (MAA) in the EU).

#### 1.80 Net Sales

The term "Net Sales" shall mean, for a Licensed Product in a particular period, the amount calculated by subtracting from the Sales of such Licensed Product for such period: (i) a lump sum deduction of [...\*\*\*...] of Sales in lieu of those deductions that are not accounted for on a Licensed Product-by-Licensed Product basis (e.g., freight, postage charges, transportation insurance, packing materials for dispatch of goods, custom duties); (ii) uncollectible amounts accrued during such period based on a proportional allocation of the total bad debts accrued during such period and not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Licensed Product for such period; (iii) credit card charges (including processing fees) accrued during such period on such Sales and not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Licensed Product for such period; and (iv) government mandated fees and taxes and other government charges accrued during such period not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Licensed Product for such period, including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body. For clarity, no deductions taken in calculating Sales under Section 1.119 may be taken a second time in calculating Net Sales.

With respect to a Combination Product, Net Sales of such Combination Product eligible for royalties shall be adjusted to subtract the Relative Commercial Value of any Other Component of such Combination Product in accordance with Section 12.9.4.

To the extent that Roche or its Affiliates or Sublicensees receives consideration other than or in addition to cash upon the Sale of a Licensed Product, or the performance of any services (including preliminary treatments or follow-up treatments) related to such Licensed Product, Net Sales will include the fair market value of such additional consideration.

#### 1.81 Option Data Criteria

The term "Option Data Criteria" shall mean, for each Collaboration Target, the categories of information (including the criteria within such categories) for a Product in accordance with the Phase I Plan with respect to such Collaboration Target, which categories are set forth in Appendix 1.81, and the criteria within such categories will be determined on a Collaboration Target-by-Collaboration Target basis and finalized by the JDC prior to the filing of the first IND for such Collaboration Target.

# 1.82 Option Data Package

The term "Option Data Package" shall mean, for each Collaboration Target, (i) a document setting forth the available data resulting from the Phase I Studies conducted by BPM for such Collaboration Target, including the applicable Option Data Criteria, (ii) the availability of the data

for such Phase I Studies in an organized and clean format in the Clinical Study database for such Collaboration Target through the Option Data Package Trigger for such Collaboration Target, and (iii) if applicable, the availability of the data of any Phase I Studies conducted by Roche in an organized and clean format for a [...\*\*\*...] through the Option Data Package Trigger for such [...\*\*\*...]. For clarity, "BPM's Portion" of the Option Data Package shall mean the items set forth in clauses (i) and (ii) of this Section 1.82.

#### 1.83 Option Data Package Trigger

The term "Option Data Package Trigger" shall mean, for each Collaboration Target, the earlier of (a) the date the JDC has determined that the Option Data Criteria have been met, or (b) the cut-off date determined by the JDC pursuant to Section 3.1.3.

# 1.84 Option Exercise Date

The term "Option Exercise Date" shall mean, on a Collaboration Target-by-Collaboration Target basis, the date on which an Option Exercise Notice delivered by Roche to BPM for such Collaboration Target pursuant to Section 3.1.3 takes effect.

#### 1.85 Option Exercise Notice

The term "Option Exercise Notice" shall mean the written notice Roche delivers to BPM to exercise its Option Right with respect to a Collaboration Target.

# 1.86 Option Period

The term "Option Period" shall mean, for each Collaboration Target, the period beginning the date the MTD for the first Product for such Collaboration Target is designated by the JDC and ending upon the earliest of (i) the date that such Collaboration Target becomes a Leftover Target, (ii) [...\*\*\*...] after Roche's receipt of the Option Data Package for such Collaboration Target, (iii) the date such Collaboration Target becomes a Terminated Target, (iv) the date upon which a Product (including Backup Compounds) for such Collaboration Target is no longer in GLP Tox Studies, in Phase I Studies, or progressing from GLP Tox Studies to Phase I Studies, or (v) [...\*\*\*...] after achievement of Lead Series Identified Criteria has been confirmed by the JRC for such Collaboration Target if Initiation of the GLP Tox Study has not been achieved for such Collaboration Target prior to such date.

## 1.87 Option Right

The term "Option Right" shall mean, with respect to a Collaboration Target, Roche's right to obtain an exclusive (subject to BPM's retained rights if applicable) commercial license with respect to that Collaboration Target in accordance with Section 3.1.

#### 1.88 Other Compound

The term "Other Compound" shall mean any compound made under the Research Plan for a given Collaboration Target that does <u>not</u> satisfy the Compound Criteria as determined by the JRC and is not a Library Compound as of the Effective Date. An Other Compound includes all salts, polymorphs, metabolites, prodrugs, isomers, enantiomers and stereoisomers of such compound, in each case that do <u>not</u> satisfy the Compound Criteria and are not a Library Compound as of the Effective Date.

## 1.89 Out of Pocket Costs

The term "Out of Pocket Costs" shall mean, with respect to certain activities hereunder direct expenses paid or payable by either Party or its Affiliates to Third Parties and specifically identifiable and incurred to conduct such activities for Collaboration Compounds, Products, Licensed Products or Companion Diagnostics, as applicable, including payments to contract

personnel (including contractors, consultants, CROs and subcontractors) in each case pursuant to the Phase I Plans or Development Plans.

#### 1.90 Party

The term "Party" shall mean BPM or Roche, as the case may be, and "Parties" shall mean BPM and Roche collectively.

#### 1.91 Part 1

The term "Part 1" shall mean the activities under the Research Plan and Phase I Plan for the Collaboration Targets [...\*\*\*...], [... \*\*\*...], and [...\*\*\*...].

#### 1.92 Part 2

The term "Part 2" shall mean the activities under Screening, Target Validation and the Research Plans and Phase I Plans for the Targets selected for activities in Part 2 that become Collaboration Targets.

#### 1.93 Patent Rights

The term "Patent Rights" shall mean all rights under any patent or patent application, in any country of the Territory, including any patents issuing on such patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, division, continuation or continuation-in-part of any of the foregoing.

#### 194 Person

The term "Person" shall mean any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or any other similar entity.

#### 1.95 Pharmacovigilance Agreement

The term "Pharmacovigilance Agreement" shall mean an agreement entered into by the Parties to set forth the protocols and procedures for reporting adverse events and complying with reporting requirements set forth by Regulatory Authorities.

#### 1.96 Phase I Development Costs

The term "Phase I Development Costs" shall mean, with respect to each Phase I Plan, and subject to the cap in Section 5.1.3, those (i) costs and expenses directly incurred (including personnel costs and Allocable Overhead associated with employees and contractors of a Party) with the performance of any Phase I Studies for Collaboration Compounds or Products for such Collaboration Target, (ii) costs associated with research or development of Companion Diagnostics, and (iii) fees charged by Third Party service providers and other Out-of-Pocket Costs reasonably incurred in connection with the performance of any Phase I Study with respect to Collaboration Compounds or Products for such Collaboration Target, in each case, in accordance with the applicable Phase I Plan and that are recorded as an expense in accordance with IFRS or GAAP as applicable consistently applied. Phase I Development Costs shall include (A) the cost of studies on the toxicological, pharmacokinetic, metabolic, pharmacodynamic or clinical aspects of such Product conducted by individual investigators or consultants in accordance with the applicable Phase I Plan and (B) expenses for data management, statistical designs and studies, document preparation, and other expenses associated with the clinical testing program for the applicable Phase I Plan. For clarity, Phase I Development Costs for each Product shall include (i) manufacturing and supply costs and expenses associated with the Phase I Plan for such Product, and (ii) costs related to preparing and filing Filings associated with the Phase I Plan for such Product (including associated filing fees, translation expenses, and legal and other

professional service fees). All manufacture and supply costs and expenses for Roche Clinical Compounds and Roche Marketed Products shall be at Roche's sole expense. For clarity, Phase I Development Costs shall exclude (a) capital expenditures, and (b) Development Costs.

#### 1.97 Phase I Plan

The term "Phase I Plan" shall mean, for each Collaboration Target, a plan and budget describing the one or more Phase I Studies to be conducted with respect to such Collaboration Target in the Field that will be established and approved by the JDC, with the goal to provide the Option Data Package for such Collaboration Target.

#### 1.98 Phase I Program

The term "Phase I Program" shall mean the activities undertaken by the Parties pursuant to the Phase I Plans for all Collaboration Targets.

#### 1.99 Phase I Study

The term "Phase I Study" shall mean a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a) (FDCA), as amended from time to time, and the foreign equivalent thereof.

#### 1.100 Phase II Study

The term "Phase II Study" shall mean a human clinical trial, for which the primary endpoints include a determination of dose ranges and/or a preliminary determination of efficacy in patients being studied as described in 21 C.F.R. § 312.21(b) (FDCA), as amended from time to time, and the foreign equivalent thereof.

## 1.101 Phase III Study

The term "Phase III Study" shall mean a human clinical trial that is prospectively designed to demonstrate statistically whether a product is safe and effective for use in humans in a manner sufficient to obtain regulatory approval to market such product in patients having the disease or condition being studied as described in 21 C.F.R. § 312.21(c) (FDCA), as amended from time to time, and the foreign equivalent thereof.

## 1.102 Pivotal Study

The term "Pivotal Study" shall mean, with respect to any Licensed Product, a Clinical Study that at the time of commencement (or any later expansion of patient enrollment, if applicable), is expected by the JDC to be the basis for Regulatory Approval of such Licensed Product.

#### 1.103 Post-Marketing Study

The term "Post-Marketing Study" shall mean a non-human or human clinical study of a Licensed Product initiated after receipt of Regulatory Approval for such Licensed Product in a country or territory, which is required by the Regulatory Authority in such country or territory to maintain the Regulatory Approval for such Licensed Product in such country or territory.

#### 1.104 Product

The term "Product" shall mean, on a Collaboration Target-by-Collaboration Target basis, any pharmaceutical product that, prior to Roche's exercise of its Option Right for such Collaboration Target, contains a Collaboration Compound with respect to such Collaboration Target generated under a Research Plan, including without limitation any Combination Product. One Product can be distinguished from another Product by containing a different Collaboration Compound as its active pharmaceutical ingredient. For clarity, a Reversion Product will not be considered a Product.

#### 1.105 Program

The term "Program" shall mean the program to develop and commercialize Licensed Products directed to a specific Collaboration Target in the Field in the Territory. Subject to the program switch right in Section 3.1.4, a Program shall be numbered in accordance with the order in which Roche exercises its Option Right so that "**Program 1**" is the Program to develop and commercialize Licensed Products directed to the first Collaboration Target for which Roche exercises its Option Right; "**Program 2**" is the Program to develop and commercialize Licensed Products directed to the second Collaboration Target for which Roche exercises its Option Right; "**Program 3**" is the Program to develop and commercialize Licensed Products directed to the third Collaboration Target for which Roche exercises its Option Right; "**Program 4**" is the Program to develop and commercialize Licensed Products directed to the fourth Collaboration Target for which Roche exercises its Option Right; and "**Program 5**" is the Program to develop and commercialize Licensed Products directed to the fifth Collaboration Target for which Roche exercises its Option Right.

# 1.106 Regulatory Approval

The term "Regulatory Approval" shall mean any approvals, licenses, registrations or authorizations by Regulatory Authority, necessary for the manufacture and sale of a Licensed Product in the Field in a regulatory jurisdiction in the Territory.

#### 1.107 Regulatory Authority

The term "Regulatory Authority" shall mean any national, supranational (*e.g.*, the European Commission, the Council of the European Union, the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity including the FDA, in each country involved in the granting of Regulatory Approval for the Licensed Product.

#### 1.108 Research Plan

The term "Research Plan" shall mean, for each Collaboration Target, a plan describing the screening activities and preclinical development of Library Compounds, Other Compounds and Collaboration Compounds (including Backup Compounds) for such Collaboration Target in the Field up to and including GLP Tox Studies and that is approved by the JRC. Each Research Plan shall also comprise the properties and their related criteria to be measured at defined points of preclinical development.

# 1.109 Research and Development Term

The term "Research and Development Term" shall mean the period beginning upon the Effective Date and ending upon the earlier of (i) the exercise of the last Option Right available for exercise, or (ii) the expiration of the Option Period for the last Collaboration Target available for exercise.

## 1.110 Roche Clinical Compounds

The term "Roche Clinical Compounds" shall mean clinical-stage compounds controlled by Roche or its Affiliates (but not Products or Licensed Products) and provided for combination Clinical Studies with Products or Licensed Products.

# 1.111 Roche Group

The term "Roche Group" shall mean collectively Roche, its Affiliates and its Sublicensees.

#### 1.112 Roche Know-How

The term "Roche Know-How" shall mean (a) all Know-How that Roche and its Affiliates Controls as of the Effective Date or during the Agreement Term to the extent used by Roche or its Affiliates to perform activities under this Agreement (including Roche Sole IP and Roche's interest in Joint IP) (but excluding Supplemental Studies unless BPM opts-in pursuant to Section 7.2), and (b) with respect to Program 2 and Program 4, any Know-How that Roche or its Affiliates uses in Exploiting any Licensed Products for Program 2 and Program 4 (as applicable) (but excluding Supplemental Studies unless Roche opts-in pursuant to Section 7.2), and in each case (a) and (b) that is necessary or useful to perform activities under this Agreement.

# 1.113 Roche Marketed Products

The term "Roche Marketed Products" shall mean marketed products controlled by Roche or its Affiliates (but not Products or Licensed Products) and provided for combination Clinical Studies with Products or Licensed Products.

# 1.114 Roche Patent Rights

The term "Roche Patent Rights" shall mean (a) all Patent Rights that Roche and its Affiliates Controls as of the Effective Date or during the Agreement Term to the extent used by Roche or its Affiliates to perform activities under this Agreement (including Roche Sole IP and Roche's interest in Joint IP) (but excluding Supplemental Studies unless BPM opts-in pursuant to Section 7.2), and (b) with respect to Program 2 and Program 4, any Patent Rights that Roche or its Affiliates uses in Exploiting any Licensed Products for Program 2 and Program 4 (as applicable) (but excluding Supplemental Studies unless Roche opts-in pursuant to Section 7.2), and in each case (a) and (b) that are necessary or useful to perform the activities under this Agreement. The Patent Rights identified in Appendix 1.114 ("Excluded Patent Rights") are specifically excluded from the Roche Patent Rights.

#### 1.115 Roche Sole IP

The term "Roche Sole IP" shall mean all Patent Rights and Know-How arising from a Roche Invention and all [...\*\*\*...].

#### 1.116 Roche Territory

The term "Roche Territory" shall mean (a) in the case of Program 1, Program 3, and Program 5, all countries of the world, and (b) in the case of Program 2 and Program 4, ROW.

#### 1.117 ROW

The term "ROW" shall mean all countries of the world excluding the US.

#### 1.118 Royalty Term

The term "Royalty Term" shall mean, for each Licensed Product, on a country-by-country basis, the period of time beginning with First Commercial Sale of a Licensed Product in a country and ending on the latest of (i) twelve (12) years after First Commercial Sale in such country of such Licensed Product, (ii) the last to expire Composition of Matter Claim, and (iii) the end of any regulatory exclusivity for such Licensed Product. To the extent the only Valid Claim in the Collaboration Compound IP or BPM IP or any patent rights owned or in-licensed by Roche (only pursuant to Program 2 or Program 4) Covers an approved use of a Licensed Product, the Royalty Term shall expire on a country-by-country basis on the later of (a) twelve (12) years after First Commercial Sale in such country of such Licensed Product or (b) the end of the first Calendar Quarter in which a Generic Product enters the market in such country.

#### 1.119 Sales

The term "Sales" shall mean, for a Licensed Product in a particular period, the sum of (i) and (ii):

(i) the amount stated in the Roche Holding AG "Sales" line of its externally published audited consolidated financial statements with respect to such Licensed Product for such period (excluding sales to any Sublicensees that are not Affiliates of Roche). This amount reflects the gross invoice price at which such Licensed Product was sold or otherwise disposed of (other than for use as clinical supplies or free samples) by Roche and its Affiliates to such Third Parties (excluding sales to any Sublicensees that are not Affiliates of Roche) in such period reduced by gross-to-net deductions, if not previously deducted from such invoiced amount, taken in accordance with the then currently used IFRS.

By way of example, the gross-to-net deductions taken in accordance with IFRS as of the Effective Date include the following:

- (a) credits, reserves or allowances granted for (i) damaged, outdated, returned, rejected, withdrawn or recalled Licensed Product, (ii) wastage replacement and short-shipments; (iii) billing errors and (iv) indigent patient and similar programs (*e.g.*, price capitation);
- (b) governmental price reductions and government mandated rebates;
- (c) chargebacks, including those granted to wholesalers, buying groups and retailers;
- (d) customer rebates, including cash sales incentives for prompt payment, cash and volume discounts; and
- (e) taxes and any other governmental charges or levies imposed upon or measured by the import, export, use, manufacture or sale of a Licensed Product (excluding income or franchise taxes).

For purposes of clarity, sales by Roche and its Affiliates to any Sublicensee shall be excluded from "Sales".

(ii) for Sublicensees that are not Roche Affiliates (and excluding Compulsory Sublicensees), the sales amounts reported to Roche and its Affiliates in accordance with the Sublicensee contractual terms and their then-currently used accounting standards. For the purpose of clarity, any such Sublicensee sales as reported to Roche in accordance with Compulsory Sublicense agreements shall be excluded from the sales amount.

#### 1.120 Screening

The term "Screening" shall mean the activities performed jointly by Roche and BPM at the beginning of Part 2 in accordance with this Agreement. The JRC shall approve the Screening plan and any changes thereto.

#### 1.121 Screening Hit

The term "Screening Hit" shall mean any Library Compound identified as a hit after Screening.

#### 1.122 Sublicensee

The term "Sublicensee" shall mean an entity to which Roche or BPM, as applicable, has licensed or sublicensed rights (through one or multiple tiers), other than through a Compulsory Sublicense, pursuant to this Agreement.

#### **1.123 Target**

The term "Target" shall mean any protein identified by its Entrez/HUGO number, including all splice variants, mutants, natural variants, and the like reasonably associated with such Entrez/HUGO number, which may be inhibited or modulated by Library Compounds, Other Compounds, Collaboration Compounds, Products, and/or Licensed Products.

## 1.124 Target Hypothesis

The term "Target Hypothesis" shall mean any hypothesis for a Screening Hit established by both Parties.

# 1.125 Target Validation

The term "Target Validation" shall mean the activities, including further *in vitro* assays, performed jointly by Roche and BPM following Screening in Part 2 to achieve validation of the Collaboration Targets for which a Target Hypothesis has been established. The JRC shall approve the Target Validation plan and any changes thereto.

# 1.126 Terminated Target

The term "Terminated Target" shall mean any Collaboration Target that has under Section 21.3.1 become a "Terminated Target."

#### 1.127 Territory

The term "Territory" shall mean (i) with respect to Roche, the Roche Territory, and (ii) with respect to BPM, the BPM Territory.

#### 1.128 Third Party

The term "Third Party" shall mean a person or entity other than (i) BPM or any of its Affiliates or (ii) a member of the Roche Group.

#### 1.129 US

The term "US" or "United States" shall mean the United States of America and its territories and possessions.

#### 1.130 US\$

The term "US\$" shall mean US dollars.

#### 1.131 Valid Claim

The term "Valid Claim" shall mean a claim in any (i) unexpired and issued patent that has not been disclaimed, revoked or held invalid by a final non-appealable decision of a court of competent jurisdiction or government agency, or (ii) pending patent application being prosecuted in good faith and has been pending for no more than [...\*\*\*...] from the earliest priority date.

# 1.132 Additional Definitions

Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	Section
AAA	23.3
Accounting Period	13.1
Acquired Party	21.2.3
Alliance Director	8.10
Allowable Exception	7.3.3
Arbitral Tribunal	23.3.1
Bankruptcy Code	22
Biomarker IP	16.1
BPM	Preamble
BPM Deferral Election	7.3.4
BPM Invention	1.62
BPM Member	8.3
BPM Other Program	2.5.4
BPM Specific Patent Rights	16.5(a)
BPM Trademarks	16.4
BPM's Portion	1.82
Brid's Portion  Breaching Party	21.2.1
	8.3
Chairperson [***]	
	[***]
Compulsory Profit Share Percentage	12.9.8
Compulsory Sublicense	1.33
Compulsory Sublicensee	1.33
CREATE Act	16.9
Decision Period	16.10
Deferrable Amount	7.3.4
Development Event	12.7
Disclosing Party	1.34
Excluded Patent Rights	1.114
Exclusive Terms Period	2.2
Expedited Arbitration	23.3.3
Expedited Dispute	23.3.3
Expert Committee	12.9.4
Finance Officers	12.5
[***]	[***]
Global Trademarks	16.4
GLP Tox Study	1.60
[***]	[***]
H-W Suit Notice	16.13
Indemnified Party	18.3
Indemnifying Party	18.3
Initiating Party	16.10
Insulated Chemistry Expert	4.1.5
Joint Invention	1.62
Label Pursuit	7.3.1
Members	8.3
	1

Definition	Section
Non-Acquired Party	21.2.3
Non-Breaching Party	21.2.1
Non-Selling Party	11.2
Option Exercise Fee	12.4
Other Component	1.27(a)
Other Compound IP	16.1
Patent Term Extensions	16.14
Payment Currency	13.3
Peremptory Notice Period	21.2.1
Pool	4.1.6
Program 1	1.105
Program 2	1.105
Program 3	1.105
Program 4	1.105
Program 5	1.105
Publishing Notice	20.4
Publishing Party	20.4
Receiving Party	1.34
Redacted Agreement	20.5
Register	16.8
Relative Commercial Value	12.9.4
Reversion License	21.3.1(f)
Reversion Product	21.3.1
Roche	Preamble
Roche Basel	Preamble
Roche Invention	1.62
Roche Member	8.3
[***]	[***]
Roche Transfer Activities	21.3.4.4(d)
Roche US	Preamble
[***]	[***]
Samples	21.3.4.4(b)
Selling Party	11.2
Sensitive Information	21.2.3
Settlement	16.10
Shared Development Cost Budget	7.3.3
SPCs	16.14
Suit Notice	16.10
Supplemental Study	7.3.2
Supplemental Study Opt-In Right	7.3.2
Supply Agreement	9.1
Switch	3.1.4
Technology Transfer	9.2
Third Party Acquisition	2.5.4

# 2. Grant of License and Exclusivity

#### 2.1 Licenses

#### 2.1.1 Research Cross Licenses

Subject to the terms and conditions of this Agreement, Roche hereby grants to BPM a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.2), non-exclusive license under Roche Know-How and Roche Patent Rights for BPM to perform its research activities under the Research Plans and development activities under the Phase I Plans, in each case in the Field and during the Research and Development Term.

Subject to the terms and conditions of this Agreement, BPM hereby grants to Roche a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.1), non-exclusive license under BPM IP and Collaboration Compound IP for Roche to perform its research activities under the Research Plans and development activities under the Phase I Plans, in each case in the Field and during the Research and Development Term.

# 2.1.2 Development and Commercial License for Program 1, Program 3 and Program 5

Subject to Roche exercising its Option Right with regard to a Collaboration Target for Program 1, Program 3 or Program 5 (as applicable) as set forth in Section 3.1, BPM hereby grants to Roche, effective upon the Option Exercise Date for such Collaboration Target, a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.1), exclusive (even as to BPM but subject to BPM's retained rights, as applicable) license under BPM IP and Collaboration Compound IP to Exploit Licensed Products and Companion Diagnostics for Program 1, Program 3 or Program 5 (as applicable) in the Field in the Roche Territory.

With respect to the Excluded Field, under this Agreement, Roche shall not (and shall require its Affiliates and Sublicensees to not) research, develop, manufacture or commercialize any Library Compound, Collaboration Compound, Other Compound, Product or Licensed Product for Program 1, Program 3 or Program 5 (as applicable) in the Excluded Field. For clarity, the foregoing restriction does not apply to any of Roche's or its Affiliate's or Sublicensee's research, development, manufacture or commercialization programs or activities outside of this Agreement.

Notwithstanding any other provision of this Agreement, for the purposes of the license grants under this Section 2.1.2 with respect to any Licensed Product that is a Combination Product, (i) such license will only include a license with respect to the Collaboration Compound in such Combination Product, and (ii) in no event is a license granted hereunder with respect to any Other Component of a Combination Product.

#### 2.1.3 Development and Commercial Licenses for Program 2 and Program 4

Subject to Roche exercising its Option Right with regard to a Collaboration Target for Program 2 or Program 4 (as applicable) as set forth in Section 3.1, BPM hereby grants to Roche, effective upon the Option Exercise Date for such Collaboration Target, a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.2), exclusive (even as to BPM but subject to BPM's retained rights, as applicable) license under BPM IP and Collaboration Compound IP to Exploit Licensed Products and Companion Diagnostics for Program 2 or Program 4 (as applicable) in the Field in the Roche Territory.

Notwithstanding the foregoing, for Program 2 or Program 4, BPM retains the right under the BPM IP and Collaboration Compound IP, with the right to grant licenses through multiple tiers, to

develop each Product or Licensed Product (as applicable) in the Field anywhere in the world, in each case solely as and to the extent permitted in any Phase I Plan or Development Plan or as otherwise permitted under Section 7.2 or elsewhere under this Agreement, and in each case, solely for Regulatory Approval and commercialization in the BPM Territory.

With respect to the Excluded Field, under this Agreement, Roche shall not (and shall require its Affiliates and Sublicensees to not) research, develop, manufacture or commercialize any Library Compound, Collaboration Compound, Other Compound, Product or Licensed Product for Program 2 or Program 4 in the Excluded Field. For clarity, the foregoing restriction does not apply to any of Roche's or its Affiliate's or Sublicensee's research, development, manufacture or commercialization programs or activities outside of this Agreement.

Notwithstanding any other provision of this Agreement, for the purposes of the license grants under this Section 2.1.3 with respect to any Licensed Product that is a Combination Product, (i) such license will only include a license with respect to the Collaboration Compound in such Combination Product, and (ii) in no event is a license granted hereunder with respect to any Other Component of a Combination Product.

Subject to Roche exercising its Option Right with regard to a Collaboration Target for Program 2 or Program 4 (as applicable), Roche hereby grants to BPM, effective upon the Option Exercise Date for such Collaboration Target, a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.2 and Section 2.3.2), exclusive (even as to Roche but subject to Roche's retained rights, as applicable) license, under Roche Know-How and Roche Patent Rights to Exploit Licensed Products and Companion Diagnostics for Program 2 or Program 4 (as applicable) in the Field in the BPM Territory.

# 2.1.4 Manufacturing Licenses

Subject to the terms and conditions of this Agreement, BPM hereby grants to Roche a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.1), worldwide, non-exclusive license under BPM IP and Collaboration Compound IP for Roche to manufacture and have manufactured Collaboration Compounds, Products and Licensed Products solely to perform its activities under Section 9.1.

Subject to the terms and conditions of this Agreement, Roche hereby grants to BPM a non-transferable (except as provided in Section 23.4), sublicensable (subject to Sections 9.3 and 9.4), worldwide, non-exclusive license under Roche Patent Rights, Roche Know-How and [...\*\*\*...] for BPM to manufacture and have manufactured Collaboration Compounds, Products and Licensed Products solely to perform its activities under Section 9.1.

Subject to the terms and conditions of this Agreement, Roche hereby grants to BPM a non-transferable (except as provided in Section 23.4), sublicensable (subject to Sections 9.3 and 9.4), worldwide, non-exclusive license under [...\*\*\*...] for BPM to manufacture and have manufactured Other Compounds and any derivatives thereof.

# 2.1.5 Licenses to Conduct Supplemental Studies

Subject to the terms and conditions of this Agreement, BPM hereby grants to Roche a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.1),

worldwide, non-exclusive license under BPM IP and Collaboration Compound IP for Roche to conduct Supplemental Studies in compliance with Section 7.3.2.

Subject to the terms and conditions of this Agreement, Roche hereby grants to BPM a non-transferable (except as provided in Section 23.4), sublicensable (subject to Section 2.3.2), worldwide, non-exclusive license under Roche Patent Rights and Roche Know-How for BPM to conduct Supplemental Studies in compliance with Section 7.3.2.

#### 2.1.6 Rights of Reference

Each Party hereby grants to the other Party, and at the request of the other Party will grant to the other Party's Affiliates, a "Right of Reference", as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including all CMC information as well as data made, collected or otherwise generated in the conduct of any Clinical Studies or upon exercise of the Supplemental Study Opt-In Right, Supplemental Studies, or early access/named patient programs for the applicable Products or Licensed Products) included in or used in support of any regulatory filing, Regulatory Approval, drug master file or other regulatory documentation (including orphan drug applications and designations) maintained on behalf of such Party (or its Affiliates) that relates to any Product or Licensed Product, to the extent necessary or useful to obtain Regulatory Approval of a Product or Licensed Product in the BPM Territory or the Roche Territory, as applicable, and such Party will provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous law outside of the United States). In addition, upon reasonable request of either Party (on behalf of itself or a Sublicensee), the other Party will obtain and provide to the requesting Party certificates or other formal or official attestations concerning the regulatory status of the Products or Licensed Products in the BPM Territory or the Roche Territory, as applicable (e.g., Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments), at the requesting Party's request, and provided further that such attestations are reasonably necessary for the requesting Party to exercise its rights under this Agreement. Notwithstanding anything to the contrary in this Agreement other than for safety concerns, neither Party will withdraw or inactivate any regulatory filing that the other Party references or otherwise uses pursuant to this Section 2.1.6.

# 2.2 Right of First Negotiation and [...\*\*\*...]

During the Agreement Term, if BPM elects to sublicense or divest to a Third Party part or all of its development or commercialization rights in the BPM Territory pursuant to Program 2 and/or Program 4, then BPM shall promptly notify Roche of its decision to do so and Roche shall have a right of first negotiation to enter into an exclusive negotiation period with BPM in order to reach agreed terms for such a sublicense or divestment. Roche shall inform BPM within [...\*\*\*...] after receipt of notification from BPM ("Exclusive Terms Period") as to whether Roche is interested in entering into an exclusive negotiation period. If Roche provides written notice to BPM during the Exclusive Terms Period, then the Parties shall negotiate a term sheet within an additional [...\*\*\*...] period, then the Parties shall negotiate a definitive agreement within an additional [...\*\*\*...] negotiation period.

If the Parties are unable to reach terms on a term sheet in such [...\*\*\*...] period or on a definitive agreement in the additional [... \*\*\*...] negotiation period, then, at BPM's written election, BPM shall have the right to either (a) negotiate and, subject to [... \*\*\*...], enter into a sublicense or divestment agreement with a Third Party in accordance with Section 2.3.2, or (b) commence Expedited

Arbitration proceedings by providing written notice to Roche to resolve any disputed terms in such term sheet or definitive agreement. [...\*\*\*...] If Roche provides written notice to discontinue such Expedited Arbitration proceedings within such [... \*\*\*...] period, then [...\*\*\*...] shall terminate and BPM shall have the right to negotiate and enter into a sublicense or divestment agreement with a Third Party in accordance with Section 2.3.2. [...\*\*\*...]

If BPM negotiates a sublicense or divestment agreement with a Third Party after either (1) the Parties are unable to reach terms of a term sheet within the [...\*\*\*...] period or terms of a definitive agreement within the additional [...\*\*\*...] negotiation period and either (x) BPM does not exercise its right to commence Expedited Arbitration proceedings or (y) BPM provides written notice to discontinue such Expedited Arbitration proceedings, or (2) Roche does not exercise such right of first negotiation during the Exclusive Terms Period, then [...\*\*\*...].

In all events, this Section 2.1.5 will not apply to (A) any Change of Control of BPM or other permitted assignment of this Agreement under Section 23.4, (B) any bona fide agreement with a CRO, under which such CRO performs contract services on behalf of BPM or any of its Affiliates for the research, development, manufacture or commercialization of any Collaboration Compound, Other Compound, Product or Licensed Product as permitted under this Agreement on a fee-for-services basis, it being understood that under an agreement for such fee-for-services, fees paid to the Third Party for such services may include milestones or royalties, (C) any agreement permitted in compliance with the terms of this Agreement with any academic institution or other not-for-profit Third Party regarding any Collaboration Compound, Other Compound, Product or Licensed Product, or (D) any agreement with a distributor regarding any Licensed Product for Program 2 and Program 4 in the BPM Territory.

If Roche does not exercise such right of first negotiation during the Exclusive Terms Period, then BPM shall have the right to negotiate and, subject to [...\*\*\*...] enter into a sublicense or divestment agreement with a Third Party in accordance with Section 2.3.2.

#### 2.3 Sublicenses

## 2.3.1 Roche's Scope of Permissible Sublicensing

The license granted by BPM to Roche in Section 2.1.2 and Section 2.1.3 may be sublicensed by Roche through multiple tiers, provided that (i) Roche will ensure that the financial terms included in Section 12 that are applicable to the scope of the sublicense granted remain unchanged, (ii) BPM's obligations to such sublicensed Affiliate or Sublicensee will be no broader than BPM's obligations were to Roche under this Agreement prior to Roche's grant of such a sublicense, (iii) Roche will be liable for any act or omission of any such sublicensed Affiliate or Sublicensee that is a breach of any of Roche's obligations under this Agreement as though the same were a breach by Roche, and BPM will have the right to proceed directly against Roche without any obligation to first proceed against such sublicensed Affiliate or Sublicensee, (iv) Roche will ensure that Roche receives from the Sublicensee all rights necessary for Roche to grant to BPM the rights and licenses upon termination of the Agreement set forth in Section 21.3 and (v) such sublicensed Affiliate or Sublicensee will undertake obligations of confidentiality and non-use regarding Confidential Information that are at least as protective as those undertaken by Roche with respect to Confidential Information pursuant to Section 20 hereof. Roche, as soon as reasonably practicable thereafter, shall provide BPM with a copy of any executed sublicense agreement with a Third Party other than [...\*\*\*...], or a Third Party acting only as a distributor (which copy may be redacted to remove provisions which are not necessary to monitor compliance with this Section 2.3.1).

The license granted by BPM to Roche in Section 2.1.1 may be sublicensed by Roche to a permitted CRO to perform Roche's assigned responsibilities under the Research Plans and Phase I Plans upon prompt written notice to BPM.

The license granted by BPM to Roche in Section 2.3.1 may be sublicensed by Roche to a permitted CRO to perform Roche's assigned responsibilities under Section 9.1.

# 2.3.2 BPM's Scope of Permissible Sublicensing

The license granted by Roche to BPM in Section 2.1.3 may be sublicensed by BPM through multiple tiers, provided that (i) BPM will ensure that the financial terms included in Section 12 that are applicable to the scope of the sublicense granted remain unchanged, (ii) Roche's obligations to such sublicensed Affiliate or Sublicensee will be no broader than Roche's obligations were to BPM under this Agreement prior to BPM's grant of such a sublicense, and (iii) BPM will be liable for any act or omission of any such sublicensed Affiliate or Sublicensee that is a breach of any of BPM's obligations under this Agreement as though the same were a breach by BPM, and Roche will have the right to proceed directly against BPM without any obligation to first proceed against such sublicensed Affiliate or Sublicensee, (iv) BPM will ensure that BPM receives from the Sublicensee all rights necessary for BPM to grant to Roche the rights and licenses upon termination of the Agreement set forth in Section 21.3 and (v) such sublicensed Affiliate or Sublicensee will undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are at least as protective as those undertaken by BPM with respect to Confidential Information pursuant to Section 20 hereof.

The license granted by Roche to BPM in Section 2.1.1 may be sublicensed by BPM to a permitted CRO to perform BPM's assigned responsibilities under the Research Plans and Phase I Plans upon written notice to Roche.

# 2.4 BPM Third Party Payments

BPM will be responsible for all payments associated with any agreements related to the BPM IP that exist as of the Effective Date, except as otherwise agreed to in writing. For clarity, to the extent payments under those agreements are incurred by BPM pursuant to the Research Plan or Phase I Plan, such payments will not be reimbursed by Roche unless they are specifically included under the Research Plan budget or Phase I Plan budget as an amount to be reimbursed by Roche.

In the event that, after the Effective Date and prior to any Change of Control of BPM, BPM in-licenses BPM IP that would be deemed Controlled for purposes of the licenses granted to Roche under Section 2.1 but for BPM owing payments under the agreement for such in-licensed BPM IP on account of any sublicense granted thereunder to Roche or its Affiliates or Sublicensees, BPM will notify Roche of the existence of and anticipated amounts of such payments and Roche will have the right to decline a sublicense to such in-licensed BPM IP or take such sublicense, in which case Roche agrees to comply with any obligations under such agreement of BPM that apply to Roche and of which Roche was informed by BPM, including any obligation to make such payments. In the event Roche elects to take such sublicense, Roche will make such payments to BPM within thirty (30) days of receiving an invoice from BPM for the same.

#### 2.5 Exclusivity

#### 2.5.1 BPM Exclusivity with regard to Collaboration Targets

On a Collaboration Target-by-Collaboration Target basis, BPM and its Affiliates shall work exclusively with Roche during the Option Period with respect to such Collaboration Target. BPM and its Affiliates shall continue to work exclusively with Roche on each Collaboration Target for which Roche exercises its Option Right until the earliest of (i) (a) for Program 1, Program 3 and Program 5, the First Commercial Sale by the Roche Group in the Roche Territory of the first Licensed Product with respect to such Collaboration Target, or (b) for Program 2 and Program 4, the First Commercial Sale by the Roche Group or the BPM Group in the Territory of the first Licensed Product with respect to such Collaboration Target, (ii) such Collaboration Target becomes a Leftover Target, or (iii) such Collaboration Target becomes a Terminated Target.

# 2.5.2 BPM Exclusivity with regard to Cancer Immunotherapy

BPM and its Affiliates shall work exclusively with Roche in the field of cancer immunotherapy until Target Validation for Part 2 is completed and the Pool is established by the JRC, but in any event for no more than thirty (30) months after the Effective Date. [... \*\*\*...] Excluded Targets and Leftover Targets (and research and development activities with respect thereto), and customary screening and early-stage chemistry and biology work performed by and on behalf of BPM in the ordinary course, shall not be subject to or otherwise prohibited by this Section 2.5.2. The conduct of general screening activities by or on behalf of BPM or its Affiliates shall not be deemed a breach of this Section 2.5.2 unless and until BPM or its Affiliates decides to pursue a Target for additional development.

# 2.5.3 BPM Rights if Roche is not Exclusive for a Collaboration Target

If Roche or its Affiliates gain access (such as through licensing or acquisition from a Third Party) to a compound or product targeting a Collaboration Target prior to exercising its Option Right for such Collaboration Target, then Roche shall immediately notify BPM in writing and BPM shall have the right upon written notice to Roche to terminate (i) Roche's Option Right to such Collaboration Target and (ii) all activities under the Research Plan and Phase I Plan for such Collaboration Target. If BPM opts for such termination, then such Collaboration Target will become a Leftover Target and all associated Collaboration Compounds and Products will become Reversion Products. [...\*\*\*...]

If Roche or its Affiliates gain access (*e.g.*, via licensing or acquisition or internal program, or any other way) to a compound or product targeting a Collaboration Target after exercising its Option Right for such Collaboration Target, then without affecting the rights and obligations of the parties under this Agreement, for clarity, BPM shall have no right of termination as set forth above and Roche shall continue to use Commercially Reasonable Efforts to develop and commercialize Licensed Products corresponding to such Collaboration Target.

In the case of Program 2 or Program 4, if Roche or its Affiliates gain access (*e.g.*, via licensing or acquisition or internal program, or any other way) to a compound or product targeting a Collaboration Target of such Program 2 or Program 4 and exercises its Option Right for such Collaboration Target (before or after gaining such access), and such compound or product has initiated (i.e., the date that a human is first dosed with the compound or product in a human clinical study) (i) a Phase II Study in the case of a compound or product accessed from a Third Party or internally (other than from [...\*\*\*...]) or (ii) a Phase III Study in the case of a compound or product

accessed from [...\*\*\*...], then BPM's obligation of exclusivity under Section 2.5.1 with respect to such Collaboration Target shall automatically and immediately terminate. Roche shall as soon as practicable notify BPM in writing upon any such initiation of such Phase II Study or Phase III Study (as applicable).

#### 2.5.4 Limitations on BPM Exclusivity Obligations

The Parties hereby acknowledge and agree that (I) after expiration of the obligations set forth in Section 2.5.2, Sections 2.5.1 and 2.5.2 will not apply to any compound or product that is intended to modulate (including inhibit) any target(s) other than a Collaboration Target; and (II) BPM retains (for itself and its Affiliates and licensees and subcontractors) (A) the right to research (but not preclinically or clinically develop or commercialize) Collaboration Compounds, Products and Licensed Products outside of the applicable Research Plans, (B) the right, solely to the extent reasonably necessary for any such research, to manufacture Collaboration Compounds, Products and Licensed Products outside of the applicable Research Plans, and (C) the rights under the license grants in Section 2.1 or elsewhere in this Agreement or elsewhere retained under this Agreement.

Notwithstanding Section 2.5.1 and Section 2.5.2, and subject to the next paragraph, in the event that BPM or its Affiliates acquire a Third Party or a portion of the business of a Third Party (whether by merger, stock purchase, purchase of assets, in-license or other means) (a "**Third Party Acquisition**") that is, prior to such Third Party Acquisition, conducting a research, development or commercialization program or activities that, if conducted by BPM at such time, would be a breach of BPM's exclusivity obligation in Section 2.5.1 or Section 2.5.2 (a "**BPM Other Program**"), BPM may elect [...\*\*\*...]. BPM will not be deemed in breach of Section 2.5.1 and Section 2.5.2 with respect to such BPM Other Program so long as BPM complies with the terms of Section 2.5.1 and Section 2.5.2 and provided that such BPM Other Program is conducted independently of BPM's activities under this Agreement and without any use of any Roche Know-How, Roche Patent Rights or Roche Confidential Information or material use (other than the retained rights above) of the Collaboration Compounds.

In the event of a Change of Control of BPM, the exclusivity obligations of BPM set forth in Section 2.5.1 and Section 2.5.2 will not apply to any research, development or commercialization program or activities that, if conducted by BPM at such time would be a breach of BPM's exclusivity obligations in Section 2.5.1 or Section 2.5.2, (I) is owned, in-licensed or otherwise controlled by a Third Party described in the definition of "Change of Control" or its Affiliates prior to the closing of such Change of Control or (II) becomes owned, in-licensed or otherwise controlled by such Third Party or its Affiliates (other than by BPM or any of its direct or indirect subsidiary Affiliates) after the closing of such Change of Control, in each case ((I) and (II)) if such BPM Other Program is conducted independently of BPM's activities under this Agreement and without any use of any Roche Know-How, Roche Patent Rights or Roche Confidential Information or material use (other than the retained rights above) of the Collaboration Compounds.

With respect to the two preceding paragraphs of this Section 2.5.4, BPM and its Affiliates (including such Third Party and its Affiliates under the preceding paragraph) will adopt reasonable procedures (which include appropriate administrative, physical and technical safeguards, including underlying operating system and network security controls and other firewalls) to prevent the use of any Roche Know-How, Roche Patent Rights or Roche Confidential Information or material use (other than the retained rights above) of the Collaboration Compounds in a manner that is not in compliance with the two preceding paragraphs of this Section 2.5.4.

#### 3. Option of Roche

# 3.1 Option Right

#### 3.1.1 General

On a Collaboration Target-by-Collaboration Target basis, Roche is granted up to five (5) exclusive Option Rights to obtain an exclusive or co-exclusive license to Exploit Products containing a Collaboration Compound directed to the Collaboration Target to which the Option Right pertains in the Field in the Territory. Once the Option Right for a Collaboration Target is exercised, such Products become "Licensed Products" and the program for the development and commercialization of such Licensed Products becomes a "Program." The designation of a Program as Program 1, Program 2, Program 3, Program 4 or Program 5 will occur as specified in the definition of Program.

# 3.1.2 Grant of Option Right

On a Collaboration Target-by-Collaboration Target basis, BPM hereby grants to Roche during the Option Period an exclusive Option Right for each Collaboration Target to obtain the licenses set forth in Section 2.1.2, Section 2.1.3 and Section 2.1.4 with respect to such Collaboration Target, Licensed Products and Program.

# 3.1.3 Exercise of Option Right

In the event the Option Data Package Trigger is determined pursuant to Section 1.83(a), for each Collaboration Target, within [... \*\*\*...] after the Option Data Package Trigger, (i) each Party will deliver its portion of the Option Data Package with respect to such Collaboration Target, and (ii) BPM will afford Roche the information rights under Section 3.2. In the event that Roche determines that BPM's Portion of an Option Data Package for a Collaboration Target is incomplete or insufficient, then Roche shall provide written notice to BPM identifying all such deficiencies. If BPM disputes the existence of any such deficiencies, BPM may, at its election, refer such dispute for resolution in accordance with Section 8.8.3. If BPM's Portion of such Option Data Package for a Collaboration Target is determined to be incomplete or insufficient, BPM shall promptly upon curing all deficiencies re-deliver an updated version of BPM's Portion of such Option Data Package for such Collaboration Target to Roche; provided that Roche may not request a further updated version of BPM's Portion of such Option Data Package for such Collaboration Target for a period of [...\*\*\*...].

On a Collaboration Target-by-Collaboration Target basis, Roche shall have the right to exercise its Option Right during the Option Period for a given Collaboration Target. Roche will exercise an Option Right for a Collaboration Target, if at all, by properly delivering an Option Exercise Notice for such Collaboration Target at any time during the Option Period for such Collaboration Target.

In the event the Option Data Package Trigger is not determined pursuant to Section 1.83(a), the JDC will set a cut-off date for the data resulting from the Phase I Studies conducted by the Parties for each Collaboration Target so that such data may be included in an Option Data Package for such Collaboration Target in a timely fashion. Such cut-off date shall be determined as follows:

- (a) [...\*\*\*...]
- (b) [...\*\*\*...]

In the event that (a) a Product is for a [...\*\*\*...], (b) such Product satisfies all Option Data Criteria other than the [...\*\*\*...], and (c) Roche wishes to extend the Option Period for such Collaboration Target until all of the Option Data Criteria are satisfied (but in any event no longer than the [...\*\*\*...] anniversary of the date the MTD for the first Combination Product for such [...\*\*\*...] is confirmed by the JDC plus [...\*\*\*...]), then Roche shall provide written notice to BPM of Roche's election to extend the Option Period and pay to BPM an Option Period extension fee equal to (v) [...\*\*\*...] for the first Collaboration Target for which Roche exercises its extension right under this Section 3.1.3, (w) [...\*\*\*...] for the second Collaboration Target for which Roche exercises its extension right under this Section 3.1.3, (x) [...\*\*\*...] for the third Collaboration Target for which Roche exercises its extension right under this Section 3.1.3, (y) [...\*\*\*...] for the fourth Collaboration Target for which Roche exercises its extension right under this Section 3.1.3, and (z) [...\*\*\*...] for the fifth Collaboration Target for which Roche exercises its extension right under this Section 3.1.3. Such Option Period extension fee shall be due and payable by Roche to BPM within thirty (30) days after the determination that such Product satisfies all Option Data Criteria other than the [...\*\*\*...]. The Parties agree that [...\*\*\*...] of any such Option Period extension fee payment [...\*\*\*...] in accordance with Section 12.4, provided that (i) each Option Period extension fee payment [...\*\*\*...] only if Roche exercises its Option Right for such Collaboration Target, and (ii) any amounts that are [...\*\*\*...] in accordance with Section 12.4 (but may not be applied to any other payments under this Agreement). [...\*\*\*...] for each Collaboration Target [...\*\*\*...] will be due and payable after Roche's exercise of its Option Right for such Collaboration Target in accordance with Section 12.4. In the event that (a) a Product is for a [...\*\*\*...], (b) such Product satisfies all Option Data Criteria other than the [...\*\*\*...], and (c) Roche does not pay the Option Period extension fee as set forth above, then such [...\*\*\*...] shall be a Terminated Target.

For any Collaboration Target to which Roche does not timely exercise its Option Right, then, effective as of the expiration of the Option Period for such Collaboration Target, (a) all research and development activities with respect to such Collaboration Target shall terminate, (b) such Collaboration Target shall become a Leftover Target, (c) BPM shall retain all rights, title and interest in and to all Library Compounds, Other Compounds, Collaboration Compounds and Products for such Collaboration Target, (d) all rights and obligations (including the licenses to Roche) under this Agreement with respect to such Collaboration Target shall terminate, (e) the right of first negotiation and matching right under Section 2.2 with respect to such Collaboration Target shall terminate, and (f) the exclusivity provisions under Section 2.5 shall terminate. For clarity, if Roche does not timely exercise its Option Right related to a given Collaboration Target, and BPM desires to continue to research, develop or commercialize such Collaboration Compound or Product in combination with a Roche Clinical Compound or Roche Marketed Products, then Roche will consider, at its sole discretion, supplying such Roche Clinical Compound or Roche Marketed Products to BPM or its designee pursuant to a supply agreement on terms and conditions to be agreed upon by the Parties in good faith.

## 3.1.4 One Time Program Switch Right

After Roche's receipt of the first Option Data Package for a Collaboration Target or at the end of the Option Period for the first Collaboration Target, Roche shall have a one-time right to exercise its Option Right for such Collaboration Target by declaring such Collaboration Target as "Program 2", thereby declaring the next most advanced Collaboration Target as designated by the JRC or JDC (as applicable) as "Program 1" (the "Switch"). If Roche elects to make the Switch, then Roche shall provide written notice to BPM prior to expiration of the Option Period for the first Collaboration Target of Roche's election to make the Switch and identify the Collaboration Target

that will be "Program 2" and the Collaboration Target that will be "Program 1". If Roche makes the Switch, then Roche shall pay both the Program 1 Option Exercise Fee and the Program 2 Option Exercise Fee as set forth in Section 12.4, subject to the limitations in the following paragraph.

In the event that Products for Program 1 and Program 2 are each being developed or planned to be developed in Phase I Studies as Products for a [...\*\*\*...] pursuant to Section 5.1.3, then, simultaneously with the Switch, Roche shall exercise its Option Right with respect to the next most advanced Collaboration Target as designated by the JRC or JDC (as applicable) making it "Program 1". The Program 1 Option Exercise Fee shall be payable as set forth in Section 12.4, i.e. [...\*\*\*...] within [...\*\*\*...] after Roche exercises its Option Right and receipt of an invoice from BPM. If such next most advanced Collaboration Target has reached MTD more than [...\*\*\*...] prior to the Switch election, then the Program 2 Option Exercise Fee (i.e., [...\*\*\*...]) shall be payable at the same time as the Program 1 Option Exercise Fee. If such next most advanced Collaboration Target has either not yet reached MTD or not reached MTD within [...\*\*\*...] preceding the Switch, then the Program 2 Option Exercise Fee (i.e., [...\*\*\*...\*\*\*...]) shall be payable only (i) after BPM has provided Roche with the Option Data Package for the Collaboration Target declared as Program 1 as per the Switch, and Roche has determined, within [...\*\*\*...] after Roche receives the Option Data Package, to not exercise its termination right with respect to the Collaboration Target declared as Program 1 as per the Switch, or (ii) upon Roche Initiating a Clinical Study of a Product or Licensed Product against the Collaboration Target declared as Program 1 as per the Switch, payments of the Option Exercise Fee for each such Program shall be in accordance with Section 3.1.3 and Section 12.4.

# 3.2 Information Sharing for Option Rights

After the Option Data Package Trigger for each Collaboration Target and for the remainder of the Option Period with respect to such Collaboration Target, (i) Roche shall have the right to perform reasonable due diligence (including visits to the facilities in which the data were generated and interviews with the persons generating the data) with respect to such Collaboration Target and the applicable Collaboration Compounds and Products, and (ii) representatives of Roche shall have the opportunity to ask questions of and receive answers from representatives of BPM related to the work that has been conducted and the data that have been generated with respect to such Collaboration Target and the applicable Collaboration Compounds and Products. BPM shall respond to Roche's inquiries in a timely fashion and without delay and shall not withhold any material information regarding such Collaboration Target and the applicable Collaboration Compounds and Products from Roche in response to Roche's inquiries. For clarity, the disclosure and use of any structures or structural information of the Collaboration Compounds and Products pursuant to this Section 3.2 will be subject to the terms of Section 4.1.4, *mutatis mutandis*.

#### 4. Research Collaboration

#### 4.1 Conduct of the Research

# 4.1.1 Scope

On a Collaboration Target-by-Collaboration Target basis, BPM shall have lead responsibility for the conduct of all research of Library Compounds, Other Compounds and Collaboration Compounds in the Field in the Territory. The activities conducted under each Research Plan will be overseen by the JRC. For clarity, prior to exercise of its Option Right for a Collaboration Target,

Roche and its Affiliates shall not conduct any research activities under this Agreement with respect to such Collaboration Target except as expressly permitted in the Research Plans. It is understood and agreed that (a) Roche shall not, under this Agreement, research, develop, manufacture or commercialize any Library Compounds, Other Compounds or Collaboration Compounds (and corresponding Products) unless such activities are included in a Research Plan or Phase I Plan, and (b) on a Collaboration Target-by-Collaboration Target basis, upon the start of the first GLP Tox Study of a Collaboration Compound satisfying the CCS Criteria for such Collaboration Target (*e.g.*, the most advanced such Collaboration Compound for such Collaboration Target), BPM shall not be required under this Agreement to conceive or make any new compounds as potential Collaboration Compounds for such Collaboration Target.

# 4.1.2 Diligent Efforts

On a Collaboration Target-by-Collaboration Target basis, Roche and BPM shall each use Commercially Reasonable Efforts to perform their respective tasks and obligations in conducting all activities ascribed to it in the then-current Research Plan for such Collaboration Target in the Field, in accordance with the time parameters set forth therein.

#### 4.1.3 Research Plans

Unless decided otherwise by the JRC, the Research Plans will be updated at least annually by the JRC and approved by the JRC. The Research Plans will set forth (i) the scope of the research and the resources that will be dedicated to the activities contemplated, including the responsibilities of each Party, (ii) specific objectives for each year, which objectives will be updated or amended, as appropriate, by the JRC as research progresses, and (iii) key deliverables for each Party. The Parties shall prepare a Research Plan for (a) the first three (3) Collaboration Targets (each of [...\*\*\*...], [...\*\*\*...] and [...\*\*\*...]), within thirty (30) days after the Effective Date, and (b) for each additional Collaboration Target, within thirty (30) days after the designation of such Target as a Collaboration Target, which the JRC shall minute. The JRC shall review the Research Plans on an ongoing basis and may amend the Research Plans. Any such changes shall be reflected in written amendments to the Research Plans.

#### 4.1.4 Backup Compounds

The JRC and JDC shall ensure that the Research Plan and Phase I Plan for each Collaboration Target contains a plan for the research and development of Backup Compounds. [...\*\*\*...]. Progress of up to [...\*\*\*...] Collaboration Compounds satisfying CCS Criteria through GLP Tox Studies for a Collaboration Target shall be at BPM's sole expense. Additional Backup Compounds may be progressed through a GLP Tox Study at Roche's sole discretion and expense (including any supply thereof) as part of the Research Plan and under the supervision of the JRC, provided that BPM will have the right to conduct (or have conducted) any such GLP Tox Study, and if BPM elects such right then Roche shall reimburse BPM for any personnel costs, Allocable Overhead or Out of Pocket Expenses incurred by BPM with respect thereto. All Phase I Development Costs for the first Backup Compound for a Collaboration Target in a Phase I Study shall be shared as set forth in Section 12.5 (including subject to the cap stated therein); provided that BPM shall only be obligated to fund one (1) Collaboration Compound for a Collaboration Target at a time in a Phase I Study. Thereafter, all Phase I Development Costs for any Backup Compound for a Collaboration Target in a Phase I Study shall be at Roche's sole expense and discretion (including any supply thereof) as part of the Phase I Plan and under the supervision of the JDC, provided that BPM will have the right to conduct (or have conducted) any such Phase I

Study, and if BPM elects such right then Roche shall reimburse BPM for any Phase I Development Costs incurred by BPM with respect thereto.

# 4.1.5 Part 1 Activities

In Part 1, the Parties will work on the three (3) specified Collaboration Targets: [...\*\*\*...], [...\*\*\*...] and [...\*\*\*...]. Prior to the JRC determining that [...\*\*\*...] has satisfied [...\*\*\*...], the Parties may upon mutual written agreement replace [...\*\*\*...] with another Collaboration Target. The Parties will select an additional two (2) Collaboration Targets in Part 2, as described in Section 4.1.6.

For each Collaboration Target, BPM will select Library Compounds of different scaffolds offering different starting chemistry points, and exhibiting adequate kinase potency, activity in binding, enzyme and/or biochemical and cell-based assays, kinase selectivity, and ADME characteristics.

Such Library Compounds shall be derivatized by BPM to improve potency, selectivity and ADME profile characteristics (via application of applicable kinase binding assays, cellular target engagement measurements, and *in vitro* ADME profiling), and thereby establish structure-activity relationships of different compound series, including Other Compounds and Collaboration Compounds. [...\*\*\*...].

Further optimization of potency, selectivity and ADME profile characteristics of Library Compounds, Collaboration Compounds and Other Compounds by BPM during Lead Optimization shall enable *in vivo* Animal POC experiments of selected Collaboration Compounds by Roche or a CRO (provided that Roche shall continue to bear responsibility for the conduct of such experiments). Additional ADME/PK/safety/stability testing and pre-formulation activities performed by BPM during Lead Optimization shall help identify Collaboration Compounds meeting CLS Criteria and finally CCS Criteria. The JRC shall discuss the use of CROs for such activities. Any CRO recommended by the JRC shall either be listed in Appendix 1.38 or otherwise approved by Roche (such approval not be unreasonably withheld, conditioned or delayed). [...\*\*\*...]. At Lead Nomination and/or during Lead Optimization, as per Section 8.4, the JRC will also recommend whether Roche's chemistry resources should be included in Lead Optimization to address issues including BPM resource constraints or to assist with problem-solving. In summary, the work during Lead Optimization is being performed by BPM, with Roche providing protein crystallography and modeling support and input to the preclinical evaluation, and the JRC recommending further Roche contributions including chemistry resources. For clarity, except as provided for in Section 21.2.3, the Roche Group is granted no right under this Agreement to perform any medicinal chemistry activities with respect to Library Compounds, Other Compounds, Collaboration Compounds, Products or Licensed Products under this Agreement unless authorized by the JRC or by the mutual agreements of the Parties.

A chemistry expert at Roche ("Insulated Chemistry Expert") shall be designated in writing by Roche to review structures of Other Compounds and Collaboration Compounds at the start of the collaboration and throughout the Lead Nomination phase. The Insulated Chemistry Expert shall independently handle the structural information and no structures provided by BPM to the Insulated Chemistry Expert can be shared with any other individuals within Roche other than members of senior management specified on Appendix 4.1.5 acting in their decision making capacity. For clarity, these structures cannot be used for any other purpose, including any research purpose. Appropriate safeguards will be established by Roche that are intended to prevent any inadvertent disclosure or improper use of these structures and any structural information related to such structures. From Lead Nomination onwards and throughout Lead Optimization, the structures of Other Compounds and Collaboration Compounds in the Lead

Optimization phase shall be shared with the Roche project team members (including Collaboration Compounds meeting Lead Series Identified Criteria, CLS Criteria and CCS Criteria).

In order to enable manufacture of batches of selected Collaboration Compounds for GLP Tox Studies, BPM or Roche (as determined by the JRC) shall initiate activities for manufacturing process optimization (including establishment of an entry into GLP Tox manufacturing process), entry into GLP Tox formulations, GLP analytics including establishment of specifications for drug substance and drug product at the appropriate time point after CLS, with specifications aligned by the JRC in accordance with Section 8.4. [...\*\*\*...] At the meeting of CCS Criteria, an entry-into-human formulation strategy shall also be available and aligned by the JRC.

Subject to Section 4.1.4, GLP Tox Studies, after confirmation of Collaboration Compound exposure with the GLP Tox batch, shall be performed by BPM in both rodent and non-rodent species [...\*\*\*...], at BPM's expense, as a final step of the preclinical phase at a CRO approved by Roche (such approval not to be unreasonably withheld, conditioned or delayed) unless the CRO is already listed in Appendix 1.38.

#### 4.1.6 Part 2 Activities

Part 2 shall start with Screening of Library Compounds selected by both Parties (e.q., the diversity set comprised in BPM Technology) in both assays performed by BPM (Jurkat-cell based) and by Roche ([...\*\*\*...]), and the screening and validation phase of Part 2 shall end on the earlier of [...\*\*\*...]. It is anticipated that the Screening phase will last approximately [...\*\*\*...]. Screening Hits shall be selected by the JRC and taken forward into Target Validation, with the Target Validation plan approved by the JRC, including any Library Compound derivatization during the Target Validation phase to test Library Compounds, Other Compounds and Collaboration Compounds. It is anticipated that at least [...\*\*\*...] as a shared effort between BPM and Roche with studies being performed by both Parties. Target Validation aims to deliver a pool of validated Collaboration Targets as determined by the JRC ("Pool"). For Collaboration Targets selected in Part 2, a Research Plan will be established prior to initiating Lead Nomination Activities based on Library Compounds, Other Compounds or Collaboration Compounds identified during the respective Target Validation. The JRC shall select the Collaboration Targets from the Pool to be further pursued in Part 2 for Lead Nomination. If the JRC is unable to reach consensus on the selection of Collaboration Targets to pursue in Part 2, then Roche and BPM shall each select one (1) Collaboration Target for Part 2. Activities from Lead Nomination onwards for such selected Part 2 Collaboration Targets shall follow the outline described under Part 1 activities. If Collaboration Compounds for a given Target from this Part 2 fail no later than in in vivo Animal POC experiments performed by or on behalf of Roche, and provided there are additional Collaboration Targets remaining in the Pool, then the JRC may replace a Collaboration Target with another Collaboration Target from the Pool. The JRC's replacement right shall not exceed two (2) Collaboration Target replacements, and shall not extend beyond completion of Animal POC experiments for such Collaboration Targets. If the JRC is unable to reach consensus on a replacement for a Collaboration Target, then [...\*\*\*...]. After the JRC's right to replace Collaboration Targets from the Pool has ended pursuant to this Section 4.1.6, all Collaboration Targets still then within the Pool shall automatically become Leftover Targets, and both Parties shall have rights to further research and develop compounds and products related to any Leftover Targets outside of the Agreement without any financial obligations owed to the other Party. For clarity, (a) the JRC shall have the right to replace [...\*\*\*...] as set forth in Section 4.1.5, (b) the JRC shall have the right to replace the fourth or fifth Collaboration Targets no later than in in vivo Animal POC experiments for such Collaboration Target as set forth in this Section 4.1.6, and (c) the JRC shall have no right to replace [...\*\*\*...] or [...\*\*\*...].

#### 4.2 Records; Reports

## 4.2.1 Progress Reports

At least quarterly during the Research and Development Term, (i) BPM shall prepare and provide to the JRC a detailed summary of the progress of the work performed by BPM under the Research Plans during the preceding Calendar Quarter and (ii) Roche shall update the JRC with a detailed summary of the progress of the work performed by Roche under the Research Plans during the preceding Calendar Quarter. Promptly upon expiry of the Research and Development Term, each Party shall provide a final written report to the JRC summarizing its activities under the Research Plans and the results thereof.

#### 4.2.2 Research Records

Each Party shall maintain records of all research conducted under the Research Plans (or cause such records to be maintained) in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of such Party in the performance of activities under the Research Plans. All laboratory notebooks shall be maintained for no less than the term of any Patent Rights issuing therefrom.

# 5. Conduct of the Phase I Program

#### 5.1 Phase I Program

#### **5.1.1** Scope

On a Collaboration Target-by-Collaboration Target basis, BPM shall have the lead responsibility for the conduct of all Phase I Studies (even if Roche elects to exercise its Option Right before the completion of Phase I Studies), other than those Phase I Studies involving Roche Clinical Compounds or Roche Marketed Products, in accordance with the Phase I Plans. Roche shall have the right to conduct all Phase I Studies involving Roche Clinical Compounds or Roche Marketed Products in accordance with the Phase I Plans. The activities conducted in connection with the Phase I Program will be overseen by the JDC. For clarity, Roche and its Affiliates shall not conduct any Phase I Studies with respect to such Collaboration Target except as expressly permitted in the Phase I Plans.

## 5.1.2 Diligent Efforts

For each Collaboration Target, Roche and BPM shall each use Commercially Reasonable Efforts to perform their respective tasks and obligations in conducting all activities ascribed to it in the then-current Phase I Plan for such Collaboration Target, in accordance with the time parameters set forth therein.

#### 5.1.3 Phase I Plan

The JDC shall strive by consensus to prepare a Phase I Plan for each Collaboration Target no later than thirty (30) days after the start of GLP Tox Studies for such Collaboration Target. Each Collaboration Target will be designated by the JDC as either a [... \*\*\*...] or a [... \*\*\*...] in the applicable Phase I Plan. [... \*\*\*...], the JDC shall amend the Phase I Plan for such Collaboration Target (if needed).

BPM shall prepare the initial draft of each Phase I Plan for any [...\*\*\*...], unless the combination is with a Roche Clinical Compound or Roche Marketed Product, in which case Roche shall prepare the initial draft of each such Phase I Plan. The JDC shall review each Phase I Plan on an ongoing basis and may amend such Phase I Plan. Any such changes shall be reflected in written amendments to such Phase I Plan. The Parties will conduct the Phase I Program in accordance with the Phase I Plans. Each Phase I Plan will set forth (i) the scope of the initial Phase I Studies for such Collaboration Target and the resources that will be dedicated to the activities contemplated within the scope of such Phase I Studies, including the responsibilities of each Party, (ii) projected patient enrollment rates consistent with Roche's historic enrollment rates for similar drug candidates in Phase I Studies, (iii) specific objectives for Calendar Year end in which such initial Phase I Studies are conducted, which objectives will be updated or amended, as appropriate, by the JDC as development progresses, and (iv) a rolling two (2) year budget for such anticipated activities to be performed during the then-current Calendar Year and the next Calendar Year, and a forecast of the budgets for each subsequent Calendar Year thereafter through completion of all development activities set forth in such Phase I Plan; provided that BPM shall have no obligation to incur any Phase I Development Costs in excess of [...\*\*\*...] for all Phase I Studies for each Phase I Plan for each Collaboration Target as further described in Section 12.5. [...\*\*\*...]

### 5.1.4 Phase I Studies

BPM shall keep Roche informed and consult with Roche as needed through the JDC on the progress of Phase I Studies conducted by BPM.

### 5.1.5 Duration

On a Collaboration Target-by-Collaboration Target basis, the Phase I Program for a Collaboration Target shall commence on the start of the first Phase I Plan for such Collaboration Target and shall continue until the expiration of the Option Period for such Collaboration Target. [...\*\*\*...].

### 5.2 Records; Reports

### 5.2.1 Progress Reports

At least quarterly during the Phase I Program, (i) BPM shall prepare and provide to the JDC a detailed summary of the progress of the work performed by BPM under the Phase I Plans during the preceding Calendar Quarter and (ii) Roche shall prepare and provide to the JDC a detailed summary of the progress of the work performed by Roche under the Phase I Plans during the preceding Calendar Quarter. Promptly upon expiry of the Research and Development Term, each Party shall provide a final written report to the JDC summarizing its activities under the Phase I Plans and the results thereof.

### 5.2.2 Phase I Records

Each Party shall maintain records of all Phase I Studies conducted under the Phase I Plans (or cause such records to be maintained) in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved by or on behalf of such Party in the performance of activities under the Phase I Plans. All laboratory notebooks shall be maintained for no less than the term of any Patent Rights issuing therefrom.

### 6. Diligence

Each Party shall use Commercially Reasonable Efforts in the conduct of each Research Plan and Phase I Plan.

For any Collaboration Target for which Roche exercises its Option Right, Roche shall use Commercially Reasonable Efforts to further develop (pursuant to the agreed Development Plan) and commercialize at least one (1) Licensed Product in at least one (1) Indication in the Field in the Roche Territory.

For Program 2 and Program 4, BPM shall use Commercially Reasonable Efforts to further develop (pursuant to the agreed Development Plan) and commercialize at least one (1) Licensed Product in at least one (1) Indication in the Field in the BPM Territory.

# 7. Development

### 7.1 Scope

Subject to the terms of this Section 7, after exercise of its Option Right for a Collaboration Target and other than with respect to the Phase I Program, (i) subject to Section 7.3, Roche shall have responsibility for the conduct of all clinical development for Licensed Products in the Field in the Territory subject to the applicable sharing of Phase I Development Costs and Development Costs, (ii) Roche shall have responsibility for the design and conduct of all research and development of Companion Diagnostics for Licensed Products in the Field in the Territory, and (iii) Roche shall have the responsibility for the design of, and the right to conduct, all Clinical Studies for a given Collaboration Target involving Roche Clinical Compounds or Roche Marketed Products. Clinical development of Licensed Products in the Field in the Territory shall be overseen by the JDC subject to Section 7.3.

### 7.2 Management

For development of Licensed Products in Program 1, Program 3, and Program 5, Roche shall keep BPM informed of clinical development activities for Licensed Products in the Field in the Roche Territory and share the Development Plan through the JDC. Roche shall be responsible for all decision making with respect to clinical development of Licensed Products in Program 1, Program 3 and Program 5 in the Field in the Roche Territory.

### 7.3 Development of Program 2 and Program 4

#### 7.3.1 Consensus and Label Pursuits

For development of Licensed Products in Program 2 and Program 4, the Parties shall strive to reach consensus on the Development Plan through the JDC with the intent to establish a global clinical plan that benefits both Parties in their respective regions for commercialization. If the JDC is unable to agree on elements of the Development Plan (as to Indications, Label Pursuits, or design of the global Clinical Studies), then Roche shall have final say with respect to the Development Plan where such Development Plan shall include no more than a total of [...\*\*\*...] (each a "Label Pursuit") of which no more than a total of [...\*\*\*...] Label Pursuits may include simultaneous Pivotal Studies) unless the Parties mutually agree otherwise, provided that if the Parties mutually agree to co-formulate a Combination Product involving Roche Clinical Compounds or Roche Marketed Products, then the Parties shall mutually agree to the applicable portion of the Development Plan. By way of example, triple negative breast cancer and hormone-receptor positive breast cancer shall be considered two (2) distinct Label Pursuits.

### 7.3.2 Supplemental Studies

Roche shall have responsibility for the conduct of all Clinical Studies for Licensed Products in the Field in the Territory pursuant to the Development Plan other than Supplemental Studies. In addition, after the first Regulatory Approval for a Licensed Product, to the extent that (a) a Party desires to conduct any Clinical Studies in a Label Pursuit for such Licensed Product that is not included in the Development Plan, (b) a Party desires to conduct any Clinical Studies for such Licensed Product that are specific to a Party's portion of the Territory, or (c) a Party desires to conduct any Post-Marketing Studies or other post-marketing commitments as mandated or agreed to be conduct with a Regulatory Authority for such Licensed Product, in each case ((a)-(c)) for such Licensed Product that the other Party does not desire to co-fund (each a "Supplemental Study"), the Party desiring to conduct such Supplemental Study(ies) may do so at its own cost and expense in its Territory or in the other Party's Territory, subject to the following limitations in this Section 7.3.2.

If a Party wants to conduct a Supplemental Study for a Licensed Product in the other Party's Territory, such Supplemental Study shall require the consent of such other Party, which consent shall not be unreasonably withheld by such other Party; provided that such consent may be reasonably withheld by such other Party if such other Party determines in good faith using industry-reasonable criteria that such Supplemental Study would likely cause commercial harm to such other Party or its Affiliates or Sublicensees in such other Party's respective Territory. At the request of the Party proposing to conduct such Supplemental Study, such other Party shall explain at the JDC the basis for its determination to withhold its consent to such Supplemental Study in such other Party's Territory. If the Party proposing to conduct the Supplemental Study believes that it is impractical or such Party will be unable to fulfill a post-marketing commitment mandated or agreed to with a Regulatory Authority unless such Supplemental Study is conducted in the other Party's Territory, the Party proposing to conduct such Supplemental Study shall have the burden of demonstrating that it is impractical or unable to conduct such Supplemental Study unless such Supplemental Study is conducted in the other Party's Territory.

The other Party shall have the right (but not the obligation) (the "Supplemental Study Opt-In Right") to access any study reports and data of such Supplemental Study(ies) that such other Party did not co-fund for purposes of Filing for Regulatory Approval in such other Party's Territory by paying [...\*\*\*...] of the Development Costs incurred by the Party conducting such Supplemental Study.

For clarity, for Program 2 and Program 4 (i) conduct of Clinical Studies (including Supplemental Studies) in non-oncology Indications shall require mutual agreement of the Parties, and (ii) conduct of Clinical Studies (including Supplemental Studies) using Roche Marketed Products shall require the written consent of Roche.

# 7.3.3 Shared Development Costs

Within sixty (60) days after exercising its Option Right with respect to each of Program 2 and Program 4, Roche shall provide BPM with an initial Development Plan and a budget for such Program outlining the planned activities and related Development Costs ("Shared Development Cost Budget") for such Development Plan. The Shared Development Cost Budget shall include the anticipated Development Costs pursuant to the Development Plan for the remainder of the then current Calendar Year and each of the next two (2) Calendar Years expected to be incurred by each Party and in total. Thereafter, annually, the Development Plan and the Shared Development Cost Budget shall be updated by the JDC such that the Shared Development Cost

Budget shall always reflect the planned activities under the Development Plan for three (3) Calendar Years. If a Party's actually incurred Development Costs for the current Calendar Year exceeds [...\*\*\*...] of its portion of the Shared Development Cost Budget, such excess portion of Development Costs shall be entirely borne by the Party that exceeded its portion of the Shared Development Cost Budget provided that (A) BPM approved the amount included in the Shared Development Cost Budget specifically attributable to the activities conducted by BPM under such Shared Development Cost Budget, and (B) the JDC shall have the right during a Calendar Year to update the Shared Development Cost Budget in the event of (i) faster than planned Clinical Study enrollment, (ii) written guidance or requirements from a Regulatory Authority that would result in amendments to the Development Plan or (iii) mutual agreement by the Parties to amend the Development Plan, each of (i), (ii) and (iii) an "Allowable Exception". Additional Development Costs incurred in a Calendar Year resulting from an Allowable Exception shall be subject to sharing of Development Costs pursuant to Section 12.6.

### 7.3.4 Deferrable Amounts

If the annual update to the Development Plan for such Program results in the Shared Development Cost Budget for the first remaining Calendar Year of the Shared Development Cost Budget increasing by more than [...\*\*\*...] from the then current Shared Development Cost Budget for the then-current Calendar Year or the second remaining Calendar Year increasing by more than [... \*\*\*...] from the then current Shared Development Cost Budget for such Program for the then-current Calendar Year, after taking into consideration any Allowable Exceptions, then BPM shall have the right to elect not to pay its share of actually incurred Development Costs for such Program for such Calendar Year exceeding such percentage of the previous Shared Development Cost Budget for such Program for such Calendar Year (such amount a "Deferrable Amount" and such election a ("BPM Deferral Election")). If BPM makes a BPM Deferral Election, Roche may elect to either (i) deduct or withhold payments payable to BPM under Section 12.7, 12.8 or 12.9 until [...\*\*\*...] of the Deferrable Amount is repaid to Roche or (ii) increase the royalty rates payable by BPM to Roche under Section 12.9.3 by [...\*\*\*...] (e.g., the first royalty tier would become [...\*\*\*...] of such Deferrable Amount in part or in full to Roche in cash. Notwithstanding the foregoing, BPM shall not have the right to make a BPM Deferral Election for any Calendar Year after the First Commercial Sale in the United States for any Licensed Product under this Agreement.

The following is an example that illustrates a possible scenario involving a Licensed Product for a [...\*\*\*...]:

In this example, the Shared Development Cost Budget was provided to BPM in June 2019 in millions of US dollars (US\$ Millions) and BPM approved the costs of activities performed by BPM.

	June-Dec 2019 (budgeted)	Jan-Dec 2020 (budgeted)	Jan-Dec 2021 (budgeted)
Roche	[***]	[***]	[***]
BPM	[***]	[***]	[***]
Total	[***]	[***]	[***]

The Shared Development Cost Budget was provided to BPM for 2020, 2021 and 2022 in millions of US dollars (US\$ Millions) and BPM approved costs of activities performed by BPM.

	June-Dec 2019 (Actual)	Jan-Dec 2020 (Budgeted)	Jan-Dec 2021 (Budgeted)	Jan-Dec 2022 (Budgeted)
Roche	[***]	[***]	[***]	[***]
BPM	[***]	[***]	[***]	[***]
Total	[***]	[***]	[***]	[***]

# As a consequence:

- For 2019, both parties share [...\*\*\*...] the amount of [...\*\*\*...] + [...\*\*\*...] = [...\*\*\*...]
- For 2019, Roche bears on its own the amount of [...\*\*\*...], which [...\*\*\*...] of the originally budgeted amount of [...\*\*\*...]
- BPM can elect the BPM Deferral Election for 2020 because the increase in total budget from [...\*\*\*...] to [...\*\*\*...] is [...

(For the below sections we assume that BPM made such election.)

- No Deferral Election can be made for 2021 because the increase in total budget from [...\*\*\*...] to [...\*\*\*...] is [...\*\*\*...]

The Shared Development Cost Budget provided to BPM for 2021, 2022 and 2023 in millions of US dollars (US\$ Millions) and BPM approved costs of activities performed by BPM.

	June-Dec 2019 (Actual)	Jan-Dec 2020 (Actual)	Jan-Dec 2021 (Budgeted)	Jan-Dec 2022 (Budgeted)	Jan-Dec 2023 (Budgeted)
Roche	[***]	[***]	[***]	[***]	[***]
BPM	[***]	[***]	[***]	[***]	[***]
Total	[***]	[***]	[***]	[***]	[***]

# As a consequence:

- For 2020, because of BPM's deferral election, both parties share [...\*\*\*...] the amount of [...\*\*\*...]
- BPM pays on its own the [...\*\*\*...], which exceeds the [...\*\*\*...] % of the previously budgeted amount of [...\*\*\*...]

- Roche pays on its own the remaining [...\*\*\*...] ([...\*\*\*...] total less [...\*\*\*...] shared costs less [...\*\*\*...] solely borne by BPM)
- Roche is entitled to a repayment of [...\*\*\*...] % of BPM's share of the [...\*\*\*...].
- BPM's share of the [...\*\*\*...] equals [...\*\*\*...] and Roche's reimbursement equals [...\*\*\*...]
- No Deferral Election for 2021 because the increase in total budget from [...\*\*\*...] to [...\*\*\*...] is [...\*\*\*...]
- No Deferral Election for 2022 because the increase in total budget from [...\*\*\*...] to [...\*\*\*...] is [...\*\*\*...]

### 7.3.5 Updates

For Program 2 and Program 4, each Party will periodically provide to the JDC, on a Calendar Quarter basis, or more frequently as reasonably requested by the JDC, an update regarding development activities conducted by or on behalf of such Party with respect to Licensed Products for such Program, as well as any Supplemental Studies, conducted by or on behalf of such Party with respect to Licensed Products for such Program. The Parties will periodically report to the JDC, but in no event less than on a Calendar Quarter basis, regarding their respective activities conducted under the Development Plan for Licensed Products for such Program. In addition, each Party will promptly share with the other Party all material developments and information that it comes to possess relating to the development of any Licensed Products for such Program and all other data and information that either Party may reasonably request to support Filings in a mutually agreed format, including (a) safety concerns for Licensed Products for such Program, and (b) study reports and data generated from Clinical Studies of such Licensed Products for such Program; provided however, that excluding safety concerns or as required under the Pharmacovigilance Agreement, a Party will not be obligated to share any study reports and data generated from Supplemental Studies conducted by or on behalf of such Party unless the non-proposing Party has not exercised its Supplemental Study Opt-In Right other than to permit the non-proposing Party to determine whether to exercise its Supplemental Study Opt-in Right.

#### 7.3.6 Records

Each Party will maintain scientific records, in sufficient detail and in sound scientific manner appropriate for Patent and regulatory purposes and in compliance with cGCP with respect to activities intended to be submitted in regulatory filings (including INDs and BLAs), which will fully and accurately reflect all work done and results achieved in the performance of the Development activities, Clinical Studies (including Supplemental Studies) with respect to Licensed Products by such Party.

#### 8. Governance

#### 8.1 Joint Research Committee

Within thirty (30) days after the Effective Date, the Parties shall establish a JRC to oversee all activities under the Research Plans.

### 8.2 JDC

Within thirty (30) days after the first Collaboration Compound achieving CLS Criteria, the Parties shall establish a JDC to oversee development of Products and Licensed Products.

#### 8.3 Members

The JRC and JDC shall each be composed of six (6) persons ("Members"). Roche and BPM each shall be entitled to appoint three (3) Members with appropriate seniority, responsibilities and functional expertise within the applicable Party to make decisions arising within the scope of the JRC's or JDC's, as applicable (each such appointee of Roche, a "Roche Member," and each such appointee of BPM, a "BPM Member"); provided that one Roche Member shall have CMC-related decision-making authority on behalf of Roche at all times. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a Member shall notify the other Party at least ten (10) days prior to the next scheduled meeting of the JRC or JDC, as applicable. Both Parties shall use reasonable efforts to keep an appropriate level of continuity in representation. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part or the whole meeting with prior written notification to the JRC or JDC, as applicable. Members may be represented at any meeting by another person designated by the absent Member. Each committee is chaired by a Member ("Chairperson"). The JRC shall be chaired by a BPM Member. The JDC shall be chaired by a Roche Member.

### 8.4 Responsibilities of the JRC

The JRC shall have the responsibility and authority to:

- (a) approve each Research Plan and any revisions thereto;
- (b) review and oversee the execution of the Research Plans;
- (c) approve the Screening plan and any changes thereto;
- (d) select Screening Hits for Target Validation;
- (e) select Collaboration Targets in Part 2 in accordance with Section 4.1.6;
- (f) approve the Target Validation plan and any changes thereto;
- (g) approve validated Collaboration Targets to be allocated to the Pool in Part 2;
- (h) maintain a list of Collaboration Targets;
- (i) establish timelines for research decision points;
- (j) determine Compound Criteria;
- (k) determine whether criteria have been met (Compound Criteria, Lead Series Identified Criteria, CLS Criteria, CCS Criteria);
- (l) select all Backup Compounds;
- (m) maintain a list of all Collaboration Compounds, including Backup Compounds;
- (n) determine and maintain a list of all Collaboration Targets in order of advancement of status;
- (o) review the research efforts of the Parties;
- (p) identify appropriate resources necessary to conduct the Research Plans (including recommending whether Roche's chemistry resources should be included in Lead Optimization, *e.g.* in order to increase the number of parallel activities on multiple series in a Research Plan or for multiple Research Plans or to address specific optimization questions in Lead Optimization);
- (q) determine when and where to perform any pre-formulation activities, salt screening, and polymorph screening in accordance with CLS Criteria and CCS Criteria;

- (r) align on the drug substance and drug product specifications for the batches used for the GLP Tox Studies;
- (s) align on the drug substance and drug product strategy, including stability program, and its execution for the drug product used for the GLP Tox Studies and Phase I Studies;
- (t) determine whether drug substance and/or drug product batches for Phase I Studies shall be made at a CRO acceptable to Roche or by Roche itself using its facilities;
- (u) oversee manufacture and release of drug substance and drug product batches to be used for Phase I Studies;
- (v) review the GLP Tox Study protocol *e.g.* with respect to study design, dose selection or GLP exposure measurements;
- (w) determine whether drug substance and/or drug product batches for GLP-Tox Studies shall be made at a CRO acceptable to Roche or by Roche itself using its facilities;
- (x) oversee manufacture and release of drug substance and drug product batches to be used in GLP-Tox Studies;
- (y) establish, set expectations and mandates for, oversee and disband JOTs;
- (z) recommend action items to each Party's respective decision making bodies; and
- (aa) attempt to resolve any disputes on an informal basis.

The JRC shall have all responsibility and authority regarding overseeing activities under the Research Plans, other than as expressly set forth in this Agreement. The JRC shall have no responsibility and authority other than that expressly set forth in this Section, unless mutually agreed by the Parties.

### 8.5 Responsibilities of the JDC

The JDC shall have the responsibility and authority to:

- (a) develop and approve initial Phase I Plans and any revisions thereto;
- (b) approve Development Plans and any revisions thereto;
- (c) review and oversee the execution of the Phase I Plans and Development Plans;
- (d) oversee the initial Phase I Studies for Products prior to Roche's exercise of an Option Right;
- (e) determine and maintain a list of all Collaboration Targets in order of advancement of status;
- (f) designate the MTD for each Product;
- (g) designate the cut-off date for the data resulting from the Phase I Studies conducted by the Parties for each Collaboration Target in accordance with Section 3.1.3;
- (h) oversee development of Licensed Products after Roche's exercise of an Option Right;
- (i) establish timelines and criteria for development decision points;
- (j) determine whether development criteria have been met;
- (k) review the development efforts of the Parties, including for Companion Diagnostics;
- (l) identify appropriate resources necessary to conduct the Phase I Plans and Development Plans;

- (m) review and approve Phase I Development Costs and Development Costs in accordance with the allocations set forth in Sections 12.5 and 12.6;
- (n) depending on the Clinical Studies following Phase I Studies, devise at the latest upon start of Phase I Studies the appropriate CMC-strategy for drug substance and drug product to be used in either Phase II Studies or Phase III Studies and oversee its execution (with Roche deciding where such manufacture of Phase II and Phase III Study supply, both for drug substance and drug product, should occur (including prior to Roche exercising its Option Right);
- (o) define the drug substance and drug product specifications for the batches used for Phase I Studies and any batches made prior to Roche exercising its Option Right for the subsequent Phase II Studies and/or Phase III Studies after Option Right exercise;
- (p) determine whether a [...\*\*\*...] or should be re-designated pursuant to Section 5.1.3;
- (q) establish, set expectations and mandates for, oversee and disband JOTs;
- (r) recommend action items to each Party's respective decision making bodies; and
- (s) attempt to resolve any disputes on an informal basis.

The JDC shall have all responsibility and authority regarding the clinical development of Products and Licensed Products, other than as expressly set forth in this Agreement. The JDC shall have no responsibility and authority other than that expressly set forth in this Section, unless mutually agreed by the Parties.

## 8.6 Meetings

The Chairperson or his/her delegate will be responsible for sending invitations and agendas for all JRC or JDC, as applicable, meetings to all Members of each committee at least ten (10) days before the next scheduled meeting of the JRC or JDC, as applicable. During the Research and Development Term, the venue for the meetings shall be agreed by the JRC or JDC, as applicable. The JRC or JDC, as applicable shall hold meetings at least once per Calendar Quarter, either in person or by tele-/video-conference, and in any case as frequently as the Members of the JRC or JDC, as applicable may agree shall be necessary, but not more than six (6) times each Calendar Year. After the Research and Development Term the JDC shall meet once per Calendar Quarter, provided that if there is no on-going development for either Program 2 or Program 4, the JDC shall meet twice per Calendar Year. The Alliance Director of each Party may attend the JRC and/or JDC meetings as a permanent participant.

#### 8.7 Minutes

The Chairperson of a committee will be responsible for designating a Member to record in reasonable detail and circulate draft minutes of meetings to all members of the committee for comment and review within twenty (20) days after the relevant meeting. The Members of the committee shall have ten (10) days to provide comments. The Party preparing the minutes shall incorporate timely received comments and distribute finalized minutes to all Members of the committee within thirty-five (35) days of the relevant meeting. The Chairperson approves the final version of the minutes before its distribution.

#### 8.8 Decisions

# 8.8.1 Decision Making Authority

The JRC shall decide matters within its responsibilities set forth in Section 8.4. The JDC shall decide matters within its responsibilities set forth in Section 8.5.

#### 8.8.2 Consensus; Good Faith

In general, the Parties intend to govern this collaboration through empowered joint committees that operate by consensus while making its decisions with speed. The Parties recognize that there may be exceptions to this principle where reaching consensus is not possible and one Party will need to make a final decision on a given matter in order to preserve the importance of progressing with speed. With this in mind, the Members of a committee shall act in good faith to cooperate with one another and seek agreement with respect to issues to be decided by that committee. The Parties shall endeavor to make decisions by consensus.

# 8.8.3 Pre-Exercise of Option Right Escalation

If the JRC or JDC is unable to decide a matter arising before Roche's exercise of its Option Right by consensus, then such matter shall be referred to the Chief Executive Officer of BPM or equivalent position or his/her nominee and the Head of Roche Partnering or equivalent position or his/her nominee for resolution, who together shall use reasonable and good faith efforts to reach a decision by consensus within thirty (30) days after the date such matter is referred to them. If the Parties still fail to reach a decision within such thirty (30) days, then the final decision shall be BPM's in the case of a decision by the JRC and Roche's in the case of a decision by the JDC, which shall be exercised in good faith. Any such decision shall constitute a decision of the JRC or JDC, as applicable. Notwithstanding the above, (a) decisions that impact the payment of fees under Section 12.2, the use of Roche facilities or resources pursuant to Section 4.1.5 or Section 8.4 or the use of each Party's resources outside of the scope of this Agreement shall require consensus and shall not be subject to this Section 8.8.3, (b) Roche shall have the final decision-making authority with respect to the design of each Phase I Plan, (c) Roche shall have the final decision-making authority with respect to the conduct of any Clinical Studies of a Product or Licensed Product in combination with either a Roche Marketed Product or a Roche Clinical Compound that Roche elects to conduct, and (d) BPM shall have the final decision-making authority with respect to the conduct of all other Phase I Clinical Studies.

### 8.9 Information Exchange

BPM and Roche shall exchange the information in relation to its activities under this Agreement through the JRC or JDC, as applicable, and BPM and Roche may ask reasonable questions in relation to the above information and offer advice in relation thereto and each Party shall give due consideration to the other Party's input. Notwithstanding the above, a committee may determine other routes of information exchange.

#### 8.10 Alliance Director

Each Party shall appoint one (1) person to be its point of contact with responsibility for facilitating communication and collaboration between the Parties (each, an "Alliance Director"). The Alliance Directors shall be permanent participants of committee meetings (but not Members of the committees) and may attend JOT meetings as appropriate. The Alliance Directors shall facilitate resolution of potential and pending issues and potential disputes to enable the committees to reach consensus and avert escalation of such issues or potential disputes.

### 8.11 Limitations of Authority

No committee shall have any authority to amend or waive any terms of this Agreement, nor shall any committee have the authority to determine whether a Party is in breach of this Agreement.

### 8.12 Expenses

Each Party shall be responsible for its own expenses including travel and accommodation costs incurred in connection with the JRC, JDC and any other committees established under this Agreement.

#### 8.13 Lifetime

The JRC shall exist for so long as work is being conducted under a Research Plan in accordance with this Agreement. The JDC shall exist for so long as a Product or Licensed Product remains in clinical development under a Development Plan. The lifetime of any other committee established pursuant to Section 8.14 will be agreed to by the Parties at the time of inception.

#### 8.14 Other Committees

The Parties may mutually agree to establish such additional joint committees as deemed necessary to achieve the objectives and intent of this Agreement. Any additional committees shall be required to consist at all times of an equal number of BPM Members and Roche Members.

# 9. Manufacture and Supply

### 9.1 Manufacturing Right

Prior to Roche's exercise of its Option Right for a Collaboration Target, the JRC will determine which Party has responsibility for the manufacture of Collaboration Compounds and Products, subject to the oversight of the JRC, in accordance with the applicable Research Plan and Phase I Plan for such Collaboration Target. If requested by a Party, the other terms under which a Party will manufacture and supply Collaboration Compounds and Products to the other Party will be set forth in one or more manufacturing and supply agreements to be entered into between the Parties (each a "Supply Agreement"). Such Supply Agreements will contain customary terms and conditions, including quality and supply failure remedies, and otherwise be consistent with this Agreement and Roche quality standards. If the Parties cannot agree to the terms of a Supply Agreement within ninety (90) days of initiation of discussions, such matter will be decided by the Expert Committee in accordance with the terms and conditions set forth in Section 12.9.4, *mutatis mutandis*.

After Roche's exercise of its Option Right for a Collaboration Target, subject to the oversight of the JDC, Roche shall have the right to manufacture all Licensed Products for such Collaboration Target throughout the Territory, subject to this Section 9.1. For Licensed Products in the BPM Territory pursuant to Program 2 and Program 4, (i) Roche, at its option, can elect to transfer the manufacturing process to BPM (or a CRO that is reasonably acceptable to Roche) whereby BPM (or such CRO) would then have responsibility to manufacture its own supply of such Licensed Product at its own costs; or (ii) BPM, at its option, can elect to use a CRO that is acceptable to Roche to perform such manufacturing activities on behalf of BPM in the BPM Territory if such CRO provides a price that is at least [...\*\*\*...] lower than the per unit cost for a Licensed Product than offered by Roche taking into account projected supply volume discounts. The costs of any such manufacturing process transfer pursuant to clause (i) of the preceding sentence shall be shared equally by the Parties, and pursuant to clause (ii) of the preceding sentence shall be borne solely by BPM. For Licensed Products supplied to BPM by Roche in the United States pursuant to Program 2 and Program 4, Roche shall supply such Licensed Products for clinical supply at

[...\*\*\*...] and for commercial supply at [...\*\*\*...][...\*\*\*...]. The other terms under which Roche will manufacture and supply Licensed Products to BPM will be set forth in one or more Supply Agreements. Such Supply Agreements will contain customary terms and conditions, including quality and supply failure remedies, and otherwise be consistent with this Agreement and Roche quality standards. If the Parties cannot agree to the terms of a Supply Agreement within ninety (90) days of initiation of discussions, such matter will be decided by the Expert Committee in accordance with the terms and conditions set forth in Section 12.9.4, *mutatis mutandis*. At BPM's request, the Parties will include provisions in such Supply Agreements relating to the manufacture and supply of Companion Diagnostics or Roche Marketed Products for use with Licensed Products for Program 2 and Program 4. Either Party shall have the right to manufacture at risk, or have a CRO approved by Roche manufacture at risk, a Product prior to Roche exercising its Option Right for a Collaboration Target. If Roche exercises its Option Right for a Collaboration Target and Roche accepts the quality of a batch of the applicable Product, then the cost to manufacture such batch shall be a Development Cost. If Roche does not exercise its Option Right for a Collaboration Target, then the cost to manufacture such batch of the applicable Product shall be borne by the Party that manufactured or had manufactured the batch.

# 9.2 Technology Transfer

Roche shall have the right, but not obligation, to request a Technology Transfer (as defined below) at any time however no later than [...\*\*\*...] after exercising its Option Right for a given Program. Within [...\*\*\*...] upon such request of Roche, BPM shall complete the transfer of all its Know-How within the BPM IP relating to the manufacturing of the Collaboration Compounds, Products and Licensed Products to Roche and/or one or more CROs designated by and contracting directly with Roche with the goal of enabling Roche and/or its designated CRO to manufacture Collaboration Compounds, Products and Licensed Products ("**Technology Transfer**"). The Parties will agree in good faith on a Technology Transfer protocol defining the scope and conditions of transfer. The cost of such Technology Transfer shall be shared equally.

BPM shall maintain in full force and effect all agreements relating to the manufacture of Collaboration Compounds and Products with Third Parties in effect as of the date of Roche's request of transfer so that Roche has uninterrupted access to clinical supply prior to and during any manufacturing transition from BPM to Roche.

# 9.3 Inspection Right

Roche shall have the right, at any time prior to exercising its Option Right to conduct an inspection (including a cGMP audit) of BPM's manufacturing sites at BPM or at the CRO's facility, as applicable and, with respect to CROs, subject to confidentiality obligations. BPM shall cooperate in good faith in all respects to allow Roche to expediently complete its due diligence.

## 9.4 Review of Draft CRO Agreements

Prior to entering into any new CRO agreements for manufacturing, including supply and quality agreements, related to Collaboration Compounds or Products, BPM shall provide Roche with any draft agreements with CROs for Roche to review and comment. BPM shall consider in good faith all reasonable comments of Roche.

### 10. Regulatory

### 10.1 Responsibility

Prior to Roche's exercise of its Option Right for a Collaboration Target, (a) BPM shall own and file all INDs and hold the regulatory responsibility under each Phase I Plan for each Collaboration Target that is designated as a [...\*\*\*...], and for each [... \*\*\*\*...] not involving a Roche Marketed Product or a Roche Clinical Compound and (b) Roche shall own and file all INDs and hold the

regulatory responsibility under each Phase I Plan for each Collaboration Target that is designated as a [...\*\*\*...] that involves a Roche Marketed Product or a Roche Clinical Compound; provided in each case ((a) and (b)) that a Party shall only file an IND pursuant to the JDC deciding to do so. The responsible Party shall be responsible for pursuing, compiling and submitting the IND and all related Filing documentation, and for interacting with Regulatory Authorities, for such Collaboration Target; provided that the other Party shall have the right to review and comment on any material Filing prior to submission to the relevant Regulatory Authority, and, if the other Party exercises such right, the responsible Party will reasonably consider to consult with and address any concerns raised by the other Party in connection with such activities. Additionally, promptly following submission of any material Filing, the responsible Party shall provide the other Party with the technical format data, the case file and any regulatory dossiers containing information necessary or useful to the responsible Party in connection with its Filings for all Licensed Products including, but not limited to Clinical Study dossiers, regulatory correspondence, Regulatory Authority meeting minutes and study reports from completed non-clinical and Clinical Studies in a format that is agreed to by the Parties. The responsible Party or its Affiliates shall own and file in their discretion all Filings and INDs for such Collaboration Target in the Field in all countries. For all completed study reports, the responsible Party shall provide necessary documentation to confirm data reliability, as required by Article 43 of the Japanese Pharmaceutical Affairs Law Enforcement Regulations and related notifications, including, but not limited to original author signatures, raw data lists, GLP and GCP compliance information. The responsible Party shall supply the other Party with a copy of all material communications related to such Collaboration Target in the Field to or from the Regulatory Authorities for all Major Countries. Upon request of the other Party, the responsible Party shall supply the other Party with a copy of all such communications to or from the Regulatory Authorities for all Major Countries.

After Roche's exercise of its Option Right for a Collaboration Target, subject to Sections 7.2, 12.5 and 12.6, Roche shall be solely responsible for all regulatory affairs related to Licensed Products in the Field in the Roche Territory including the preparation and Filings, as well as any or all Regulatory Approvals required to Exploit Licensed Products in the Field in the Roche Territory. Roche shall be responsible for pursuing, compiling and submitting all Filing documentation, and for interacting with Regulatory Authorities, for all Licensed Products in all countries in the Roche Territory; provided that for Program 2 and Program 4, BPM shall have the right to review and comment on any material Filing for Program 2 or Program 4 prior to submission to the relevant Regulatory Authority, and, if BPM exercises such right, Roche will reasonably consider to consult with and address any concerns raised by BPM in connection with such activities. Roche will use Commercially Reasonable Efforts, to the extent reasonably practicable, to permit BPM to have, at BPM's expense, one (1) mutually acceptable representative of BPM attend, solely as a nonparticipating observer, material, substantive meetings, including pre-IND and end of Phase II Study meetings, with the Regulatory Authorities pertaining to all Licensed Products in Program 2 or Program 4. Additionally, promptly following submission of any material Filing for Program 2 or Program 4, Roche shall provide BPM with the technical format data, case file and any regulatory dossiers containing information necessary or useful to BPM in connection with its Filings for all Licensed Products including, but not limited to Clinical Study dossiers, regulatory correspondence, Regulatory Authority meeting minutes and study reports from completed non-clinical and Clinical Studies in a format that is agreed to by the Parties. Roche or its Affiliates shall own and file in their discretion all Filings and Regulatory Approvals for all Licensed Products in the Field in all countries of the Roche Territory. For all completed study reports, BPM shall provide necessary documentation to confirm data reliability, as required by Article 43 of the Japanese Pharmaceutical Affairs Law Enforcement Regulations and related notifications, including, but not limited to original author signatures, raw data lists, GLP and GCP compliance information. Roche shall supply BPM with a copy of all material communications related to Licensed Products in the

Field to or from the Regulatory Authorities for all Major Countries in the Roche Territory. Upon request of BPM, Roche shall supply BPM with a copy of any communications to or from the Regulatory Authorities for all Major Countries in the Roche Territory. Such terms shall apply *mutatis mutandis* with respect to Licensed Products for Program 2 and Program 4 in the BPM Territory (i.e., BPM shall have all such rights and obligations in lieu of Roche), other than Combination Products in Program 2 or Program 4 that include a Roche Marketed Product, in which case Roche shall be solely responsible for all regulatory affairs worldwide related to such Combination Product in Program 2 or Program 4 as set forth above. For Combination Products in Program 2 or Program 4 that include a Roche Marketed Product, Roche will provide BPM with reasonable advance notice of all substantive meetings with the Regulatory Authorities pertaining to each such Combination Product, or with as much advance notice as practicable under the circumstances.

Prior to Roche's starting Clinical Study enrollment activities for Licensed Products, BPM shall transfer to Roche all relevant historical clinical safety data. Safety information on serious adverse events shall be provided in CIOMS format and safety information on non-serious adverse events shall be provided in English Line Listing format.

At a date to be defined by Roche after exercise of an Option Right for a Collaboration Target, BPM shall transfer and assign to Roche all INDs with respect to Products for such Collaboration Target in the Field in its possession and control, except for filings with a US Regulatory Authority in the case of Program 2 and Program 4. Prior to the transfer, BPM shall provide to Roche copies of all material correspondence with the Regulatory Authorities with respect to such Products for such Collaboration Target. In addition, at a date defined by Roche after exercise of an Option Right for a Collaboration Target, BPM shall transfer and assign to Roche any regulatory dossiers containing information necessary or useful to Roche in connection with its Filings for all Licensed Products for such Collaboration Target in the Field in the Roche Territory, including, but not limited to Clinical Study dossiers, regulatory correspondence, Regulatory Authority meeting minutes and study reports from completed non-clinical and Clinical Studies. For all completed study reports for Licensed Products for such Collaboration Target in the Roche Territory, BPM shall provide to Roche necessary documentation to confirm data reliability, as required by Article 43 of the Japanese Pharmaceutical Affairs Law Enforcement Regulations and related notifications, including original author signatures, raw data lists, GLP and GCP compliance information. All documentation is to be provided in English.

# 10.2 Reporting Adverse Events

### 10.2.1 Report

The Parties agree to inform each other about serious adverse events occurring or having occurred in connection with the use of a Product or Licensed Product that comes into its knowledge. The Parties agree to handle data and information about adverse events occurring or having occurred in connection with the use of a Product or Licensed Product according to the guidelines in the respective territory, for example, those recited in the FDCA and the similar requirements of the Canadian or European regulatory authorities, requirements of the Regulatory Authority and/or requirements of any other relevant Regulatory Authority in the Territory.

BPM shall be solely responsible for reporting adverse drug experiences to Regulatory Authorities in the BPM Territory in the case of Program 2 and Program 4. In all other cases, Roche, as the party owning the Filings and Regulatory Approvals shall be solely responsible for reporting adverse drug experiences to the regulatory authorities in the Roche Territory.

### **10.2.2 Pharmacovigilance Agreement**

The Parties mutually agree to execute a separate Pharmacovigilance Agreement as deemed applicable by the Parties specifying the procedures and timeframes for compliance with Applicable Law pertaining to safety reporting of each Product and Licensed Product and their related activities.

#### 11. Commercialization

### 11.1 Responsibility

Roche, at its own expense, shall have sole responsibility and decision making authority for the marketing, promotion, sale and distribution of Licensed Products in the Roche Territory and shall book all Sales in the Roche Territory. For Program 2 and Program 4, BPM, at its own expense, shall have sole responsibility and decision making authority for the marketing, promotion, sale and distribution of Licensed Products in the BPM Territory and shall book all Sales in the BPM Territory subject to Section 12.9.4.

# 11.2 Updates

Upon request of the Party not selling a Licensed Product in a particular region (the "Non-Selling Party"), the Party selling the Licensed Product in the particular regions ("Selling Party") shall update the Non-Selling Party regarding the commercialization of the Licensed Product (i) in the Roche Territory in the Field by Roche, its Affiliates and Sublicensees, in the case where Roche is the Selling Party, or (ii) in the BPM Territory in the Field by BPM, its Affiliates and Sublicensees, in the case where BPM is the Selling Party. By November 15 of each Calendar Year, the Selling Party also shall provide a non-binding forecast of its annual sales of Licensed Products to the Non-Selling Party for the subsequent Calendar Year. If the Non-Selling Party requests an update, the Selling Party shall provide a high level summary, in writing and/or through a meeting (face to face/ telepresence/videoconference or telephone). The Non-Selling Party shall not request an update more frequently than once per Calendar Year. In addition, upon reasonable request by the Non-Selling Party in connection with financing, partnering, other strategic transaction or Non-Selling Party's reporting obligations under securities laws, the Selling Party shall provide a high level summary regarding the commercialization of the Licensed Product in the Roche Territory or BPM Territory, as applicable, in the Field by the Selling Party, its Affiliates and Sublicensees.

#### 11.3 Recalls, Market Withdrawals or Corrective Actions.

In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product in the Field in the Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of a Licensed Product in the Field in its Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, will as promptly as possible, notify the other Party by telephone or e-mail. Each Party, in consultation with the other Party, will decide whether to conduct a recall of a Licensed Product in its own Territory and the manner in which any such recall will be conducted (except in the case of a government mandated recall, when such Party may act without such advance notice but will notify the other Party as soon as possible thereafter). Except as may otherwise be agreed to by the Parties, each Party will bear the expense of any such recall in its own Territory. Each Party will make available all of its pertinent records that may be reasonably requested by the other Party in order for a Party to effect a recall of a Licensed Product in its Territory. The Parties' rights and obligations under this Section 11.3 will be subject to the terms of any Supply Agreement(s) and any Pharmacovigilance Agreement entered into between the Parties. In the event of a conflict between the provisions of any such Supply Agreements and Pharmacovigilance Agreement and

this Section 11.3, the provisions of such Supply Agreement and Pharmacovigilance Agreement will govern.

### 12. Payment

### 12.1 Initiation Payment

Within [...\*\*\*...] after the Effective Date and receipt of an invoice from BPM, Roche shall pay to BPM forty-five million US dollars (US\$45,000,000). Such payment will be non-refundable, non-creditable and not subject to set-off.

# 12.2 Pre-Option Exercise Fees

Roche shall pay to BPM up to a total of [...\*\*\*...] US dollars [...\*\*\*...], upon the achievement of milestone events with respect to Products. The event payments under this Section 12.2 shall be paid by Roche according to the following schedule of events.

Event	US Dollars (in millions)
[***]	[***]
[***]	[***]
[***] (per each Collaboration Target, up to [***] in total	[***]
payments for all five Collaboration Targets)	
[***] (per each Collaboration Target, up to [***] in total	[***]
payments for all five Collaboration Targets)	
[***] (per each Collaboration Target, up to [***] in total	[***]
payments for all five Collaboration Targets)	

Any such payments shall be paid by Roche to BPM within [...\*\*\*...] after the occurrence of the applicable event and receipt of an invoice from BPM. Each payment will be non-refundable, non-creditable and not subject to set-off.

# 12.3 Costs for Work Conducted Under Research Plans

Except as otherwise provided in this Agreement, each Party shall be responsible for its own costs incurred in the conduct of each Research Plan.

# 12.4 Option Exercise Fee

If Roche exercises its Option Right with respect to a Collaboration Target, then Roche shall pay to BPM a fee ("**Option Exercise Fee**") to exercise such Option Right as follows:

Exercise of Option Right	US Dollars (in millions)
Program 1	[***]
Program 2	[***]
Program 3	[***]
Program 4	[***]
Program 5	[***]

Subject to the provisions of Sections 3.1.3 and 3.1.4, any such payments shall be paid by Roche to BPM [...\*\*\*...] after the occurrence of the applicable event and receipt of an invoice from BPM. Each Option Exercise Fee will be non-refundable, non-creditable and not subject to set-off.

### 12.5 Phase I Development Cost Share

All Phase I Development Costs will be shared [...\*\*\*...] by BPM and [...\*\*\*...] by Roche; provided that BPM shall only be responsible for up to a maximum of [...\*\*\*...] of Phase I Development Costs for all Phase I Studies conducted pursuant to a Phase I Plan for each Collaboration Target (it being understood that such [...\*\*\*...] cap shall apply on a Collaboration Target-by-Collaboration Target basis and thus to all Products (including any Backup Compounds) for any such Collaboration Target), and any Phase I Development Costs in excess of such [...\*\*\*...] cap for a Collaboration Target shall be at Roche's sole expense; provided that if (a) there is a failure of a Product in a Phase I Study prior to the designation of the MTD for such Product for a Collaboration Target and (b) the Parties conduct a Phase I Study with a Backup Compound for a Collaboration Target, then the cap for such Collaboration Target shall be increased to a maximum of [...\*\*\*...] (it being understood that such [...\*\*\*...] cap shall apply on a Collaboration Target-by-Collaboration Target basis and thus to all Products (including any Backup Compounds) for any such Collaboration Target), and any Phase I Development Costs in excess of such [...\*\*\*...] cap for a Collaboration Target shall be at Roche's sole expense. For clarity, the allocation of Phase I Development Costs set forth in this Section 12.5 will apply regardless of whether Roche has exercised its Option Right for a Collaboration Target. Commencing the first Calendar Quarter immediately following initiation of the Phase I Program, within fifteen (15) days after the end of each Calendar Quarter during which either Party incurs any Phase I Development Costs, both Parties shall submit to a finance officer designated by BPM and a finance officer designated by Roche (the "Finance Officers") a report setting forth a good faith estimate of the Phase I Development Costs it incurred in such Calendar Quarter, as detailed in the Phase I Plans, as approved by the JDC. Within fortyfive (45) days following the end of such Calendar Quarter, each Party shall update such report to reflect the final amount of Phase I Development Costs incurred by such Party; provided that if there are any Phase I Development Costs incurred in such Calendar Quarter that a Party is unable to timely include in such financial report, then such amount shall be included and reconciled in the financial report in a future Calendar Quarter. Each such report shall specify in reasonable detail costs incurred and shall include reasonably detailed supporting information. Within fifteen (15) days after receipt of such reports, the Finance Officers shall confer and agree in writing on whether a reconciliation payment is due from one Party to the other Party, and if so, the amount of such reconciliation payment, so that the Parties share Phase I Development Costs in accordance with this Section 12.5. The Party required to pay such reconciliation payment shall make such payment to the other Party within sixty (60) days after the end of each Calendar Quarter; provided, however, that in the event of any disagreement with respect to the calculation of such reconciliation payment, any undisputed portion of such reconciliation payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within ten (10) Business Days after the date on which the Parties, using good faith efforts, resolve the dispute.

# 12.6 Development Cost Share

All Development Costs for each Program will be shared by BPM and Roche as summarized in the following table.

Exercise of Option Right	Development Cost Share	
Program 1, Program 3, and Program 5	100% paid by Roche	
Program 2 and Program 4	[***] (Roche: BPM)	
	[***] (Roche:BPM) [***]	

Notwithstanding the foregoing, Developments Costs after the preparation of the initial regulatory dossier for a Licensed Product for Program 2 and Program 4, costs related to preparing and filing subsequent Filings with respect to such Licensed Product (including associated filing fees, translation expenses, and legal and other professional service fees) will be the responsibility of each Party in its respective Territory with respect to such Licensed Products. After receipt of Regulatory Approval for such Licensed Product in a country, all costs and expenses incurred will be the responsibility of each Party in its respective Territory with respect to such Licensed Product.

For clarity, the allocation of Development Costs set forth in this Section 12.6 will apply regardless of whether Roche has exercised its Option Right for a Collaboration Target.

Commencing the first Calendar Quarter immediately following a Party incurring Development Costs under this Agreement and continuing thereafter so long as a Party incurs Development Costs under this Agreement for which reconciliation will be provided, within fifteen (15) days after the end of each Calendar Quarter during which either Party incurs any Development Costs, each Party shall submit to a finance designee of the other Party a report setting forth a good faith estimate of the Development Costs it incurred in such Calendar Quarter for such Collaboration Target, as detailed in the Development Plan, as approved by the JDC. Within forty-five (45) days following the end of such Calendar Quarter, each Party shall update such report to reflect the final amount of Development Costs incurred by such Party; provided that if there are any Development Costs incurred in such Calendar Quarter that a Party is unable to timely include in such financial report, then such amount shall be included and reconciled in the financial report in a future Calendar Quarter. Each such report shall specify in reasonable detail costs incurred and shall include reasonably detailed supporting information. Within fifteen (15) days after receipt of such reports, the finance designees from both Parties shall confer and agree in writing on whether a reconciliation payment is due from one Party to the other Party, and if so, the amount of such reconciliation payment, so that the Parties share Development Costs in accordance with this Section 12.6. The Party required to pay such reconciliation payment shall make such payment to the other Party within sixty (60) days after the end of each Calendar Quarter; provided, however, that in the event of any disagreement with respect to the calculation of such reconciliation payment, any undisputed portion of such reconciliation payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within ten (10) Business Days after the date on which the Parties, using good faith efforts, resolve the dispute.

### **12.7 Development Event Payments**

For each of Program 1, Program 3, and Program 5, Roche shall pay BPM the following one-time milestone event payments for the first achievement of each of the corresponding milestone events (each, a "**Development Event**") by the first Licensed Product for such Program to achieve such event:

Development Event for First Licensed Product	US Dollars (in millions)
[***]	[***]
[***]	[***]
[***]	[***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total	[***]

Notwithstanding the foregoing, for the purposes of construing the payments specified in the above table, if a Development Event is skipped (i.e., a later Development Event payment is payable before an earlier Development Event payment), or if Regulatory Approval is achieved in any jurisdiction with respect to a Licensed Product for a Collaboration Target without all of the preceding Development Event payments applicable to a Licensed Product having been achieved, then the skipped Development Event(s) will be deemed to have been achieved upon the achievement of the subsequent Development Event(s) or upon Regulatory Approval as applicable. Upon the achievement of a Development Event, Roche shall timely notify BPM and Development Event payments shall be paid by Roche to BPM [...\*\*\*...] from occurrence of the applicable event and receipt of an invoice from BPM. Subject to Section 7.3 and Section 12.9.6, each Development Event Payment will be non-refundable, non-creditable and not subject to set-off with respect to undisputed amounts.

#### 12.8 Sales Based Event

For the first Licensed Product pursuant to each of Program 1, Program 3, and Program 5, Roche shall pay BPM the following onetime milestone event payment for the first achievement of such milestone event by the first Licensed Product for such Program to achieve such event:

Calendar Year Net Sales Threshold	US Dollars (in millions)
Calendar Year Net Sales in the Territory of a Licensed Product	[***]
exceed [***]	

Each sales milestone payment shall be deemed earned upon achievement of the corresponding sales milestone, and Roche shall make the corresponding sales milestone payment within [...\*\*\*...] after the end of the Calendar Year in which the sales milestone threshold was achieved. Subject to Section 7.3, each sales milestone payment will be non-refundable, non-creditable and not subject to set-off with respect to undisputed amounts.

### 12.9 Royalty Payments

### 12.9.1 Royalty Term

Royalties shall be payable by the Selling Party on Net Sales or BPM Net Sales, as applicable, of Licensed Products until the expiry of the Royalty Term. Thereafter, on a Licensed Product-by-Licensed Product and country-by-country basis, the licenses granted shall be fully paid up, irrevocable and royalty-free.

# 12.9.2 Royalty Rates on Licensed Products for the Program 1, Program 3, and Program 5

Roche shall, on a Licensed Product-by-Licensed Product basis for each Licensed Product for Program 1, Program 3 or Program 5, pay to BPM royalties on Calendar Year Net Sales of a given Licensed Product in the Roche Territory as follows:

Portion of Calendar Year Net Sales of a Licensed Product:	Rate:
Up to [***]	[***]
More than [***] and up to [***]	[***]
More than [***] and up to [***]	[***]
More than [***]	[***]

For example, if worldwide Net Sales of a Licensed Product for Program 1 for a given Calendar Year are [...\*\*\*...], then royalties payable to BPM on such Net Sales of such Licensed Product for that Calendar Year shall equal [...\*\*\*...] calculated as follows:

For the purpose of calculating royalties payable on a Licensed Product for Program 1, Program 3 or Program 5, Calendar Year Net Sales and the royalty rates shall be subject to the adjustments under Sections 12.9.4 - 12.9.6 below, as applicable.

# 12.9.3 Royalty Rates on Licensed Products for Program 2 and Program 4

Roche shall, on a Licensed Product-by-Licensed Product basis for each Licensed Product for Program 2 or Program 4, pay to BPM royalties on Calendar Year Net Sales of a given Licensed Product in the Roche Territory as follows:

Portion of Calendar Year Net Sales of a Licensed Product:	Rate:
Up to [***]	[***]
More than [***] and up to [***]	[***]
More than [***] and up to [***]	[***]
More than [***]	[***]

Subject to Section 7.3, BPM shall, on a Licensed Product-by-Licensed Product basis for each Licensed Product for Program 2 and Program 4, pay to Roche royalties on Calendar Year BPM Net Sales of a given Licensed Product in the BPM Territory as follows:

Portion of Calendar Year BPM Net Sales of a Licensed Product:	Rate:
Up to [***]	[***]
More than [***] and up to [***]	[***]
More than [***] and up to [***]	[***]
More than [***]	[***]

For the purpose of calculating royalties of a Licensed Product, Calendar Year Net Sales or BPM Net Sales, as applicable, and the royalty rates shall be subject to the adjustments under Sections 12.9.4 - 12.9.6 below, as applicable.

### 12.9.4 Combination Product

If the Selling Party or its Affiliates intend to sell a Combination Product, then the Parties shall meet approximately one (1) year prior to the anticipated First Commercial Sale of such Combination Product in the Territory to negotiate in good faith and agree to an appropriate adjustment to Net Sales to reflect the relative commercial value contributed by the components of the Combination Product (the "Relative Commercial Value"). If, after such good faith negotiations not to exceed ninety (90) days, the Parties cannot agree to an appropriate adjustment, the dispute shall be initially referred to the executive officers of the Parties in accordance with Section 23.2. Should the Parties fail to agree within sixty (60) days of such referral, then the Relative Commercial Value shall be determined by the Expert Committee under the procedures set forth below.

If the Parties are unable to agree on the Relative Commercial Value, then Roche will select one (1) individual who would qualify as an Expert, BPM will select (1) individual who would qualify as an Expert, and those two (2) individuals shall select one (1) individual who would qualify as an Expert and who shall be chairman of a committee of the three Experts (the "Expert Committee"), each with a single deciding vote. The Expert Committee will promptly hold a meeting to review the issue under review, at which it will consider memoranda submitted by each Party at least fifteen (15) days before the meeting, as well as reasonable presentations that each Party may present at the meeting. The determination of the Expert Committee as to the issue under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide on issues outside the scope mandated under terms of this Agreement. If the Expert Committee is unable to come to a determination within sixty (60) days of such meeting, the matter will be decided pursuant to Section 23.3.

[...\*\*\*...]

# 12.9.5 Royalty Reductions

If royalties on a Licensed Product are payable only on the basis of clause (i) of the Royalty Term definition in Section 1.118 in a country, then the royalties in such country payable on Net Sales or BPM Net Sales, as applicable, for such Licensed Product shall be reduced by [...\*\*\*...]. The royalty rate tier applicable to the Calendar Year Net Sales or BPM Net Sales, as applicable, of such Licensed Product in such country will be applied *pro rata* on a Calendar Quarter-by-Calendar Quarter basis, with reference to the aggregate worldwide Calendar Year Net Sales or BPM Net Sales, as applicable, for each Licensed Product.

Notwithstanding the foregoing, in addition, on a country-by-country basis, upon the first entry in a country of a Generic Product with respect to a Licensed Product, the applicable royalty rate for Calendar Year Net Sales or BPM Net Sales, as applicable, in such country for such Licensed Product shall be reduced as follows:

a) If at any time after entry of a Generic Product in a country there has been a decline of the quarterly Net Sales of the applicable Licensed Product in such country greater than [...\*\*\*...] of the average level of the quarterly Net Sales of such Licensed Product achieved in the [...\*\*\*...] consecutive Calendar Quarters immediately prior to such entry, then the royalty payments due to BPM or Roche, as applicable, for such Licensed Product in such country shall be reduced by [... \*\*\*...] for the remainder of the Royalty Term.

b) If at any time after entry of a Generic Product in a country there has been a decline of the quarterly Net Sales of the applicable Licensed Product in such country greater than [...\*\*\*...] of the average level of the quarterly Net Sales of such Licensed Product achieved in the [...\*\*\*...] consecutive Calendar Quarters immediately prior to such entry, then the royalty payments due to BPM or Roche, as applicable, for such Licensed Product in such country shall be reduced by [... \*\*\*...] for the remainder of the Royalty Term.

# 12.9.6 Third Party Payments

If Roche (or BPM in the US in the case of Program 2 or Program 4) is obligated to remit payments to a Third Party in relation to Third Party issued patents that would allegedly be infringed by the marketing of a Licensed Product, then Roche (or BPM) shall be permitted to offset up to [...\*\*\*...] of any payments paid to such Third Party against any royalty payments and Development Event payments after the first NDA Filing Development Event payment for such Licensed Product otherwise payable by Roche to BPM (or by BPM to Roche in the case of Program 2 or Program 4) for such Licensed Product in the applicable Calendar Quarter. Roche's ability to make such deductions to Development Event payments pursuant to Section 12.7 shall be limited to [...\*\*\*...] of any individual Development Event payment after the first NDA Filing Development Event payment for such Licensed Product. For clarity, amounts paid by Roche to BPM (or by BPM to Roche in the case of Program 2 or Program 4) for such Licensed Product with respect to any Calendar Quarter will not be reduced as a result of this Section 12.9.6 below [...\*\*\*...] of the amount that would otherwise have been payable hereunder. [...\*\*\*...] owed by Roche to BPM (or by BPM to Roche in the case of Program 2 or Program 4) for such Licensed Product. For any payments made by Roche (or BPM) to Third Parties in relation to Third Party issued patents that are (i) used by Roche (or BPM) for both Licensed Products and other products (including Roche Clinical Compounds or Roche Marketed Products) or applications, the Parties will agree on an equitable apportionment of such payments to reflect the fair value attributable to the Licensed Products under this Section 12.9.6 as compared to other products (including Roche Clinical Compounds or Roche Marketed Products) or applications, so that Roche's or BPM's right [... \*\*\*...] under this Section 12.9.6 is limited to fair value attributable to the Licensed Products only. If the Parties are unable to agree on an equitable apportionment of such payments, then either Party may refer such dispute to Expedited Arbitration.

### 12.9.7 Maximum Deductions

Notwithstanding anything foregoing, in no event shall the royalty paid for Net Sales of Licensed Products hereunder be reduced by more than an amount equal to [...\*\*\*...] of the royalties otherwise due for Net Sales of such Licensed Products, per the applicable royalty rates set forth above.

## 12.9.8 Apportionment of Compulsory Sublicensee Consideration

Compulsory Sublicense Compensation received by the Selling Party from a Compulsory Sublicensee shall be shared with the Non-Selling Party on an equivalent profit share percentage (the "Compulsory Profit Share Percentage") calculated for the respective Calendar Year as follows:

[...\*\*\*...]

At the end of the Calendar Year, the Selling Party shall pay to the Non-Selling Party the Compulsory Sublicense Compensation under a given country or region of the Territory multiplied

by the Compulsory Profit Share Percentage. For clarity, any sales or payments by Compulsory Sublicensees under a Compulsory Sublicense shall not be considered as Net Sales or BPM Net Sales, as applicable, and shall not give rise to any royalty payment under Section 12.9.2 of this Agreement.

### 12.10 Disclosure of Payments

Each Party acknowledges that the other Party may be obligated to disclose this financial arrangement, including all fees, payments and transfers of value, as may be advisable or required under Applicable Law, including the US Sunshine Act.

### 12.11 Only One Royalty

Only one royalty will be due with respect to the sale of the same unit of Licensed Product. Only one royalty will be due hereunder on the sale of a Licensed Product even if the manufacture, use, sale, offer for sale or importation of such Licensed Product infringes more than one Composition of Matter Claim.

## 13. Accounting and reporting

### 13.1 Timing of Payments

The Selling Party shall calculate royalties on Net Sales or BPM Net Sales, as applicable, quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of an "**Accounting Period**") and shall pay royalties on Net Sales or BPM Net Sales, as applicable, [...\*\*\*...] after the end of each Accounting Period in which such Net Sales or BPM Net Sales, as applicable, occur. Subject to Section 7.3 and Section 12.9.6, all payments of royalties are non-refundable, non-creditable and not subject to set-off with respect to undisputed amounts.

### 13.2 Late Payment

Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at [...\*\*\*...], as reported by Reuters from time to time, calculated on the number of days such payment is overdue.

#### 13.3 Method of Payment

Royalties on Net Sales and all other amounts payable hereunder shall be paid in US Dollars (the "**Payment Currency**") to account(s) designated by the Party to which payments are to be made.

#### 13.4 Currency Conversion

When calculating the Sales of any Licensed Product that occur in currencies other than the Payment Currency, Roche shall convert the amount of such sales into Swiss Francs and then into the Payment Currency using Roche's then-current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements (at the Effective Date, YTD average rate as reported by Reuters).

# 13.5 Reporting

Within ten (10) days after the end of a Calendar Quarter for which royalties are payable to a Party under Section 12.9, the paying Party shall deliver to the other Party in writing for the relevant Calendar Quarter, on a Licensed Product-by-Licensed Product basis, an estimate of the Sales, in the case of Roche, or BPM gross sales for Licensed Products, in the case of BPM.

With each payment Roche shall provide BPM in writing for the relevant Calendar Quarter on a Licensed Product-by-Licensed Product basis the following information:

(a) Sales in Swiss Francs;

- (b) Net Sales in Swiss Francs;
- (c) adjustments made pursuant to Section 12.9.4;
- (d) Net Sales in Swiss Francs after adjustments made pursuant to Section 12.9.3 in Swiss Francs;
- (e) exchange rate used for the conversion of Net Sales from Swiss Francs to the Payment Currency pursuant to Section 13.4;
- (f) Net Sales after adjustments made pursuant to Section 12.9.4 in the Payment Currency;
- (g) royalty rate pursuant to Section 12.9.2;
- (h) adjustments made pursuant to Sections 12.9.5 and 12.9.6 (subject to the cap in Section 12.9.7);
- (i) total royalty payable in the Payment Currency after adjustments made pursuant to Sections 12.9.5 and 12.9.6 (subject to the cap in Section 12.9.7); and
- (j) calculation and each Party's amount of the Compulsory Profit Share Percentage.

With each payment BPM shall provide Roche in writing for the relevant Calendar Quarter on a Licensed Product-by-Licensed Product basis the following information with regard to Program 2 and Program 4:

- (a) BPM Sales in US dollars;
- (b) BPM Net Sales in US dollars;
- (c) Adjustments made pursuant to Section 12.9.4;
- (d) BPM Net Sales in US dollars after adjustments made pursuant to Section 12.9.4 in the US dollars;
- (e) royalty rate pursuant to Section 12.9.2;
- (f) adjustments made pursuant to Sections 12.9.5 and 12.9.6 (subject to the cap in Section 12.9.7);
- (g) total royalty payable in US dollars after adjustments made pursuant to Sections 12.9.5 and 12.9.6 (subject to the cap in Section 12.9.7); and
- (h) calculation and each Party's amount of the Compulsory Profit Share Percentage.

### 14. Taxes

The Non-Selling Party shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to the Non-Selling Party under this Agreement.

Roche may withhold from payments due to BPM amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. Roche will provide BPM all relevant documents and correspondence, and will also provide to BPM any other cooperation or assistance on a reasonable basis as may be necessary to enable BPM to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Roche will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include Roche making payments from a single source in the US, where necessary and possible.

BPM may withhold from payments due to Roche amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. BPM will provide Roche all relevant documents and correspondence, and will also provide to Roche any other cooperation or assistance on a reasonable basis as may be necessary to enable Roche to claim exemption from such withholding taxes and to receive a refund of such withholding

tax or claim a foreign tax credit. BPM will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include BPM making payments from a single source in the US, where necessary and possible.

Apart from any such permitted withholding and those deductions expressly included in the definitions of Net Sales or BPM Net Sales, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies.

### 15. Auditing

### 15.1 Right to Audit

The Selling Party shall keep, and shall require its Affiliates and Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all royalties payable under this Agreement. Each Party shall keep, and shall require its Affiliates and Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all Phase I Development Costs and Development Costs payable under this Agreement. Such books of accounts shall be kept at their principal place of business. At the expense of the auditing Party, the auditing Party shall have the right to engage an internationally recognized independent public accountant reasonably acceptable to the audited Party to perform, on behalf of the auditing Party, an audit of such books and records of the audited Party and its Affiliates that are deemed necessary by the independent public accountant to report on Net Sales of Licensed Product, Phase I Development Costs and/or Development Costs for the period or periods requested by the auditing Party and the correctness of any financial report or payments made under this Agreement.

Upon timely request and at least sixty (60) working days' prior written notice from the auditing Party, such audit shall be conducted in the countries specifically requested by the auditing Party, during regular business hours in such a manner as to not unnecessarily interfere with the audited Party's normal business activities. Such audit shall be limited to results in the three (3) Calendar Years prior to audit notification. Accordingly, if the auditing Party does not request an audit of a given Calendar Year for a given country on or before the third (3<sup>rd</sup>) anniversary of the end of such Calendar Year, then the audited Party will be deemed to have accepted the payments and reports for such country in such Calendar Year.

Such audit shall not be performed more frequently than once per Calendar Year nor more frequently than once with respect to records covering any specific period of time.

All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying royalty statements, shall be treated as the audited Party's Confidential Information subject to the obligations of this Agreement and need neither be retained more than one (1) year after completion of an audit hereof, if an audit has been requested; nor more than two (2) years from the end of the Calendar Year to which each shall pertain; nor more than one (1) year after the date of termination of this Agreement.

### 15.2 Audit Reports

The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The auditors shall share all draft audit reports with the audited Party before the draft report is shared with the auditing Party and before the final document is issued. The final audit report shall be shared with the audited Party at the same time it is shared with the auditing Party.

### 15.3 Over- or Underpayment

If the audit reveals an overpayment, the auditing Party shall reimburse the audited Party for the amount of the overpayment within thirty (30) days. If the audit reveals an underpayment, the audited Party shall make up such underpayment with the next payment or, if no further payments are owed by the audited Party, then the audited Party shall reimburse the auditing Party for the amount of the underpayment within thirty (30) days. The auditing Party shall pay for the audit costs if the underpayment of the audited Party exceeds [...\*\*\*...] of the aggregate amount of payments owed with regard to the statements subject to the audit. Section 13.2 shall apply to this Section 15.3.

# 16. Intellectual Property

# 16.1 Ownership of Inventions

The following terms and conditions shall apply to the ownership of Inventions unless provided for otherwise in this Agreement:

Each Party shall remain owner of its Patent Rights and Know-How.

BPM shall solely own Inventions solely related to any improvements to the BPM Technology and all Patent Rights and Know-How relating thereto (which will be treated as BPM Technology).

Prior to exercise of an Option Right for each Collaboration Target by Roche, all Collaboration Compounds and all Other Compounds for a given Collaboration Target or other Targets, including their methods of manufacture [...\*\*\*...] and use, and all Patent Rights and Know-How relating thereto (including Collaboration Compound IP) shall be solely owned by BPM (with all of the foregoing that are not "Collaboration Compounds" or "Collaboration Compound IP" referred to herein as "Other Compound IP").

All Patent Rights and Know-How generated under this Agreement to the extent related to biomarkers or bioreagents, including their methods of manufacture and use, (the "**Biomarker IP**") shall be owned jointly by the Parties (with US rules on joint ownership to apply worldwide).

After exercise of an Option Right for each Collaboration Target by Roche, all Patent Rights and Know-How arising from the development or commercialization of Licensed Products, including their methods of manufacture and use, that is generated by (i) either Party individually shall be owned by such generating Party or (ii) both Parties jointly shall be owned jointly by the Parties (with US rules on joint ownership to apply worldwide).

Subsequent to exercise of an Option Right for a given Collaboration Target, the Roche Group shall not generate additional compounds directed to such Collaboration Target under this Agreement.

Subject to the foregoing, all Patent Rights and Know-How generated under this Agreement to the extent related to Collaboration Targets, including their methods of manufacture and use (other than Collaboration Compound IP, BPM Technology, Other Compound IP, Biomarker IP or [...\*\*\*...]), shall be owned jointly by the Parties (with US rules on joint ownership to apply worldwide).

Inventions (including Patent Rights and Know-How) first made during the course of the performance of activities under this Agreement will be determined in accordance with United States patent laws for determining inventorship. BPM and Roche each shall require all of its employees, consultants and contractors to assign all Inventions conceived by them to Roche and/or BPM, to the extent required by this Agreement.

Except as specifically set forth herein, this Agreement shall not be construed, by estoppel, implication or otherwise, as (i) giving any of the Parties any license, right, title, interest in or ownership to any Confidential Information; (ii) granting any license or right under any Patent Rights or Know-How; or (iii) representing any commitment by either Party to enter into any additional agreement. Notwithstanding anything in this Agreement to the contrary, all in-licensed Patent Rights or Know-How Controlled by a Party hereto will be subject to the applicable Third Party agreement.

# 16.2 Patent Rights Owned Jointly

Subject to the licenses granted in this Agreement, all Joint Patent Rights shall be fully exploitable by both Parties without the consent of the other Party and without the need by either Party to account to the other Party for such exploitation. At the reasonable written request of a Party, the other Party will grant such consents in writing and confirm that no such accounting is required to effect the foregoing regarding any such jointly-owned Patent Rights. Subject to in all events to the rest of this Section 16, the Handling and enforcement of any Joint Patent Rights will be jointly managed by the Parties on mutually agreeable terms to be entered into by the Parties at the time any such Joint Patent Rights are first filed, and all recoveries and out-of-pocket costs and expenses arising from those activities, absent further agreement, will be shared equally by the Parties (provided that sufficient advance written notice of any such costs or expenses is given to the Party not incurring same), provided that if either Party elects not to pay any such costs or expenses for any such Patent, the Parties will meet and agree upon an equitable way to treat such Patent. In the event that one Party desires to proceed with any Handling or enforcement of a Joint Patent Right, and the other Party does not, then the Party desiring to proceed may proceed with such action at the proceeding Party's expense, and the proceeding Party may abandon such activities at any time without the consent of the other Party.

# 16.3 German Statute on Employee's Inventions

In accordance with the German Statute on Employees' Inventions, each Party agrees to claim the unlimited use of any Invention conceived, reduced to practice, developed, made or created in the performance of, or as a result of, any research by employees of any German Affiliates or any other persons acting on behalf of such German Affiliates. For the avoidance of doubt, each Party is responsible for fulfilling the obligations towards their employees under the German Statute of Employee's Inventions.

# 16.4 Trademarks and Labeling

Roche shall own the global trademarks, logos, slogans and service marks used on or in connection with Licensed Products ("Global Trademarks") worldwide, and shall, at its sole cost, be responsible for selection, procurement, maintenance, and defense of all trademarks used on or in connection with Licensed Products worldwide. For Program 2 and Program 4, BPM shall have the right to provide input for the Global Trademarks which Roche shall reasonably consider and BPM shall either use the Global Trademarks or may use other trademarks or logos of its own choosing and at its own expense on or in connection with Licensed Products in the BPM Territory. Roche shall have the first right to enforce the Global Trademarks in the Roche Territory. For Program 2 and Program 4, BPM shall have the first right to enforce the Global Trademarks in the BPM Territory. If BPM does not timely enforce the Global Trademarks in the BPM Territory, then

Roche shall have the right to enforce the Global Trademarks in the BPM Territory. Prior to commercialization of any Licensed Product in the BPM Territory bearing a Global Trademark, the Parties will enter into a trademark license agreement setting forth customary terms and conditions for using the Global Trademarks and ensuring quality and good will associated with the Global Trademarks. Notwithstanding the foregoing, BPM shall not be obligated to use such Global Trademarks and may instead select and use its own trademarks, logos, slogans and service marks on or in connection with Licensed Products for Program 2 and Program 4 in the BPM Territory (the "BPM Trademarks"). If BPM elects to use BPM Trademarks, BPM shall, at its sole cost, be responsible for selection, procurement, maintenance, and defense of all such BPM Trademarks used on or in connection with Licensed Products.

Roche shall have the right to obtain the International Non-proprietary Name (INN) from the World Health Organization and the US Adopted Name (USAN) from the US adopted Names Council (USANC) as the generic name(s) for the Licensed Products worldwide. The Parties shall consult with each other regarding the INN and USAN prior to Roche obtaining the INN and USAN, and Roche shall in good faith consider BPM's input.

In the case of Program 2 and Program 4, if BPM elects to use the Global Trademark, Roche shall grant BPM an exclusive, royalty-free license to use the Global Trademarks for the purpose of Exploiting the Licensed Products in the BPM Territory as permitted by this Agreement. Such trademark license shall be non-transferable, except that the BPM shall have the right to sublicense such rights to its Affiliates and Sublicensees in the BPM Territory.

Roche shall maintain all registrations of such Global Trademarks worldwide, and BPM shall not file any identical or similar registrations or other filings in respect of any of such Global Trademarks without Roche's prior written consent. BPM shall maintain all registrations of such BPM Trademarks, and Roche shall not file any identical registrations or other filings in respect of any of such BPM Trademarks without BPM's prior written consent.

Each Party shall use the Global Trademarks in accordance with sound trademark and trade name usage principles and in accordance with all Applicable Law as reasonably necessary to maintain the validity and enforceability of the Global Trademarks. BPM recognizes that Roche's Global Trademarks represent a valuable asset of Roche, and that substantial recognition and goodwill are associated with such name, logo and trademarks. BPM hereby agrees that, without prior written authorization of Roche, it shall not use such Global Trademarks for any purpose except as expressly permitted under this Agreement. Roche recognizes that BPM Trademarks represent a valuable asset of BPM, and that substantial recognition and goodwill are associated with such name, logo and trademarks. Roche hereby agrees that, without prior written authorization of BPM, it shall not use such BPM Trademarks for any purpose except as expressly permitted under this Agreement.

### 16.5 Prosecution by BPM

(a) Subject to the remainder of this Section 16.5, BPM shall [...\*\*\*...] (i) Handle all BPM Patent Rights and Patent Rights within Collaboration Compound IP, (ii) consult with Roche as to the Handling of such Patent Rights to the extent that, on a Collaboration Target-by-Collaboration Target, any such BPM Patent Rights Covers the chemical structure of any Collaboration Compound (collectively, for such Collaboration Target, "BPM Specific Patent Rights"), and (iii) furnish to Roche copies of all documents relevant to any such Handling for such BPM Specific Patent Rights. BPM shall furnish such documents and consult with Roche in sufficient time before any action by BPM is due to allow Roche to provide comments thereon, which comments BPM must consider but BPM shall retain

final decision-making authority with respect to such Handling. At BPM's reasonable request, Roche shall cooperate, in all reasonable ways with the Handling of all such Patent Rights. BPM agrees to file patent applications in all countries consistent with BPM's customary practices for its other internal programs. To the extent that Roche wishes for filings in additional countries, Roche shall provide BPM a list of such countries and BPM agrees to file patent applications in such additional countries [... \*\*\*...].

(b) Subject to Section 16.10, after exercise of an Option Right for each Collaboration Target, (i) Roche shall Handle, either directly or using the mutually agreed outside counsel previously utilized by BPM [...\*\*\*...] all Patent Rights within Collaboration Compound IP to the extent Covering a Licensed Product in the Field for the applicable Program 1, Program 3 and Program 5, (ii) Roche shall Handle in the Roche Territory, either directly or using the mutually agreed outside counsel used by BPM [...\*\*\*...] all Patent Rights within Collaboration Compound IP to the extent Covering a Licensed Product in the Field for a given Collaboration Target for the applicable Program 2 and 4, and (iii) BPM shall Handle in the BPM Territory, using mutually agreed upon outside counsel in consultation with Roche [...\*\*\*...] all Patent Rights within Collaboration Compound IP to the extent Covering a Licensed Product in the Field for a given Collaboration Target for the applicable Program 2 and 4. The controlling Party under this Section 16.5(b) shall [...\*\*\*...] (1) consult with the other Party as to the Handling of such Patent Rights, and (2) furnish to the other Party copies of all documents relevant to any such Handling for such Patent Rights. The controlling Party shall furnish such documents and consult with the other Party in sufficient time before any action by such controlling Party is due to allow such other Party to provide comments thereon, which comments such controlling Party must consider but the controlling Party shall retain final decision-making authority with respect to such Handling. At such controlling Party's reasonable request, the other Party shall cooperate, in all reasonable ways with the Handling of all such Patent Rights. Notwithstanding the foregoing in this Section 16.5(b), before abandoning any such Patent Rights (including electing not to file any continuation Patent Rights upon issuance of any Patent Rights), the applicable Controlling Party shall notify the other Party in advance of such abandonment to allow such other Party to elect to Handle such Patent Rights [...\*\*\*...].

### 16.6 Prosecution of Other Patent Rights

Roche shall [...\*\*\*...] Handle all Roche Patent Rights and Patent Rights within Roche Sole IP other than Joint Patent Rights (which Joint Patent Rights will be Handled under Section 16.5 if applicable or otherwise under Section 16.2). Subject to Section 16.5, BPM shall [...\*\*\*...] Handle all Patent Rights within BPM Sole IP other than Joint Patent Rights (which Joint Patent Rights will be Handled under Section 16.5 if applicable or otherwise under Section 16.2).

#### 16.7 Patent Coordination Team

Where the Parties need to consult with each other on the Handling of Patent Rights, the Parties shall establish a patent coordination team and shall adopt procedures for interacting on patent matters. The patent coordination team shall be subject to the oversight of the JDC. The patent coordination team also shall serve as a forum for promptly notifying the other Party when an Invention is made by a Party.

# 16.8 Unified Patent Court (Europe)

At any time prior to the end of the "transitional period" as such term is used in Article 83 of the Agreement on a Unified Patent Court between the participating Member States of the European Union, for a given relevant EU Patent Right, Roche may request in writing that BPM either (i) opt out from the exclusive competence of the Unified Patent Court or (ii) if applicable, withdraw a

previously-registered opt-out, and BPM shall notify the Registry, pay any such registry fee and take such other action as may be necessary to effect the opt-out or opt-out withdrawal ("**Register**"). BPM shall Register within five (5) days of receipt of Roche's written request, or such other time parameters specified by Roche.

### 16.9 CREATE Act

It is the intention of the Parties that this Agreement is a "joint research agreement" as that phrase is defined in the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the "CREATE Act"). Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the CREATE Act when exercising its rights under this Agreement, but with respect to any Patent Rights with the BPM IP or Collaboration Compound IP, only with the prior written consent of BPM in its sole discretion, and with respect to any Patent Rights within the Roche IP, only with the prior written consent of Roche in its sole discretion. In the event that a Party intends to invoke the CREATE Act, once agreed to by the other Party if required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof.

# 16.10 Infringement

Each Party shall promptly provide written notice to the other Party during the Agreement Term of any (i) known infringement or suspected infringement by a Third Party of any BPM IP, Patent Rights within Collaboration Compound IP, Roche Patent Rights or Joint Patent Rights, or (ii) known or suspected unauthorized use or misappropriation by a Third Party of any BPM Know-How, Roche Know-How or Joint Know-How, in each case if and to the extent involving any commercialization of any Licensed Product (or other compounds that satisfy the Compound Criteria) for the applicable Collaboration Target in the Field, and shall provide the other Party with all evidence in its possession and Control supporting such infringement or unauthorized use or misappropriation.

Within ten (10) Business Days after a Party provides or receives such written notice ("**Decision Period**"), such Party in its Territory (i.e., Roche in the Roche Territory and BPM in the BPM Territory), in its sole discretion, shall decide whether or not to initiate a suit or action in the Territory regarding such infringement or unauthorized use or misappropriation and shall notify the other Party in writing of its decision in writing ("**Suit Notice**").

If Roche decides to bring a suit or take action in the Roche Territory with respect to such infringement or unauthorized use or misappropriation, once the applicable Suit Notice is provided, Roche may immediately commence such suit or take such action in the Roche Territory. In the event that Roche (i) does not in writing advise BPM within the Decision Period that Roche will commence suit or take action, or (ii) fails to commence suit or take action within a reasonable time after providing Suit Notice, BPM shall thereafter have the right to commence suit or take action in the Roche Territory and shall provide written notice to Roche of any such suit commenced or action taken by BPM. If BPM decides to bring a suit or take action in the BPM Territory with respect to such infringement or unauthorized use or misappropriation, once the applicable Suit Notice is provided, BPM may immediately commence such suit or take such action in the BPM Territory. In the event that BPM (i) does not in writing advise Roche within the Decision Period that BPM will commence suit or take action, or (ii) fails to commence suit or take action within a reasonable time after providing Suit Notice, Roche shall thereafter have the right to commence suit or take action in the BPM Territory and shall provide written notice to BPM of any such suit commenced or action taken by Roche.

Upon written request, the Party bringing suit or taking action ("**Initiating Party**") shall keep the other Party informed of the status of any such suit or action and shall provide the other Party with copies, to the extent the Initiating Party is lawfully permitted to do so, of all substantive documents or communications filed in such suit or action. The Initiating Party shall have the sole and exclusive right to select counsel for any such suit or action, and any actions that otherwise would have been Handled with respect to any Patent Rights subject to this Section 16 will be controlled by the Initiating Party to the extent reasonably related to such suit or action.

The Initiating Party shall, except as provided below, pay all expenses of the suit or action, including the Initiating Party's attorneys' fees and court costs. Any damages, settlement fees or other consideration received as a result of such suit or action shall be allocated as follows:

- (a) First, to reimburse the Initiating Party for its costs and, if any remains, to the other Party for any advisory counsel fees and costs; and
- (b) Second, the balance, if any, (1) to the extent a lost profits award, shall be treated as Net Sales and subject to royalty obligations under this Agreement, and (2) to the extent a royalty or other type of award, will be paid [...\*\*\*...].

If the Initiating Party believes it is reasonably necessary or desirable to obtain an effective remedy, upon written request the other Party agrees to be joined as a party to the suit or action but shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to the suit or action. At the Initiating Party's written request, the other Party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance. The other Party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.

The Initiating Party may settle, consent judgment or otherwise voluntarily dispose of the suit or action ("Settlement") without the written consent of the other Party but only if such Settlement can be achieved without adversely affecting the other Party (including any of its Patent Rights). If a Settlement could adversely affect the other Party, then the written consent of the other Party would be required, which consent shall not be unreasonably withheld, conditioned or delayed.

#### 16.11 Defense

If an action for infringement of Patent Rights or trade secrets misappropriation is commenced against either Party, its licensees or its sublicensees related to the conduct of the activities within the scope of the Research Plan, or the development, manufacture, use or sale of a Product in the Roche Territory, then Roche shall have the right (but not the obligation) to defend such action at its own expense, and BPM shall assist and cooperate with Roche, at Roche's expense, to the extent necessary in the defense of such suit. Roche shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion, so long as such settlement or adverse judgment does not adversely affect the rights of the BPM Group (including any Patent Rights owned or inlicensed by any of them). Roche shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement entered into by it with such Third Party. If an action for infringement of Patent Rights or trade secrets misappropriation is commenced against either Party, its licensees or its sublicensees related to the development, manufacture, use or sale of a Product in the BPM Territory, then BPM shall have the right (but not the obligation) to defend such action at its own expense, and Roche shall assist and cooperate with BPM, at BPM's expense, to the extent necessary in the defense of such suit. BPM shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion, so long

as such settlement or adverse judgment does not adversely affect the rights of the Roche Group (including any Patent Rights owned or in-licensed by any of them). BPM shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement entered into by it with such Third Party.

The Parties shall cooperate with each other in connection with any such claim, suit or proceeding and shall keep each other reasonably informed of all material developments in connection with any such claim, suit or proceeding.

Notwithstanding the above, neither Party shall enter into any settlement of any such claim under this Section 16.11 without the prior written consent of the other Party if such settlement would require such other Party to be subject to an injunction or to make any monetary payment to such Party or any Third Party, or admit any wrongful conduct by such other Party or its Affiliates, or would limit or restrict the claims of or admit any invalidity and/or unenforceability of any of the Patent Rights owned or inlicensed by such other Party, or have any impact on activities outside the Field.

### 16.12 Common Interest Disclosures

With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property and/or technology owned by Third Parties, the Parties agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the activities under the Research Plans or Library Compounds, Other Compounds, Collaboration Compounds, Products or Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the conduct of the activities under the Research Plans or Library Compounds, Other Compounds, Collaboration Compounds, Products or Licensed Products. Accordingly, the Parties agree that all such information and materials obtained by BPM and Roche from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of this Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Party.

#### 16.13 Hatch-Waxman

Notwithstanding anything herein to the contrary, should a Party receive a certification for a Licensed Product pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, known as the Hatch-Waxman Act), as amended, or its equivalent in a country other than the US, with respect to any activities under this Agreement in the Field, then such Party shall immediately provide the other Party with a copy of such certification. For each Licensed Product, Roche in the Roche Territory, and BPM in the BPM Territory, shall have thirty (30) days from date on which it receives or provides a copy of such certification to provide written notice to the other Party ("H-W Suit Notice") whether such first Party will bring suit, at its expense, within a forty-five (45) day period from the date of such certification. Should such thirty (30) day period expire without such first Party bringing suit or providing such H-W Suit Notice, then such other Party shall be free to immediately bring suit in its name.

#### **16.14 Patent Term Extensions**

With respect to Patent Rights within the Collaboration Compound IP with application in the Field, the Parties shall use Commercially Reasonable Efforts to obtain all available patent term extensions, adjustments or restorations, or supplementary protection certificates ("SPCs", and together with patent term extensions, adjustments and restorations, "Patent Term Extensions", in each case for such Patent Rights within Collaboration Compound IP with Field applicability). For Licensed Products with application in the Field in the Roche Territory, BPM shall execute such authorizations and other documents and take such other actions as may be reasonably requested by Roche to obtain such Patent Term Extensions, including designating Roche as its agent for such purpose as provided in 35 USC § 156. BPM shall retain those rights for Licensed Products in the BPM Territory. All filings for such Patent Term Extensions shall be made by Roche for Licensed Products in the Roche Territory and by BPM for Licensed Products in the BPM Territory; provided, that in the event that the lead Party elects not to file for a Patent Term Extension, the lead Party shall (a) promptly inform the other Party of its intention not to file and (b) grant BPM the right to file for such Patent Term Extension. Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining patent term restorations, extensions and/or SPCs wherever applicable to such Patent Rights within Collaboration Compound IP.

# 17. Representations and Warranties

### 17.1 Third Party Patent Rights

[...\*\*\*...] represents and warrants, as of the Effective Date, that it has no knowledge of the existence of any patent or patent application owned by or licensed to any Third Party that could prevent the activities contemplated by this Agreement in the Territory.

### 17.2 Ownership of Patent Rights

[...\*\*\*...]represents and warrants, as of the Effective Date, that it is the exclusive owner of all right, title and interest in, or is the exclusive licensee of, the [...\*\*\*...].

#### 17.3 Inventors

[...\*\*\*...]represents and warrants, as of the Effective Date, that (a) it has obtained the assignment of, or an exclusive license under, all interest and all rights or licenses thereunder with respect to the [...\*\*\*...] necessary to grant the licenses granted hereunder and (b) all of its employees, officers and consultants have executed agreements requiring assignment to it of all Inventions made by such individuals during the course of and as a result of their association with it.

#### 17.4 Grants

To its knowledge and belief, each of BPM and Roche represents and warrants, as of the Effective Date, that it has the lawful right to grant Roche or BPM, respectively, and each of their Affiliates the rights and licenses described in this Agreement.

#### 17.5 Authorization

Each of BPM and Roche represents and warrants, as of the Effective Date, that its execution, delivery and performance of this Agreement and all instruments and documents to be delivered by it hereunder: (i) are within its corporate power and authority; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision any of its formation or governance documents; (iv) to its knowledge, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which it is a party

or by which it or any of its property is bound, which violation would have an adverse effect on its financial condition or on its ability to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other Person, which has not been made or obtained previously.

### 17.6 Validity of Patent Rights

[...\*\*\*...] represents and warrants, as of the Effective Date, that it is not in possession of information that could render invalid and/or unenforceable any claims that are in any of the [...\*\*\*...]. [...\*\*\*...] has no knowledge of any inventorship disputes concerning any [...\*\*\*...].

### 17.7 Ownership and Validity of Know-How

[...\*\*\*...] represents and warrants, as of the Effective Date, that its Know-How is legitimately in its possession and, to its knowledge, has not been misappropriated from any Third Party. [...\*\*\*...] has taken reasonable measures to protect the confidentiality of its Know-How.

# 17.8 No Claims

Each of BPM and Roche represents and warrants, as of the Effective Date, that there are no claims or investigations, pending or threatened against it or any of its Affiliates, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially adversely affect its ability to perform its obligations hereunder.

### 17.9 No Conflict

To its knowledge, each of BPM and Roche represents and warrants, as of the Effective Date that neither it nor any of its Affiliates is or will be under any obligation to any person, contractual or otherwise, that is conflicting with the terms of this Agreement or that would impede the fulfillment of BPM's obligations hereunder.

### 17.10 No Other Representations

EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS.

### 18. Indemnification

# 18.1 Indemnification by Roche

Roche shall indemnify, hold harmless and defend BPM and its directors, officers, employees and agents from and against any and all Third Party liabilities, losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts BPM becomes legally obligated to pay because of breach of contract by Roche or any claim or claims against it to the extent that such claim or claims arise out of Roche's and its Affiliates' actions or inactions in connection with activities under this Agreement, including the Exploitation of any Library Compounds, Other Compounds, Collaboration Compounds, Products or Licensed Products, except to the extent such liabilities, losses, expenses, costs and amounts are due to the breach of this Agreement by BPM or the gross negligence or willful misconduct or failure to act of BPM.

### 18.2 Indemnification by BPM

BPM shall indemnify, hold harmless and defend Roche and its directors, officers, employees and agents from and against any and all Third Party liabilities, losses, expenses, cost of defense

(including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Roche becomes legally obligated to pay because of breach of contract by BPM or any claim or claims against it to the extent that such claim or claims arise out of BPM's and BPM's Affiliates' actions or inactions in connection with activities under this Agreement, including the Exploitation of any Library Compounds, Other Compounds, Collaboration Compounds, Products or Licensed Products, except to the extent such liabilities, losses, expenses, costs and amounts are due to the breach of this Agreement by Roche or the gross negligence or willful misconduct or failure to act of Roche.

### 18.3 Procedure

In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("Indemnified Party"), the Indemnified Party shall promptly notify the other Party ("Indemnifying Party") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

### 19. Liability

## 19.1 Limitation of Liability

Subject to Section 19.2, neither Party shall be liable to the other Party as a result of failure or delay to develop and/or commercialize any Collaboration Compound, Product or Licensed Product, as applicable, including but not limited to, (a) a delay in timelines, (b) delay or failure to recruit patients, (c) a change in its respective study protocols, or (d) failure of the other Party to obtain Regulatory Approval for any Collaboration Compound, Product or Licensed Product, as applicable.

#### 19.2 Disclaimer

THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY SET FORTH HEREIN. BPM AND ROCHE DISCLAIM ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, WITH RESPECT TO EACH OF THEIR RESEARCH, DEVELOPMENT AND COMMERCIALIZATION EFFORTS HEREUNDER, INCLUDING, WITHOUT LIMITATION, WHETHER THE PRODUCTS CAN BE SUCCESSFULLY DEVELOPED OR MARKETED, THE ACCURACY, PERFORMANCE, UTILITY, RELIABILITY, TECHNOLOGICAL OR COMMERCIAL VALUE, COMPREHENSIVENESS, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WHATSOEVER OF THE PRODUCTS. EXCEPT FOR INDEMNIFICATION UNDER ARTICLE 18 AND BREACH OF NON-DISCLOSURE AND NON-USE UNDER ARTICLE 20, IN NO EVENT SHALL EITHER BPM OR ROCHE BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY.

## 20. Obligation Not to Disclose Confidential Information

### 20.1 Non-Use and Non-Disclosure

Subject to the remainder of this Section 20, during the Agreement Term and for five (5) years thereafter, a Receiving Party shall (i) treat Confidential Information provided by Disclosing Party as it would treat its own information of a similar nature, (ii) take all reasonable precautions not to

disclose such Confidential Information to Third Parties, without the Disclosing Party's prior written consent, and (iii) not use such Confidential Information other than for fulfilling its obligations or exploit its licenses and other rights under this Agreement.

#### 20.2 Permitted Disclosure

Notwithstanding the obligation of non-use and non-disclosure set forth in Section 20.1, the Parties recognize the need for certain exceptions to this obligation, specifically set forth below, with respect to press releases, patent rights, publications, and certain commercial considerations.

#### 20.3 Press Releases

The Parties may, individually or jointly, issue a press release announcing the existence and selected key terms of this Agreement, in a form substantially similar to the template attached as Appendix 20.3.

Roche shall issue press releases in accordance with its internal policy that typically does not issue a second press release until Phase I proof of concept has been achieved for a Product and Roche has exercised its Option Right with respect to the Collaboration Target. Roche shall provide BPM with a copy of any draft press release related to the activities contemplated by this Agreement at least two (2) weeks prior to its intended publication for BPM's review. BPM may provide Roche with suggested modification to the draft press release. Roche shall consider BPM's suggestions in issuing its press release.

BPM shall only issue press releases related to the activities contemplated by this Agreement that have either (i) been approved by Roche or (ii) are required to be issued by BPM as a matter of law and BPM has received a competent legal opinion to that effect. In all circumstances, BPM shall provide Roche with a draft press release at least two (2) weeks prior to its intended publication for Roche's review, unless a shorter time period is required as a matter of law and BPM has received a competent legal opinion to that effect. During such period, Roche shall (a) approve the draft press release and permit BPM to issue the press release, (b) contact BPM to discuss modification to the draft press release, or (c) contact BPM and disapprove the press release. If Roche asks for modification, then BPM shall either make such modification or work with Roche to arrive at a press release that Roche approves. Notwithstanding any of the foregoing, BPM may issue a press release upon the achievement of any milestone event (including the amount and payment of such milestone payment for any such milestone event) without obtaining the consent of Roche announcing the achievement of such event.

To ensure communication alignment, responses (if any) to inquiries by media or other Third Parties after issuance of a permitted press release by BPM (solely or jointly with Roche) shall consist solely of the press release language or shall follow the response guidelines that may be mutually developed by the Parties except to the extent additional or varying disclosure is required by a Regulatory Authority, including the United States Securities and Exchange Commission (or foreign equivalent) to comply with either Party's disclosure obligations as a public company.

### 20.4 Publications

During the Agreement Term, the following restrictions shall apply with respect to disclosure by any Party of Confidential Information in any publication or presentation:

Both Parties acknowledge that it is their policy for the studies and results thereof to be registered and published in accordance with their internal guidelines. Roche, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries that are maintained by or on behalf of Roche. BPM shall not publish

any studies, clinical trials or results thereof on its clinical trial registry, provided however, that Roche's clinical trial registry can be accessed via a link from BPM's clinical trial registry.

A Party ("**Publishing Party**") shall provide the other Party with a copy of any proposed material publication or presentation at least thirty (30) days (or sixty (60) days in the case of a manuscript) prior to submission for publication so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and if such other Party notifies ("**Publishing Notice**") the Publishing Party in writing, within such thirty (30) day period (or sixty (60) day period in the case of a manuscript) after receipt of the copy of the proposed publication, presentation, or manuscript, that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived and/or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection or (ii) could be expected to have a material adverse effect on the commercial value of any Confidential Information disclosed by the other Party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than ninety (90) days from the date of the Publishing Notice.

#### 20.5 Commercial Considerations

Nothing in this Agreement shall prevent a Receiving Party or its Affiliates from disclosing Confidential Information of the Disclosing Party and the existence and terms of this Agreement to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or commercialization of a Product or Licensed Product in the Territory or to obtain patents in accordance with this Agreement; provided that such Confidential Information will be disclosed only to the extent reasonably necessary to do so, and where permitted, subject to confidential treatment, (ii) Third Parties acting on behalf of the Receiving Party, to the extent reasonably necessary for the Receiving Party to perform its obligations or exercise its rights under this Agreement, (iii) Third Parties requesting Clinical Study data information (in accordance with the Receiving Party's then-current data sharing policy), (iv) Third Parties to the extent reasonably necessary to market the Licensed Products in the Territory, (v) its Affiliates, consultants, CROs, licensees or Sublicensees, and its and their directors, officers, employees, agents or advisors (including accountants, attorneys, consultants, bankers, financial advisors and members of advisory boards) who reasonably require Confidential Information, are informed of the confidential nature of such information and are bound by non-use and confidentiality obligations with respect to such Confidential Information, and (vi) any bona fide potential or actual sources of debt or equity financing or parties to a merger, acquisition or similar transaction (including attorneys, accountants, consultants, bankers or financial advisors of the foregoing) who reasonably require such Confidential Information as part of their due diligence investigations and who are informed of the confidential nature of such information and this Agreement and are bound by obligations of non-use and confidentiality with respect to such Confidential Information. The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Law, including the rules and regulations of the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a securities exchange on which its or its Affiliate's securities are listed (or to which an application for listing has been submitted), to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party, such Confidential Information is disclosed only to the extent reasonably necessary to do so and,

to the extent practicable, takes reasonable and lawful actions to minimize the degree of such disclosure.

The Parties acknowledge that either or both Parties may be obligated to make a filing (including to file a copy of this Agreement) with the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority. Each Party will be entitled to make such a required filing, provided that it will (a) submit in connection with such filing the redacted copy of this Agreement in a form mutually agreed to by the Parties (the "Redacted Agreement"), (b) request, and use commercially reasonable efforts consistent with Applicable Laws to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in the Redacted Agreement, for a period of at least ten (10) years, (c) promptly deliver to the other Party any written correspondence received by it or its representatives from the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority with respect to such confidential treatment request and promptly advise the other Party of any other material communications between it or its representatives with the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority with respect to such confidential treatment request, (d) upon the written request of the other Party, if legally justifiable, request an appropriate extension of the term of the confidential treatment period, and (e) if the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority requests any changes to the redactions set forth in the Redacted Agreement, use commercially reasonable efforts consistent with Applicable Laws to support the redactions in the Redacted Agreement as originally filed and not agree to any changes to the Redacted Agreement without, to the extent practical, first discussing such changes with the other Party and taking the other Party's comments into consideration when deciding whether to agree to such changes (provided that a Party will only be required to make such efforts to support such redactions once). Each Party will be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

#### 21. Term and Termination

#### 21.1 Commencement and Term

This Agreement shall commence upon the Effective Date and continue for the Agreement Term.

#### 21.2 Termination

#### 21.2.1 Termination for Breach

A Party ("Non-Breaching Party") shall have the right to terminate this Agreement in its entirety or on a Collaboration Target-by-Collaboration Target or Program-by-Program basis, in the event the other Party ("Breaching Party") is (i) in material breach of any of its material obligations under this Agreement with respect to Program 1, Program 3, or Program 5, or (ii) in material breach of any of its material obligations under this Agreement in a manner that fundamentally frustrates the transactions contemplated by this Agreement with respect to Program 2 or Program 4, in either (i) or (ii) to this Agreement or such Collaboration Target or Program (as applicable). The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach and the Collaboration Target(s) or Program(s) for which, the Non-Breaching Party intends to have this Agreement terminate. The Breaching Party shall have a period of ninety (90) days after such written notice is provided ("Peremptory Notice Period") to cure such breach. If the alleged Breaching Party has a *bona fide* dispute as to whether such breach occurred or has been cured, it will so notify the Non-Breaching Party within the Peremptory Notice Period, and the expiration of the Peremptory Notice Period shall be tolled until such dispute is resolved pursuant to Section 23.2. Upon a determination of breach or failure to cure, the Breaching Party may have

the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in its entirety or with respect to such Collaboration Target(s) or Program(s) effective as of the expiration of the Peremptory Notice Period.

#### 21.2.2 Insolvency

A Party shall have the right to terminate this Agreement if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

### 21.2.3 Effects of Change of Control

If there is a Change of Control, then the Party experiencing such Change of Control ("Acquired Party") shall provide written notice to the other Party ("Non-Acquired Party") at least thirty (30) days prior to completion of such Change of Control, subject to any confidentiality obligations of the Acquired Party then in effect (but in any event shall notify the Non-Acquired Party within fifteen (15) days after completion of such Change of Control).

The Change of Control Group in connection with such Change of Control shall not utilize any of the Non-Acquired Party's solely owned (with respect to the Acquired Party) Know-How or Patent Rights licensed to the Acquired Party under this Agreement, or Inventions or Confidential Information (but not Joint Know-How, Joint Patent Rights or Joint Inventions) (such solely-owned items, collectively, "Sensitive Information"), except as otherwise permitted by the Agreement.

Following closing of the Change of Control, the Acquired Party and the Change of Control Group shall adopt in writing reasonable procedures to prevent the disclosure of Sensitive Information beyond the Acquired Party's and the Change of Control Group's personnel who need to know the Sensitive Information solely for the purpose of fulfilling the Acquired Party's obligations, and exercising the Acquired Party's licenses and other rights, under this Agreement.

In addition, in the event that (a) BPM is acquired through a Change of Control by a [...\*\*\*...] (based on [...\*\*\*...]) within [... \*\*\*...] after the Effective Date and (b) within [...\*\*\*...] after such Change of Control, BPM experiences a significant delay with respect to key deliverables included in the Research Plan for either [...\*\*\*...] or [...\*\*\*...] in effect as of the Change of Control and is unable to make up such delay to the anticipated Research Plan for [...\*\*\*...] and/or [...\*\*\*...] as applicable in the following [...\*\*\*...], then, in lieu of exercising Roche's right to terminate this Agreement in accordance with Section 21.2.1, for any Collaboration Compounds that the JRC has determined have satisfied [...\*\*\*...] for Collaboration Targets [...\*\*\*...] or [... \*\*\*...] or [... \*\*\*...] and assume the medicinal chemistry efforts previously performed by BPM for such Collaboration Compounds that the JRC has determined have satisfied [...\*\*\*...] as determined by the JRC. All other activities pursuant to the Research Plan shall be managed by the JRC in accordance with Section 8.4 and Section 4.1.3. For clarity, the foregoing rights (i) shall not apply to any Library Compounds or Other Compounds that have not satisfied Lead Series Identified Criteria for Collaboration Targets [... \*\*\*...] or [...\*\*\*...] or [...\*\*\*...] (as applicable), or any other Collaboration Targets, and (ii) shall terminate in full [...\*\*\*...] after the Effective Date.

#### 21.2.4 Termination by Roche without Cause

Prior to exercise of its first Option Right, Roche shall have the right to terminate this Agreement as a whole or on a Collaboration Target-by-Collaboration Target basis, upon one hundred twenty (120) days prior written notice. Following the exercise of its first Option Right, Roche shall have the right to terminate this Agreement at any time as a whole, on a Collaboration Target-by-Collaboration Target basis, on a Program-by-Program basis, or, after First Commercial Sale, upon a country-by-country basis, upon (a) prior to First Commercial Sale of the first Licensed Product for such Collaboration Target or Program, one hundred twenty (120) days prior written notice or (b) after the First Commercial Sale of the first Licensed Product for such Collaboration Target or Program, one hundred eighty (180) days prior written notice. The effective date of termination under this Section 21.2.4 shall be the date one hundred twenty (120) days (or one hundred eighty (180) days as the case may be) after Roche provides such written notice to BPM.

#### 21.2.5 Termination by BPM for Roche Suspension of Development

On a Program-by-Program basis, if (i) after the exercise of Roche's Option Right with respect to a Collaboration Target for such Program, the Roche Group is no longer proceeding with the development of a Licensed Product for a period of [...\*\*\*...], and (ii) such discontinuation was not due to events outside of the reasonable control of the Roche Group (including actions taken by Regulatory Authorities, any Third Party litigation relating to the safety of a Licensed Product), then BPM will have the right, in its sole discretion, to terminate this Agreement with respect to such Program upon sixty (60) days written notice to Roche. In the event that the Roche Group does not proceed with development of the applicable Program as a result of events outside its reasonable control, the [...\*\*\*...] period or portion thereof shall be extended on a day for day basis during the period of time such events continue to exist.

#### 21.3 Consequences of Termination

# 21.3.1 Termination by BPM for Breach by Roche, Roche Insolvency, by Roche Without Cause, or by BPM for Roche Suspension of Development or Commercialization

Upon any termination by BPM for breach by Roche pursuant to Section 21.2.1 or 21.2.5 or for an Insolvency Event of Roche pursuant to Section 21.2.2 or by Roche without cause pursuant to Section 21.2.4, on the effective date of termination (a) the rights and licenses granted by BPM to Roche under this Agreement shall terminate in their entirety or on a Collaboration Target-by-Collaboration Target basis or Program-by-Program basis or on a country-by-country basis, as applicable, (b) except as set forth in this Section 21.3.1, the rights and obligations of the Parties hereunder will terminate with respect to the Collaboration Target, Program, or country and any applicable Collaboration Target shall become a "**Terminated Target**," and (c) Roche will execute all documents and take all such further actions as may be reasonably requested by BPM in order to give effect to the foregoing clauses.

If BPM desires to continue to Exploit Licensed Product(s) (or any derivatives, improvements, modifications or enhancements against the applicable Target, thereof) (collectively, the "**Reversion Products**") in the Field after such termination, BPM shall give a Continuation Election Notice to Roche within ninety (90) days of the effective date of termination. If Roche receives such a timely Continuation Election Notice, and to the extent reasonably requested by BPM:

(a) As promptly as practicable after the effective date of termination, Roche shall, to the extent Roche has the right to do so under Applicable Law, assign and transfer to BPM or BPM's designee possession and ownership of all governmental or regulatory filings, regulatory materials, pricing approvals and Regulatory Approvals, all copies of material correspondence and conversation logs relating to the Exploitation of the Reversion Products, all final pre-clinical and clinical study reports and clinical study protocols, Global

Trademarks, and all data, including non-clinical and clinical data and other material sales and marketing related information in Roche's possession and control related to Reversion Product(s) or the corresponding Collaboration Target(s) to the extent necessary or reasonably useful for BPM to continue to Exploit the Reversion Product(s) in the Field. All data and other information shall be transferred in the form and format in which it is maintained by Roche. Original paper copies shall only be transferred, if required by Applicable Law. Roche shall not be required to prepare or finalize any new data, reports or information solely for purposes of transfer to BPM.

- (b) Roche shall appoint BPM as Roche's or Roche's Affiliates' (and to the extent permitted by the applicable sublicense, its Sublicensees') agent for all Reversion Product-related matters involving Regulatory Authorities in the Roche Territory until all Regulatory Approvals, regulatory materials, pricing approvals and other governmental or regulatory filings required to be assigned to BPM hereunder have, in fact, been assigned to BPM or its designee, but in no event longer than the one (1) year anniversary of the effective date of termination. In the event of failure to obtain assignment of any of the items required to be assigned under this Section 21.3.1, Roche hereby consents and grants to BPM or its designee the right to access and reference (without any further action required on the part of Roche, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to all Reversion Products.
- (c) If the effective date of termination is after First Commercial Sale of a Reversion Product, then, to the extent permitted by Applicable Law, Roche or its Affiliates (or to the extent permitted by the applicable sublicense, its Sublicensees) will appoint BPM or its designee as its exclusive distributor of such Reversion Products in the Roche Territory and grant BPM or its designee the right to appoint sub-distributors, until such time as all Regulatory Approvals in the Roche Territory have been transferred to BPM or its designee, but in no event longer than the one (1) year anniversary of the effective date of termination.
- (d) Roche shall assign and transfer all Clinical Study agreements, to the extent such agreements have not been cancelled and are assignable without Roche paying any material consideration or commencing litigation in order to effect an assignment of any such agreement.
- (e) BPM shall, upon transfer from Roche pursuant to this Section 21.3.1, have the right to disclose such filings, approvals and data to (i) governmental agencies of the country to the extent required or desirable to secure government approval for the development, manufacturing or sale of Reversion Product(s) in the country, (ii) Third Parties acting on behalf of BPM, its Affiliates or licensees, to the extent reasonably necessary for the Exploitation of Reversion Product(s) in the country, and (iii) Third Parties to the extent reasonably necessary to Exploit Reversion Product(s) in the country.
- (f) Roche shall grant (without any further action required on the part of BPM) to BPM (a) an exclusive (even as to Roche), perpetual, irrevocable (except as set forth below), license, with the right to grant sublicenses through multiple tiers, under the Roche Patent Rights and Roche Know-How, including Roche's interest in the Joint Patent Rights and Joint Know-How, solely to the extent necessary to allow BPM, its Affiliates or licensees to Exploit the Reversion Product(s) in the Field in the terminated country(ies), and (b) a non-exclusive, worldwide, perpetual, irrevocable (except as set forth below) license, with the right to grant sublicenses through multiple tiers, under the Roche Patent Rights and Roche Know-How, including Roche's interest in the Joint Patent Rights and Joint Know-How,

solely to the extent necessary to allow BPM, its Affiliates or licensees to research, have researched, develop, have developed, use, have used, make, have made, import, have imported, export and have exported (including all research, development and manufacturing activities) Reversion Product(s) in the Field anywhere in the world in order to market, have marketed, distribute, have distributed, sell, have sold and offer for sale and have offered for sale (including all commercialization activities) such Reversion Product(s) in the Field in the terminated country(ies) (collectively, the "Reversion License"). Royalties would be payable by BPM to Roche on worldwide BPM Net Sales depending upon the stage of development of the applicable Reversion Product at the time of termination as set forth in the following table:

Stage of Development of the	Royalty payable on portion of	Royalty payable on portion of
applicable Reversion Product on the	BPM Net Sales up to and	BPM Net Sales greater than [
effective date of termination	including [***]	***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Payments would be made by BPM to Roche in a manner analogous to that set forth in Section 12.9.1 and 12.9.3 (provided that BPM shall have no obligation to pay royalties to Roche for Net Sales of Reversion Products for Program 2 or Program 4 in the BPM Territory), including adjustments in a manner analogous to those set forth in Sections 12.9.4 - 12.9.6 and 12.9.8. Notwithstanding anything to the contrary in this Section 21.3.1(f), Roche will have the right to terminate the licenses granted to BPM in this Section 21.3.1(f) with respect to a Reversion Product in full upon one hundred and twenty (120) days' prior written notice to BPM in the event of any material breach by BPM of its payment obligations under this Section 21.3.1(f). Notwithstanding the foregoing, any such termination under this Section 21.3.1(f) will not be effective if such breach has been cured within one hundred and twenty (120) days after written notice thereof is given by Roche to BPM specifying the nature of the alleged breach.

For clarity, the Parties acknowledge and agree that with respect to any the Roche Patent Rights or Roche Know-How that is inlicensed by the Roche Group, BPM will be responsible for any payments due to a Third Party with respect thereto and BPM's rights will be subject to the terms of the applicable Third Party agreement. At BPM's written request, the Parties will enter into commercially reasonable prosecution and enforcement and defense terms for the Roche Patent Rights or Roche Know-How with respect to the Reversion Products, and BPM will bear the costs of such prosecution, enforcement and defense activities to the extent related to such Reversion Products.

- (g) Roche will promptly transfer and assign to BPM all of Roche's and its Affiliates' rights, title and interests in and to Roche's Global Trademark(s) solely used to identify the Reversion Products (but not any house marks, or logos or any trademark of Roche or its Affiliates, containing the word "Roche" or any such Affiliate) owned by Roche and used for the Reversion Products in the Field.
- (h) If BPM so requests, and to the extent permitted under Roche's obligations to Third Parties on the effective date of termination, Roche will transfer to BPM any Third Party agreements relating solely to the Exploitation of the Reversion Products to which Roche

- is a party, subject to any required consents of such Third Party, which Roche will use Commercially Reasonable Efforts to obtain promptly.
- (i) Roche will execute all documents and take all such further actions as may be reasonably requested by BPM in order to give effect to the foregoing clauses.

#### 21.3.2 Termination by Roche for Breach by BPM or BPM Insolvency

Upon material breach by BPM or BPM's Insolvency, Roche shall have the right to terminate this Agreement in accordance with Section 21.2.1 or Section 21.2.2, as applicable.

If Roche exercises its aforementioned right to terminate, then, on the effective date of termination, (a) all rights and licenses granted to either Party under this Agreement with respect to such Collaboration Target(s) or Program(s) with terminate; (b) except as set forth in this Section 21.3.2, the rights and obligations of the Parties hereunder shall terminate with respect to such Terminated Target(s) as of the effective date of such termination; and (c) BPM will execute all documents and take all such further actions as may be reasonably requested by Roche in order to give effect to the foregoing clauses.

In the event of a material breach of this Agreement by BPM with respect to Program 2 or Program 4 (as applicable), then, following the expiration of all applicable notice and cure periods, and, if any dispute is initiated under Section 23.3.1 before the expiration of the applicable cure period with respect to the basis for the asserted basis of such termination, the confirmation by the arbitrators of the facts claimed by Roche to be the basis for termination under Section 21.2.1, Roche may elect, at its sole option, upon written notice to BPM that, in lieu of exercising its right to terminate this Agreement pursuant to Section 21.2.1 for Program 2 or Program 4 (as applicable), the licenses and other rights granted by BPM to Roche under this Agreement with respect to such Program remain in effect in accordance with their respective terms; provided, however, that (a) the Roche Territory for such Program shall mean all countries of the world, and Roche will be deemed granted all rights and obligations relating thereto, (b) Roche shall have the right to offset the full amount of any losses incurred by Roche as a result of such material breach by BPM with respect to such Program from any future payments relating to such Program due and payable to BPM under this Agreement, and (c) the Development Cost Share for such Program shall be 100% paid by Roche.

#### 21.3.3 Sublicenses

Irrespective of anything to the contrary in this Agreement, any existing, sublicense granted by Roche to Third Parties under Section 2.1.2 or Section 2.1.3 of this Agreement (and any further sublicenses thereunder) shall, upon the written request of Roche, remain in full force and effect, provided that (i) such Third Party Sublicensee is not then in breach of its sublicensee agreement (and, in the case of termination by BPM for breach by Roche, that such Third Party Sublicensee and any further sublicensees did not cause the breach that gave rise to the termination by BPM); and (ii) and such Third Party Sublicensee agrees to be bound to BPM under the terms and conditions of such sublicensee agreement.

#### 21.3.4 Other Obligations

## 21.3.4.1 Obligations Related to Ongoing Activities

If BPM does not provide a timely Continuation Election Notice, then each Party (a) shall have the right to cancel all ongoing obligations and (b) shall complete all non-cancellable obligations.

If BPM provides such timely Continuation Election Notice, then from the date of notice of termination until the effective date of termination, Roche shall continue all activities contemplated by this Agreement, including preparatory activities, ongoing as of the date of notice of termination. However, Roche shall not be obliged to initiate any new activities not ongoing at the date of notice of termination.

After the effective date of termination, neither Roche nor BPM shall have an obligation to perform and/or complete any activities except as expressly stated herein.

Notwithstanding the foregoing, in case of termination by BPM under Section 21.2.1, Section 21.2.2 or Section 21.2.5 or by Roche under Section 21.2.4, upon the request of BPM, Roche shall complete any Clinical Studies related to the Licensed Product(s) that are being conducted under its IND(s) for the Licensed Product(s) and are ongoing as of the effective date of termination; provided, however, that

- (i) both BPM and Roche in their reasonable judgment have concluded that completing any such Clinical Studies does not present an unreasonable risk to patient safety; and
- (ii) Roche shall have no obligation to recruit or enroll any additional patients after the date of termination;
- (iii) Roche shall transfer all Clinical Studies to BPM as soon as practicable, and
- (iv) BPM agrees to reimburse Roche for all of its Development Costs that arise after the effective date of termination in completing such Clinical Studies.

In the event that BPM does not elect to have Roche complete any Clinical Studies related to the Licensed Product(s) that are being conducted under Roche's IND(s) for the Licensed Product(s) and are ongoing as of the effective date of termination, then Roche will wind down such ongoing Clinical Studies, subject to the Parties' sharing any remaining Phase I Development Costs or Development Costs for such Clinical Studies.

## 21.3.4.2 Obligations Related to Manufacturing

### a) Clinical Supplies

In the case of termination by BPM according to Section 21.2.1, Section 21.2.2 or Section 21.2.5 or by Roche under Section 21.2.4, if BPM elects to develop the Reversion Products, Roche shall transfer all existing and available clinical material to BPM at [...\*\*\*...] and upon the request of BPM. After such transfer is effectuated, (i) Roche shall have no obligation to perform any additional activities concerning the clinical supplies (*e.g.*, retesting, analyses) and (ii) BPM shall assume all liability for the use of such material. At BPM's request, immediately after notice of termination, Roche will cooperate to accelerate the transfer of the technology necessary to manufacture the clinical material to BPM or its designee as soon as practicable, and Roche will leverage its relationships with CROs to enable BPM to assume responsibility for manufacturing.

#### b) Commercial Supplies

In the case of termination by BPM according to Section 21.2.1 or Section 21.2.2 or by Roche under Section 21.2.4, if a Reversion Product is marketed in any country of Territory on the date of the notice of termination of this Agreement, upon the request of BPM, Roche shall manufacture and supply such Reversion Product to BPM for a period that shall not exceed [... \*\*\*\*...] from the effective date of the termination of this Agreement at [...\*\*\*...]. BPM shall use Commercially Reasonable Efforts to take over the manufacturing as soon as reasonably possible after the effective date of termination.

#### 21.3.4.3 Ancillary Agreements

Unless otherwise agreed by the Parties, the termination of this Agreement shall cause the automatic termination of all ancillary agreements related hereto, including but not limited to the Manufacturing and Supply Agreement(s), if any, and the Pharmacovigilance Agreement.

#### 21.3.4.4 Limitations on Grant-Backs; Transfer Expenses

For purposes of clarity, irrespective of anything to the contrary in this Agreement:

- (a) All assignments, transfers and licenses from Roche to BPM or other obligations of Roche under Section 21.3 are solely with respect to Reversion Product(s) that are not Combination Product(s) or Companion Diagnostic(s). Such transfers, licenses and obligations do not extend to other therapeutically active ingredients or products, even if physically mixed, combined or packaged together with a Reversion Product, and even if a Reversion Product is intended (according to the investigation plan, proposed labeling or actual labeling, as applicable) for use with such other therapeutically active ingredients or products.
- (b) In connection with research studies or Clinical Studies, Roche may have collected human samples and related clinical information for additional limited research and development programs ("Samples"). Legal and contractual restrictions may apply to such Samples, in particular as Samples may qualify as personal identifiable information. BPM acknowledges and accepts that notwithstanding anything herein, at the request of BPM and subject to BPM compensating Roche for all costs incurred by Roche in transferring such Samples, Roche shall use Commercially Reasonable Efforts to transfer any such Samples to BPM to the extent permitted under Applicable Law and consistent with Roche's business practices.
- (c) Nothing in this Agreement shall be construed as granting BPM any license under the Excluded Patent Rights.
- (d) Within thirty (30) days after the date of a Continuation Election Notice, BPM shall make a payment to Roche of [...\*\*\*...] as consideration for the transfer activities performed by Roche under Sections 21.3.1 and 21.3.4 ("Roche Transfer Activities"), which amount shall be creditable against any royalties payable by BPM to Roche pursuant to Section 21.3.1(f). Roche shall be under no obligation to provide Roche Transfer Activities prior to receipt of the Minimum Transfer Payment.

#### 21.3.4.5 Royalty and Payment Obligations

Termination of this Agreement by a Party, for any reason, shall not release the other Party from any obligation to pay royalties or make any other payments that are payable prior to the effective date of termination. However, termination of this Agreement by a Party, for any reason, will release a Selling Party from any obligation to pay royalties or make any payments to the Non-Selling Party that would otherwise become payable on or after the effective date of termination.

#### 21.4 Survival

Last sentence of Section 2.1.4 (Licenses), last paragraph of Section 3.1.3 (Option Right), Section 16.1 (Ownership of Inventions), Section 16.2 (Patent Rights Owned Jointly), Section 16.3 (German Statute on Employee's Inventions), Section 16.9 (CREATE Act), Section 16.12 (Common Interest Disclosures), Section 17.10 (No Other Representations), Section 21.3 (Consequences of Termination), and Section 21.4 (Survival); Article 1 (Definitions, but only to the extent necessary to interpret the Agreement), Article 12 (Payment, but only with respect to any payments accrued thereunder prior to expiration or termination), Article 13 (Accounting and

Reporting, but only with respect to any payments accrued thereunder prior to expiration or termination), Article 14 (Taxes), Article 15 (Auditing), Article 18 (Indemnification), Article 19 (Liability), Article 20 (Obligation Not to Disclose Confidential Information), Article 22 (Bankruptcy), and Article 23 (Miscellaneous) shall survive any expiration or termination of this Agreement for any reason. Expiration or termination of this Agreement for any reason will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, with respect to any breach of this Agreement. For the avoidance of doubt, termination of this Agreement will not affect any Pharmacovigilance Agreement, which will continue to survive so long as any Licensed Products thereunder are being commercialized.

#### 22. Bankruptcy

All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement by a Party to the other are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, US Code (the "Bankruptcy Code") licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Unless Roche elects to terminate this Agreement, the Parties agree that the Parties and their respective Sublicensees, as a licensees or sublicensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code (or any foreign counterpart thereto), subject to the continued performance of its obligations under this Agreement.

#### 23. Miscellaneous

## 23.1 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

#### 23.2 Disputes

Unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below or their designees, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For BPM: Chief Executive Officer For Roche: Head of Roche Partnering

#### 23.3 Arbitration

Except as otherwise expressly set forth in this Agreement (including with respect to any matters that are determined by Expedited Arbitration, Expert or Expert Committee), should the Parties fail to agree within two (2) months after such dispute has first arisen, it shall be finally settled by arbitration in accordance with the Rules of American Arbitration Association ("AAA") as in force at the time when initiating the arbitration. The tribunal shall consist of three (3) arbitrators. The place of arbitration shall be New York City, New York, US and the arbitration will be governed by the Laws of the State of New York. The language to be used shall be English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with an English translation.

#### 23.3.1 Arbitrators

Each Party shall nominate one arbitrator who are retired judges or attorneys with at least ten (10) years of relevant experience in the pharmaceutical or biotechnology industry, each of whom will be impartial and independent. Should the claimant fail to appoint an arbitrator in the request for arbitration within thirty (30) days of being requested to do so, or if the respondent should fail to appoint an arbitrator in its answer to the request for arbitration within thirty (30) days of being requested to do so, the other Party shall request the AAA to make such appointment.

The arbitrators nominated by the Parties shall, within thirty (30) days from the appointment of the arbitrator nominated in the answer to the request for arbitration, and after consultation with the Parties, agree and appoint a third arbitrator, who will act as a chairman of the three arbitrator committee (the "**Arbitral Tribunal**"). Should such procedure not result in an appointment within the thirty (30) day time limit, either Party shall be free to request the AAA to appoint the third arbitrator.

Where there is more than one (1) claimant and/or more than one (1) respondent, the multiple claimants or respondents shall jointly appoint one (1) arbitrator.

If any Party-appointed arbitrator or the third arbitrator resigns or ceases to be able to act, a replacement shall be appointed in accordance with the arrangements provided for in this clause.

### 23.3.2 Decisions; Timing of Decisions

The arbitrators shall render a written opinion setting forth findings of fact and conclusions of law with the reason therefor stated, within no later than six (6) months from the date on which the arbitrators were appointed to the dispute. A transcript of the evidence adduced at the arbitration hearing shall be made and, upon request, shall be made available to each Party.

The time periods set forth in the AAA Arbitration Rules shall be followed; provided however that the arbitrators may modify such time periods as reasonably necessary to render a written opinion in accordance with this Section 23.3.2.

The Arbitrator is empowered to award any remedy allowed by law, including money damages, prejudgment interest and attorneys' fees, and to grant final, complete, interim, or interlocutory relief, including injunctive relief.

This arbitration agreement does not preclude either Party seeking conservatory or interim measures from any court of competent jurisdiction including, without limitation, the courts having jurisdiction by reason of either Party's domicile. Conservatory or interim measures sought by either Party in any one or more jurisdictions shall not preclude the Arbitral Tribunal granting conservatory or interim measures. Conservatory or interim measures sought by either Party before the Arbitral Tribunal shall not preclude any court of competent jurisdiction granting conservatory or interim measures.

In the event that any issue shall arise which is not clearly provided for in this Section 23.3, the matter shall be resolved in accordance with the AAA Arbitration Rules.

Any arbitration proceeding hereunder shall be confidential and the arbitrators shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law or in a proceeding to enforce the results of the arbitration, neither

Party shall make (or instruct the arbitrators to make) any public announcement with respect to the proceedings or decision of the arbitrators without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrators, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law.

Notwithstanding anything to the contrary in this Agreement, any and all issues regarding the scope, construction, validity and/or enforceability of any Patent Rights shall be determined in a court of competent jurisdiction under the local patent laws of the jurisdictions having issued the Patent Rights in question.

Notwithstanding anything to the contrary in this Agreement, any and all issues regarding a breach or alleged breach of a Party's obligations under Article 20 (Obligation Not to Disclose Confidential Information) shall be determined in a court of competent jurisdiction under the laws of the State of New York, with express exclusion of its conflict of laws principles.

Fees, costs and expenses of arbitration are to be divided by the Parties in the following manner: BPM will pay for the arbitrator it chooses, Roche will pay for the arbitrator it chooses, and the Parties will share payment for the third arbitrator.

#### 23.3.3 Expedited Arbitration

If a Party exercises its rights under this Agreement to refer a dispute to expedited arbitration (an "**Expedited Dispute**"), then the Parties will follow the expedited dispute resolution process in this Section 23.3.3 (and not the dispute resolution process at the beginning of this Section 23.3 of this Agreement) ("**Expedited Arbitration**"). The Parties agree and acknowledge that any good faith dispute under Expedited Arbitration will not be deemed to be a material breach of this Agreement.

The Expedited Dispute will be submitted to fast-track, binding arbitration in accordance with the following:

- (a) Arbitration will be conducted in New York, New York under the rules of the AAA for the resolution of commercial disputes in the most expedited manner permitted by such rules. The arbitration will be heard and determined by three (3) arbitrators, each of whom will be impartial and independent. Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement regard the selection of such third (3rd) arbitrator within thirty (30) days following appointment of the second arbitrator, the third (3rd) arbitrator will be selected by the AAA. Each arbitrator will be a professional in business or licensing experienced in the valuation of biopharmaceutical products with at least ten (10) years of experience in the pharmaceutical and life sciences industries, including the conduct of research, development and commercialization collaborations. The cost of the arbitration will be borne equally by the Parties. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Laws, neither Roche nor BPM nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written agreement of Roche and BPM.
- (b) Within thirty (30) days after such matter is referred to arbitration, each Party will provide the arbitrators with a proposal and written memorandum in support of its position regarding the Expedited Dispute, as well as any documentary evidence it wishes to provide in support thereof

(each a "Brief") and the arbitrators will provide each Party's Brief to the other Party after it receives it from both Parties.

- (c) Within thirty (30) days after a Party submits its Brief, the other Party will have the right to respond thereto. The response and any material in support thereof will be provided to the arbitrators and the other Party.
- (d) The arbitrators will have the right to meet with the Parties as necessary to inform the arbitrators' determination and to perform independent research and analysis. Within thirty (30) days of the receipt by the arbitrators of both Parties' responses (or expiration of the thirty (30) day period if any Party fails to submit a response), the arbitrators will deliver their decision regarding the Expedited Dispute in writing; provided that the arbitrators will select one of the resolutions proposed by the Parties. Notwithstanding anything herein to the contrary, the Parties shall have the right to terminate such Expedited Arbitration in accordance with Section 2.2 or upon mutual agreement prior to delivery of the arbitrators' decision.

#### 23.4 Assignment

Except as provided in this Section 23.4, neither Party shall have the right to assign or otherwise transfer this Agreement or any part thereof, or its rights or obligations under this Agreement absent the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to any of its Affiliates in whole or to a party that acquires, by or otherwise in the context of a merger, acquisition, sale, reorganization, consolidation, Change of Control or other transaction involving all or substantially all of the assets of the business of the assigning Party to which the subject matter of this Agreement relates. Any permitted assignment shall be binding on the successors of the assigning Party. Any purported assignment in violation of this Section 23.4 will be void and of no force and effect.

#### 23.5 Debarment

Each Party represents and warrants that it has never been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program. In the event a Party receives notice of debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, such Party shall immediately notify the other Party in writing and such other Party shall have the right, but not the obligation, to terminate this Agreement, effective, at such other Party's option, immediately or at a specified future date.

#### 23.6 Independent Contractor

No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship to the other Party under this Agreement shall be that of independent contractor, and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

#### 23.7 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve

as far as possible the economic business intentions of the Parties. However the remaining provisions of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

#### 23.8 Waiver

The failure by either Party to require strict performance and/or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance and/or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition.

### 23.9 Appendices

All Appendices to this Agreement shall form an integral part to this Agreement.

#### 23.10 Entire Understanding

This Agreement, together with the Pharmacovigilance Agreement and any supply agreement entered into the Parties in connection with this Agreement, contains the entire understanding between the Parties hereto with respect to the within subject matter and supersedes any and all prior agreements, understandings and arrangements, whether written or oral, including, effective as of the Effective Date, that Non-Disclosure Agreement between BPM and Roche, effective as of February 9, 2015, as amended by First Amendment, dated May 1, 2015 (provided that all information disclosed or exchanged under such agreement will be treated as Confidential Information hereunder).

#### 23.11 Amendments

No amendments of the terms and conditions of this Agreement, including the Appendices attached hereto, shall be binding upon either Party hereto unless in writing and signed by both Parties.

#### 23.12 Invoices

All invoices that are required or permitted hereunder shall be in writing and sent by BPM to Roche at the following address or such other address as Roche may later provide:

F. Hoffmann-La Roche Ltd Kreditorenbuchhaltung Grenzacherstrasse 124 4070 Basel Switzerland

#### **23.13 Notice**

All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to BPM, to: Blueprint Medicines Corporation

38 Sidney Street, Suite 200

Cambridge, Massachusetts 02139

U.S.A.

Attn: Chief Executive Officer Facsimile No.: + 1 617 374-7588

and: Attn: Legal Department

Facsimile No.: + 1 617 374-7588

if to Roche, to: F. Hoffmann-La Roche Ltd

Grenzacherstrasse 124

4070 Basel Switzerland

Attn: Legal Department

Facsimile No.: +41 61 688 13 96

and: Hoffmann-La Roche Inc.

150 Clove Road

Suite 8

Little Falls, New Jersey 07424

USA

Attn. Corporate Secretary Facsimile No.: +1 973 890-8433

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day of receipt if sent by overnight courier or facsimile; or (c) on the Business Day of receipt if sent by mail.

### 23.14 Counterparts

This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or other electronic signature) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

#### 23.15 Performance by Affiliates

Each Party acknowledges and accepts that the other Party may exercise its rights and perform its obligations (including granting or continuing licenses and other rights) under this Agreement either directly or through one or more of its Affiliates. A Party's Affiliates will have the benefit of all rights (including all licenses and other rights) of such Party under this Agreement, but not be subject to such Party's obligation, unless expressly provided herein, or in the case of a permitted assignment, in accordance with Section 23.4. Accordingly, in this Agreement "Roche" will be interpreted to mean "Roche or its Affiliates" and "BPM" will be interpreted to mean "BPM or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations (including granting or continuing

licenses and other rights) under this Agreement; provided, however, that in any event each Party will remain responsible for the acts and omissions, including financial liabilities, of its Affiliates.

#### 23.16 Force Majeure

Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, earthquakes, floods, or other acts of God. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical, and will promptly undertake all reasonable efforts necessary to cure such force majeure circumstances and resume performance of its obligations hereunder.

### 23.17 Compliance with Export Regulations

Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export Laws and regulations.

### 23.18 Interpretation

Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation" and will not be interpreted to limit the provision to which it relates; (c) the word "shall" will be construed to have the same meaning and effect as the word "will"; (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any Person will be construed to include the Person's successors and assigns; (f) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in each of their entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Articles, Sections, Exhibits or Schedules will be construed to refer to Articles, Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto; (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging); (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the thencurrent amendments thereto or any replacement or successor law, rule or regulation thereof; and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or".

### 23.19 Waiver of Rule of Construction

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

## 23.20 Headings

The captions to the Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Sections hereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

## **Blueprint Medicines Corporation**

/s/ Jeffrey Albers

Name: Jeffrey Albers

Title: Chief Executive Officer

## F. Hoffmann-La Roche Ltd

/s/ Vikas Kabra /s/ Stefan Arnold

Name: Vikas Kabra Name: Stefan Arnold

Title: Head of Transaction Excellence Title: Head Legal Pharma

Hoffmann-La Roche Inc.

/s/ John P. Parise

Name: John P. Parise

Title: Authorized Signatory

## **BPM Patent Rights**

[...\*\*\*...]

## **CCS** Criteria

[...\*\*\*...]

Property	Minimum Acceptable
[***]	[***]
[***]	[***]
[***]	
[***]	[***]
[***]	[***]
[***]	
[***]	[***]

## **CLS Criteria**

Property	Criteria/Purpose
[***]	•
[***]	[**]
[***]	[***]
[***]	
[***]	[***]
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## **Approved CROs**

[...\*\*\*...]

Append	lix 1	.44
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## **Excluded Targets**

[...\*\*\*...]

## **Lead Series Identified Criteria**

Properties	Criteria/Purpose
[***]	-
	[***]
[***]	
[***]	[***]
[***]	[***]
[ *** ]	
[**]	E statute 3
[***]	[***]
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[**]	[***]
[***]	[***]
[***]	[***]
[]	[]

## **Option Data Package**

Categories of information:	
·***]	

### **Excluded Patent Rights**

[...\*\*\*...], which means (a) U.S. Patent No. [...\*\*\*...], issued [...\*\*\*...], and any and all patents issuing from divisionals, continuations, or continuations-in part of any application from which U.S. Patent No. [...\*\*\*...] claims priority, as well as reissues, reexaminations, extensions, and foreign patent counterparts, including inventors certificates, of any of the foregoing, and including any related supplemental protection certificates; and (b) U.S. Patent No. [...\*\*\*...], issued [...\*\*\*...], and any and all patents issuing from divisionals, continuations, or continuations-in-part of any application from which U.S. Patent No. [...\*\*\*...] claims priority, as well as reissues, reexaminations, extensions, and foreign patent counterparts, including inventors certificates, of any of the foregoing, and including any related supplemental protection certificates.

[...\*\*\*...], which means any of the U.S. patents listed below and any and all patents issuing from divisionals, continuations or continuations-in-part, and any reissues, reexaminations or extensions, of these patents or of any application from which these U.S. patents claim priority, as well as foreign counterparts, including inventors certificates, of the foregoing, and including any related supplemental protection certificates:

U.S. Patent No. [...\*\*\*...]

U.S. Patent No. [...\*\*\*...]

[...\*\*\*...], which means any of the U.S. patents/patent application listed below and any and all patents issuing from divisionals, continuations or continuations-in-part, and any reissues, reexaminations or extensions, of these patents or of any application from which these U.S. patents claim priority, as well as foreign counterparts, including inventors certificates, of the foregoing, and including any related supplemental protection certificates:

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U.S. Patent No. [...***...]
U.S. Patent No. [...***...]
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U.S. Patent No. [...\*\*\*...]

[...\*\*\*...], which means the following U.S. patent and any and all divisionals, continuations, continuations-in-part of any application from which these U.S patents claim priority, including reissues, reexaminations or extensions of these patents and foreign counterparts and supplementary protection certificates of the foregoing:

U.S. Patent No. [...\*\*\*...]

## **Roche Senior Management**

Global Head of Therapeutic Modalities	
Global Head of Medicinal Chemistry	
Global Head of Molecular Targeted Therapies in Oncology Discovery	
Global Head of Oncology Discovery (Oncology DTA)	

## Appendix 20.3

## Form of Press Release

[Attached]

# Blueprint Medicines Announces Worldwide Collaboration to Accelerate and Expand its Development of Novel Medicines in the Field of Cancer Immunotherapy

- Collaboration Combines Blueprint Medicines' Proprietary Drug Discovery Platform and Immunokinase Expertise with Roche's Cancer Immunotherapy Expertise
  - Blueprint Medicines to Receive \$45 Million Upfront Payment and is Eligible to Receive Additional Contingent Fees and Milestone Payments—
    - Blueprint Medicines to Host Conference Call Today at 8:00 A.M. ET —

CAMBRIDGE, Mass., March 15, 2016 – Blueprint Medicines Corporation (NASDAQ: BPMC), a leader in discovering and developing highly selective kinase medicines for patients with genomically defined diseases, today announced that it has entered into a worldwide collaboration and exclusive license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche) for the discovery, development and commercialization of up to five small molecule therapeutics targeting kinases believed to be important in cancer immunotherapy.

Under the terms of the agreement, Blueprint Medicines will receive an upfront cash payment of \$45 million and will be eligible to receive up to an additional approximately \$965 million in contingent option fees and milestone payments related to specified research, preclinical, clinical, regulatory and sales-based milestones across all five potential programs. Of the total contingent payments, up to approximately \$215 million are for option fees and milestone payments for research, preclinical and clinical development events prior to licensing across all five potential programs. In addition, the agreement provides for specified royalties and cost sharing, which are described in more detail below.

Immunokinases are intracellular targets known to regulate numerous aspects of immune response and represent an important opportunity for potentially innovative approaches to enhance the immune system's ability to recognize and eradicate tumor cells. To date, cancer immunotherapies have demonstrated important clinical benefits. However, most cancer immunotherapies have focused on antibodies or combinations with existing approved therapies and have not yet targeted immunokinases with small molecules. This collaboration seeks to develop new mechanisms of modulating the tumor immune response by targeting immunokinases with the goal of enhancing response rates and broadening the utility of using cancer immunotherapies to treat additional cancer types.

"We believe Blueprint Medicines' proprietary drug discovery platform and expertise in immunokinases, combined with our proven ability to move quickly through drug discovery, is a perfect complement to Roche's expertise with cancer immunotherapy biology and in developing and commercializing innovative therapies," said Jeff Albers, Chief Executive Officer of Blueprint Medicines. "Under this collaboration, Blueprint Medicines will lead preclinical research and development through Phase 1 proof of concept for all five programs and retain U.S. commercial rights for two programs. We believe this highly collaborative relationship will enable us to accelerate our efforts in the emerging field of cancer immunotherapy and to continue building a leading biotechnology company."

The collaboration provides for the worldwide development and commercialization of immunokinases in the field of cancer immunotherapy for up to five small molecule drug candidates as single products or possibly in combination with Roche's portfolio of therapeutics. Roche's rights are structured as an option, triggered upon achievement of Phase I proof-of-concept, for an exclusive license to each drug candidate developed under the collaboration. Blueprint Medicines will be primarily responsible for preclinical research and conduct of clinical development for each

program prior to any exercise of Roche's option for such program. If Roche exercises an option for a program, Roche will be responsible for subsequent global development for that program through registrational clinical trials. For up to three of the five programs, if Roche exercises its option, Roche will receive worldwide commercialization rights for the licensed product. For up to two of the five programs, if Roche exercises its option, Blueprint Medicines will retain commercialization rights in the United States for the licensed product, and Roche will receive commercialization rights outside of the United States for such licensed product. Blueprint Medicines will also retain worldwide rights to any drug candidates for which Roche elects not to exercise the applicable option.

For any licensed product for which Roche retains worldwide commercialization rights, Blueprint Medicines will be eligible to receive tiered royalties ranging from low double-digits to high-teens on future net sales of the licensed product. For any licensed product for which Blueprint Medicines retains commercialization rights in the United States, Blueprint Medicines and Roche will be eligible to receive tiered royalties ranging from mid-single-digits to low double-digits on future net sales in the other party's respective territories in which it commercializes the licensed product. Blueprint Medicines and Roche will share the costs of Phase 1 development for each collaboration target. In addition, Roche will be responsible for post-Phase 1 development costs for each licensed product for which it retains global commercialization rights, and Blueprint Medicines and Roche will share post-Phase 1 development costs for each licensed product for which Blueprint Medicines retains commercialization rights in the United States.

#### **Conference Call Information**

Blueprint Medicines will host a conference call and live audio webcast for investors at 8:00 A.M. ET today. To participate in the conference call, please dial 877-516-3348 (domestic) or 281-973-6089 (international) and refer to conference ID 63223687. A live webcast of the conference call will be available by visiting the Investors section of Blueprint Medicines' website at <a href="http://ir.blueprintmedicines.com">http://ir.blueprintmedicines.com</a>. The archived webcast will be available on Blueprint Medicines' website approximately 2 hours after the call and will be available for 30 days following the call.

#### **About Blueprint Medicines**

Blueprint Medicines is developing a new generation of highly selective and potent kinase medicines to improve the lives of patients with genomically defined diseases. The Company's approach is rooted in a deep understanding of the genetic blueprint of cancer and other diseases driven by the abnormal activation of kinases. Blueprint Medicines is advancing three programs in clinical development for subsets of patients with gastrointestinal stromal tumors, hepatocellular carcinoma and systemic mastocytosis, as well as multiple programs in research and preclinical development. For more information, please visit <a href="https://www.blueprintmedicines.com">www.blueprintmedicines.com</a>.

#### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the collaboration and license agreement among Blueprint Medicines and Roche, including anticipated payments, as well as the future development, manufacture and commercialization of cancer immunotherapies under the agreement; Blueprint Medicines' and Roche's ability to successfully develop and commercialize cancer immunotherapies; and Blueprint Medicines' strategy and business plans. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential,"

"continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the delay of any current or planned clinical trials or the development of Blueprint Medicines' drug product candidates, including BLU-285 and BLU-554; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the efficacy and safety of its drug product candidates; the preclinical and clinical results for Blueprint Medicines' drug product candidates, which may not support further development of such drug product candidates; and actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (SEC) on March 11, 2016, and other filings that Blueprint Medicines may make with the SEC in the future. Any forward-looking statements contained in this press release represent Blueprint Medicines' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements.

#### **Contact:**

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#### AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This Amendment, effective April 15, 2016 ("**Effective Date**"), is by and between F. Hoffmann-La Roche Ltd, with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland and Hoffmann-La Roche Inc., with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, U.S.A. (together referred to as "**Roche**") and Blueprint Medicines, located at 38 Sidney Street, Cambridge, Massachusetts 02139 ("**Blueprint**").

WHEREAS, Blueprint and Roche entered into a Collaboration and License Agreement dated March 14, 2016 ("Agreement");

NOW THEREFORE, Roche and Blueprint hereby agree as follows:

The 5th paragraph of Section 4.1.5 of the Agreement shall be deleted in its entirety and replaced by the following:

Two chemistry experts at Roche ("Insulated Chemistry Experts") shall be designated in writing by Roche to review structures of Other Compounds and Collaboration Compounds at the start of the collaboration and throughout the Lead Nomination phase. The Insulated Chemistry Experts shall independently handle the structural information and no structures provided by BPM to the Insulated Chemistry Experts can be shared with any other individuals within Roche other than members of senior management specified on Appendix 4.1.5 acting in their decision making capacity. For clarity, these structures cannot be used for any other purpose, including any research purpose. Appropriate safeguards will be established by Roche that are intended to prevent any inadvertent disclosure or improper use of these structures and any structural information related to such structures. From Lead Nomination onwards and throughout Lead Optimization, the structures of Other Compounds and Collaboration Compounds in the Lead Optimization phase shall be shared with the Roche project team members (including Collaboration Compounds meeting Lead Series Identified Criteria, CLS Criteria and CCS Criteria).

All other terms defined in the Agreement are to be interpreted as defined therein, and all other terms of the Agreement are to remain in full force and effect.

This Amendment may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives.

## **Blueprint Medicines Corporation**

/s/ Jeffrey Albers

Name: Jeffrey Albers

Title: Chief Executive Officer and President

## F. Hoffmann-La Roche Ltd

/s/ Stefan Arnold /s/ Barbara Lueckel

Name: Stefan Arnold Name: Dr. Barbara Lueckel

Title: Head Legal Pharma Title: Head of Research & Technologies Partnering

### Hoffmann-La Roche Inc.

/s/ John P. Parise

Name: John P. Parise

Title: Authorized Signatory

#### **CERTIFICATIONS**

I, Jeffrey W. Albers, certify that:

- 1. I have reviewed this report on Form 10-Q/A of Blueprint Medicines Corporation; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: July 22, 2016 By:/s/ Jeffrey W. Albers

By:/s/ Jeffrey W. Albers

Jeffrey W. Albers

President and Chief Executive Officer
(Principal Executive Officer)

#### **CERTIFICATIONS**

- I, Michael Landsittel, certify that:
  - 1. I have reviewed this report on Form 10-Q/A of Blueprint Medicines Corporation; and
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: July 22, 2016 By:/s/ Michael Landsittel

Michael Landsittel
Vice President of Finance
(Principal Financial and Accounting Officer)