# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 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, 2017

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** For the transition period from to

**Commission File Number:** 000-30235

# EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **04-3257395** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |

**210 East Grand Ave.**
**South San Francisco, CA 94080**
**(650) 837-7000**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 ☒ No ☐

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☒ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ (Do not check if a smaller reporting company) | Smaller reporting company | ☐ |
| Emerging growth company | ☐ | | |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 24, 2017, there were 292,512,348 shares of the registrant's common stock outstanding.

**EXPLANATORY NOTE**

Exelixis, Inc. (the "Company") is filing this Amendment No. 1 to its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017 (the "Form 10-Q") as an exhibit-only filing in response to comments received from the Securities and Exchange Commission regarding a request for confidential treatment of certain portions of Exhibit 10.1 originally filed with the Form 10-Q. This Amendment No. 1 to Quarterly Report on Form 10-Q/A (this "Amendment") is being filed solely to re-file Exhibit 10.1. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are filed as exhibits to this Amendment.

Except as described above, this Amendment does not reflect events occurring after the filing of the Form 10-Q and no revisions are being made pursuant to this Amendment to the Company's financial statements or any other disclosure contained in the Form 10-Q.

**SIGNATURES**

Pursuant to the requirements 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.

EXELIXIS, INC.

July 14, 2017
Date

/s/ CHRISTOPHER J. SENNER
**Christopher J. Senner**
Executive Vice President and Chief Financial Officer
*(Duly Authorized Officer and Principal Financial and Accounting Officer)*

## EXHIBIT INDEX TO FORM 10-Q/A

| Exhibit Number | Exhibit Description | Incorporation by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Exhibit/ Appendix Reference | Filing Date | |
| 10.1* | Collaboration and License Agreement dated January 30, 2017, between Exelixis, Inc. and Takeda Pharmaceutical Company Limited | | | | | X |
| 31.1 | Certification required by Rule 13a-14(a) or Rule 15d-14(a). | | | | | X |
| 31.2 | Certification required by Rule 13a-14(a) or Rule 15d-14(a). | | | | | X |

* Confidential treatment requested for certain portions of this exhibit.

**Exhibit 10.1**

# COLLABORATION AND LICENSE AGREEMENT

**This Collaboration and License Agreement** (the "**Agreement**") is entered into as of January 30, 2017 (the "**Effective Date**"), by and between **Exelixis, Inc.**, a Delaware company having an address at 210 East Grand Avenue, South San Francisco, CA 94080, USA ("**Exelixis**") and Takeda Pharmaceutical Company Limited, a Japanese corporation with principal offices located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN ("**Collaborator**"). Exelixis and Collaborator may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

## Recitals

**Whereas**, Exelixis, a biopharmaceutical company, is developing its proprietary compound known as cabozantinib for the treatment of cancer, and owns or controls certain patents, know-how, and other intellectual property relating to such compound;

**Whereas**, Collaborator, a pharmaceutical company, possesses substantial resources and expertise in the development and commercialization of pharmaceutical products;

**Whereas**, Collaborator and Exelixis desire to form a collaboration for the continued development and commercialization of cabozantinib, under which Exelixis will continue to have primary responsibility for the conduct of the global development program for cabozantinib, with Collaborator providing input and support; and Exelixis desires to obtain Collaborator's specific Japanese clinical development expertise in order for Exelixis and Collaborator to collaborate and pursue such development in Japan as the Parties agree;

**Whereas**, Collaborator desires to obtain the exclusive rights to develop and commercialize cabozantinib in Japan and to have primary responsibility for the commercialization of cabozantinib in Japan; and, Exelixis desires to manufacture and supply cabozantinib for Collaborator's development and commercialization activities in Japan;

**Whereas**, the Parties wish to establish such collaboration, all on the terms and conditions set forth below.

## Agreement

**Now, Therefore**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Exelixis and Collaborator hereby agree as follows:

## 1. Definitions

**1.1** "**Affiliate**" means, subject to the final sentence of this paragraph, with respect to any party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such party, but for only so long as such control exists. As used in this Section 1.1, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity. For the avoidance of any doubt, neither [ * ] nor [ * ] shall constitute an Affiliate of Collaborator.

**1.2** "**API**" means cabozantinib, having the chemical structure set forth in **Exhibit 1.2**.

**1.3** "**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state, and local laws, treaties, statutes, rules, regulations, administrative codes, guidance (including cGCP, cGLP and cGMP), ordinances, judgments, decrees, directives, orders, permits (including MAAs) of or from any court, Regulatory Authority, or governmental agency or authority having competent jurisdiction over or related to the subject item.

**1.4** "**Business Day**" means Monday through Friday of each week, except that a legal holiday recognized as such by the federal government of the United States and/or a national holiday in Japan shall not be regarded as a Business Day.

**1.5** "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

**1.6** "**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31.

**1.7** "**Clinical Trial**" or "**Clinical Trials**" means Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, Phase 4 Clinical Trial or Expanded Access Program as the context dictates.

**1.8** "**cGCP**" means the current clinical practice as set out in (i) ICH Harmonized Guidance on current Good Clinical Practice (CPMP/ICH/135/95), (ii) US Code of Federal Regulations, Title 21, Chapters 50, 54, 56, 58, 210, 211 and 312, as may be amended from time to time, or (iii) the equivalent law or regulation in any other applicable jurisdiction in the Collaborator Territory.

**1.9** "**cGLP**" means the current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other comparable regulatory standards in jurisdictions outside the U.S.), as they may be updated from time to time.

**1.10** "**cGMP**" means the current standards for systems to assure the proper design, monitoring, and control of processes and facilities to be used for the manufacture, processing, packing, or holding of a drug as specified by applicable laws of the relevant countries at the time of manufacturing conducted in accordance with this Agreement, defined under (i) 21 C.F.R. Part 210 and 211 or (ii) equivalent law or regulations in the Collaborator Territory.

**1.11** "**Collaborator Know-How**" means all Know-How that Collaborator or its Affiliate Controls as of the Effective Date or during the Term, including any Joint Inventions, that is used in the research, Development, manufacture, use, importation, offer for sale, sale or Commercialization of any Compound or Product in the Field. The Collaborator Know-How includes the Collaborator Data.

**1.12** "**Collaborator Patents**" means all Patents that Collaborator or its Affiliate Controls as of the Effective Date or during the Term (including any Joint Patents) that would be infringed, absent a license or other right to practice granted under such Patents, by the research, Development, manufacture, use, importation, offer for sale, sale or Commercialization of any Compound or Product in the Field (considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Collaborator or its Affiliate).

**1.13** "**Collaborator Technology**" means the Collaborator Know-How and the Collaborator Patents, including Collaborator's interest in the Joint Inventions and Joint Patents.

**1.14** "**Collaborator Territory**" means Japan.

**1.15** "**Commercialization**" means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, sales, marketing, medical support, and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling, and delivering Products to customers) of Products in the Field in or outside of the Collaborator Territory, including sales force efforts, detailing, advertising, market research, market access (including list price and reimbursement activities), medical education and information services, publication, scientific and Medical Affairs; advisory and collaborative activities with opinion leaders and professional societies including symposia, marketing, sales force training, and sales (including receiving, accepting, and filling Product orders) and distribution. "**Commercialize**" and "**Commercializing**" have correlative meanings.

**1.16** "**Commercially Reasonable Efforts**" means, with respect to a Party and its obligations under this Agreement, those commercially reasonable efforts and resources consistent with the usual practices of a similarly situated company for the development and commercialization of a pharmaceutical product originating from its own research and development department, which is at a similar stage of research, development, or commercialization, taking into account that product's profile of efficacy and safety; proprietary position, including patent and regulatory exclusivity; regulatory status, including anticipated or approved labeling and anticipated or approved post-approval requirements; present and future market and commercial potential, including competitive market conditions, and all other relevant factors, including technical, legal, business, scientific, and/or medical factors. Commercially

Reasonable Efforts requires that a Party: (i) promptly assign responsibility for each contractual obligation to specific employee(s) who are held accountable for progress and monitor such progress on an ongoing basis, (ii) set and seek to achieve specific and meaningful objectives for carrying out such obligation, and (iii) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

**1.17** "**Committee**" means the JEC, JDC, JCC or any subcommittee established by the JEC, as applicable.

**1.18** "**Competing Product**" means any product or compound, other than the Compound and Products: (a) for which the mechanism of action includes modulation of the kinase activities of cMET and/or VEGFR2, **and** (b) which directly binds and modulates the activity of: (i) VEGFR2 and/or (ii) cMET, [ * ].

**1.19** "**Competitive Field**" means the diagnosis, treatment, or prevention of cancer indications other than:

**(a)** [ * ]; and

**(b)** [ * ]; provided, however, that (i) if and when [ * ], and [ * ]; and (ii) if [ * ].

**1.20** "**Compound**" means API in a form approved by the applicable Regulatory Authority in a particular jurisdiction for use in connection with the Development or Commercialization of the Product in such jurisdiction.

**1.21** "**Confidentiality Agreement**" means that certain Confidential Disclosure Agreement between Exelixis and Collaborator dated as of [ * ].

**1.22** "**Confidential Information**" means all Know-How and other proprietary scientific, marketing, financial, or commercial information or data that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, or formulae in relation to this Agreement; provided that all Exelixis Technology will be deemed Exelixis' Confidential Information, all Collaborator Technology will be deemed Collaborator's Confidential Information, and all Joint Inventions and Joint Patents will be deemed both Parties' Confidential Information. Confidential Information shall include: (a) the terms and conditions of this Agreement, and (b) Confidential Information disclosed by either Party pursuant to the Confidentiality Agreement.

**1.23** "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents, or other intellectual property rights, the legal authority or right (whether by ownership, license, or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license, or a sublicense of or under such

Know-How, Patents, or other intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

**1.24** "**Cost of Goods**" means the fully burdened cost to manufacture Compound or Drug Product, as applicable, (the "**Supplied Product**") which means: (a) [ * ]; and (b) in the case of [ * ]. Actual unit costs shall consist of [ * ].

**1.25** "**Data**" means any and all scientific, technical, test, marketing, or sales data pertaining to any API, Compound and/or Product that is generated by or on behalf of Exelixis, Collaborator, their respective Affiliates, and, to the extent Controlled by a Party, Exelixis' other licensee(s) and Collaborator's Sublicensees, including research data, clinical pharmacology data, pre-clinical data, CMC data, clinical data, clinical study reports, or submissions made in association with an IND or MAA with respect to any API, Compound and/or Product.

**1.26** "**Development**" means all development activities for the Compound and Product (whether alone or for use together, or in combination, with another active agent or pharmaceutical product as a combination product or combination therapy) that are directed to obtaining Regulatory Approval(s) of the Product and/or lifecycle management of the Product in any country in the world, including all non-clinical, preclinical, and clinical testing and studies of the Product; toxicology, pharmacokinetic, and pharmacological studies; statistical analyses; assay development; protocol design and development; the preparation, filing, and prosecution of any MAA for the Product; development activities directed to label expansion and/or obtaining Regulatory Approval for one or more additional indications following initial Regulatory Approval; development activities conducted after receipt of Regulatory Approval, including Phase 4 Clinical Trials and Expanded Access Program; and all regulatory affairs related to any of the foregoing. "**Develop**" and "**Developing**" have correlative meanings.

**1.27** "**Development Costs**" means the costs incurred by a Party or for its account, during the Term and pursuant to this Agreement, that are specifically directed (or reasonably allocable) to the Development of a Product. The Development Costs shall include amounts that a Party pays to Third Parties involved in the Development of a Product (at cost, and excluding any Third Party Royalties), and all internal costs (calculated on an FTE basis at the then-current FTE Rate) and reasonable out-of-pocket costs incurred by or on account of a Party in performing Development work in accordance with the GDP. Development Costs shall also include [ * ]. For clarity, [ * ].

**1.28** "**Drug Product**" means, for a given Product, packaged and unlabeled product comprising the Compound in its final dosage form for such Product.

**1.29** "**Executive Officers**" the Chief Executive Officer of Exelixis and the Chief Executive Officer of Collaborator (or his/her designated person).

**1.30** "**Exelixis Know-How**" means all Know-How that Exelixis or its Affiliate Controls as of the Effective Date or during the Term, including any Joint Inventions, that is necessary or reasonably useful for the Development, use, importation, offer for sale, or sale of any Compound or Product in the Field in or for the Collaborator Territory. The Exelixis Know-How includes the Exelixis Data.

**1.31** "**Exelixis Patents**" means all Patents in the Collaborator Territory that Exelixis or its Affiliate Controls as of the Effective Date or during the Term (including any Joint Patents) that would be infringed, absent a license or other right to practice granted under such Patents, by the Development, use, importation, offer for sale, sale or Commercialization of any Compound or Product in the Field in the Collaborator Territory (considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Exelixis). The Exelixis Patents existing as of the Effective Date are set forth in **Exhibit 1.31** which shall be periodically, at least annually, updated by Exelixis or its counsel).

**1.32** "**Exelixis Technology**" means the Exelixis Know-How and the Exelixis Patents, including Exelixis' interest in the Joint Inventions and Joint Patents.

**1.33** "**Exelixis Territory**" means worldwide, excluding the Collaborator Territory (i.e., Japan).

**1.34** "**Expanded Access Program**" means the administration of the Product to named individuals who do not meet the clinical trial enrollment criteria either outside of a clinical trial or after the completion of a clinical trial. Expanded Access Programs are also known as named patient programs, named patient supply, and temporary authorization for use (including patient request treatment pursuant to Article 63-2(4) of Japanese Act on Health Insurance).

**1.35** "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

**1.36** "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

**1.37** "**FDA**" means the U.S. Food and Drug Administration or its successor.

**1.38** "**Field**" means all indications and uses in humans and animals, including, but not limited to, RCC and HCC.

**1.39** "**Finished Manufacture**" means the manufacture of Finished Product from Compound or Drug Product, as the case may be.

**1.40** "**Finished Product**" means, with respect to a given Product, (i) the applicable Compound or Drug Product, as the case may be, packaged and labeled for Development or Commercialization purposes, as applicable, in accordance with the applicable Specifications and legal requirements in the Collaborator Territory, or (ii) the Compound or Drug Product, as the case may be, along with its appropriate packaging and labeling in such other configuration as may be agreed upon by the Parties and set forth in the applicable Supply Agreement.

**1.41** "**First Commercial Sale**" means, on a Product-by-Product basis, the first commercial sale by Collaborator or any of its Affiliates or Sublicensees to a Third Party for end use of such Product in the Collaborator Territory after Regulatory Approval has been granted with respect to such Product in the Collaborator Territory.

**1.42** "**FTE**" means the equivalent of a full-time individual's work for a twelve (12) month period (consisting of a total of [ * ] hours per year of dedicated effort). Any person who devotes more or less than [ * ] hours per year on the applicable activities shall be treated as an FTE on a pro-rata basis, based upon the actual number of hours worked by such person on such activities, divided by [ * ]. For the avoidance of any doubt, the hours spent by Exelixis temporary workers and contractors on applicable activities and the hours allocated to the work of general corporate or administrative personnel shall not be incorporated into FTE.

**1.43** "**FTE Rate**" means, with respect to Exelixis' personnel, an initial rate of [ * ] U.S. Dollars ($[ * ]) per FTE per year, which rate shall apply through December 31, 2017. Thereafter, the FTE Rate for Exelixis' personnel shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) in the Consumer Price Index for All Urban Consumers for the U.S., as published by the U.S. Department of Labor, Bureau of Labor Statistics ("**CPI**"). With respect to Collaborator's personnel, "FTE Rate" means a reasonable rate in Japanese yen reasonably determined by Collaborator based on Collaborator's actual, fully-burdened costs for Collaborative Work on a case-by-case basis, provided that Collaborator shall provide Exelixis with supporting documentation for each such determination.

**1.44** "**Generic Product**" means, with respect to a Product, any pharmaceutical product that (a) contains the same API as such Product; and (b) is approved by the Regulatory Authority in such regulatory jurisdiction as a substitutable generic for such Product (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction) on an expedited or abbreviated basis based on bioequivalence or interchangeability with the Product under Article 14-4.1 of Pharmaceuticals and Medical Device Act or equivalent laws or regulations in any other jurisdiction in the Exelixis Territory.

**1.45** "**Governmental Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, or commission entitled to exercise any administrative,

executive, judicial, legislative, police, regulatory, or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

**1.46** "**HCC**" means hepatocellular carcinoma.

**1.47** "**ICH**" means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

**1.48** "**IND**" means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.

**1.49** "**Initiation**" means, with respect to a Clinical Trial, the first dosing of the first human subject in such Clinical Trial.

**1.50** "**Inventions**" means all inventions, whether or not patentable, discovered, made, conceived, or reduced to practice, in the course of activities contemplated by this Agreement.

**1.51** "**Know-How**" means all technical information, know-how, and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical materials, expertise and other technology applicable to, development, registration, use, or marketing or to methods of assaying or testing them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, and analytical, safety, nonclinical, and clinical data, regulatory documents, data and filings, instructions, processes, formulae, expertise and information, relevant to the research, development, use, importation, offering for sale or sale of, or which may be useful in studying, testing, or developing Products in the Field. Know-How excludes Patents and manufacturing know-how of the Compound or Product.

**1.52** "**MAA**" means a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in the Collaborator Territory. For clarity, MAA does not include any application for Pricing and Reimbursement Approval.

**1.53** "**MAA Approval**" means approval of an MAA by the applicable Regulatory Authority for marketing and sale of a Product in the Collaborator Territory, but excluding any Pricing and Reimbursement Approval.

**1.54** "**Medical Affairs**" or "**Medical Affairs Activities**" means activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, the Product, including by way of example: (a) activities of medical scientific liaisons who, among their other functions, may: (i) conduct service-based medical activities including providing input and assistance with consultancy meetings, proposing investigators for clinical

trials sponsored or co-sponsored by a Party or Affiliate, and providing input in the design of such trials and other research related activities; and/or (ii) deliver non-promotional communications and conduct non-promotional activities; (b) grants to support continuing medical education, symposia, or Third Party research related to the Product; (c) development, publication, and dissemination of publications relating to the Products; (d) medical information services provided in response to inquiries communicated via sales representatives or received by letter, phone call, or email; (e) conducting advisory board meetings, international advisory board activities or other consultant programs, including the engagement of key opinion leaders and health care professional in individual or group advisory and consulting arrangements; and (f) conducting company-sponsored studies (CSS) and post-marketing surveillance trials or the evaluation of area of permissible scientific and medical inquiry (including, the evaluation of applications submitted to Collaborator for support of off-label or on-label investigator-initiated trials or studies).

**1.55** "**MHLW**" means Japan's Ministry of Health, Labour and Welfare, or any successor agency thereto.

**1.56** "**Net Sales**" means, with respect to any Product, the gross amounts invoiced for sales or other dispositions of such Product by or on behalf of Collaborator and its Affiliates and Sublicensees to Third Parties in the Collaborator Territory, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise directly paid or incurred by Collaborator or its Affiliates or Sublicensees, as applicable, with respect to the sale or other disposition of such Product:

**(a)** normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of such Product (provided that such discounts are not applied disproportionately to such Product when compared to the other products of Collaborator or its Affiliate or Sublicensee, as applicable);

**(b)** credits or allowances given or made for rejection or return of previously sold Products or for retroactive price reductions and billing errors;

**(c)** rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers;

**(d)** costs of freight, carrier insurance, and other transportation charges directly related to the distribution of such Product; and/or

**(e)** taxes, duties or other governmental charges (including any tax such as a value added or similar tax, other than any taxes based on income, and annual contributions paid pursuant to the Japanese Act on Pharmaceuticals and Medical Devises Agency) directly levied on or measured by the billing amount for such Product, as adjusted for rebates and refunds.

Upon any sale or other disposition of any Product that should be included within Net Sales for any consideration other than exclusively monetary consideration on bona fide arms'-length terms, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price of the relevant Product in arm's-length transactions during the applicable reporting period generally achieved for such Product in the Collaborator Territory when such Product is sold alone and not with other products (average sales price to be measured as the aggregate Product Net Sales divided by the aggregate number of units sold in the Collaborator Territory).

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Product between Collaborator and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of Net Sales.

The supply of Product as samples, for use in non-clinical or clinical trials/studies, or for use in any test or studies reasonably necessary to comply with any applicable laws, rules, or regulations or as is otherwise normal and customary in the industry (including for use in Phase 4 Clinical Trial, Expanded Access Program or any other Medical Affairs Activities) shall not be included in the computation of Net Sales, so long as Collaborator, its Affiliates, and Sublicensees do not receive payment for such Product in excess of the Cost of Goods of such Product.

**1.57** "**Patents**" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings, and patent applications, and (b) any renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, supplementary protection certificates, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

**1.58** "**Phase 1 Clinical Trial**" means a clinical trial in any country conducted in a small number of human volunteers designed or intended to establish an initial safety profile, pharmacodynamics, or pharmacokinetics of a Product. For clarity, a Phase 1 Clinical Trial may include studies conducted in oncology patients.

**1.59** "**Phase 2 Clinical Trial**" means a clinical trial of a Product in human patients in any country to determine initial efficacy and safety and dose range finding. A Phase 2 Clinical Trial is typically conducted before embarking on a Phase 3 Clinical Trial, but may be registrational.

**1.60** "**Phase 3 Clinical Trial**" means a pivotal clinical trial of a Product in human patients in any country with a defined dose or a set of defined doses of a Product designed to ascertain efficacy and safety of such Product for the purpose of submitting a MAA to the competent Regulatory Authorities.

**1.61** "**Phase 4 Clinical Trial**" means a product support clinical trial of a Product that is commenced after receipt of MAA Approval in the country where such trial is conducted. Phase 4 Clinical Trial may include epidemiological studies, modeling and pharmacoeconomic studies and post-marketing surveillance trials.

**1.62** "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency, or any successor agency thereto.

**1.63** "**Pricing and Reimbursement Approval**" means, with respect to a Product, the approval, agreement, determination, or decision of any Governmental Authority establishing the list price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such jurisdiction.

**1.64** "**Product**" means any pharmaceutical product containing the Compound as an active ingredient, in any form, presentations, dosage, or formulation. For purposes of this Agreement, all formulations of single-agent Product containing the Compound shall be considered the same Product, and all formulations of combination products, if any, containing the same set of active agents shall be considered the same Product.

**1.65** "**Public Official or Entity**" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

**1.66** "**RCC**" means renal cell carcinoma.

**1.67** "**Regulatory Approval**" means any and all approvals (including MAA Approval, and Pricing and Reimbursement Approval), licenses, registrations, permits, notifications, and authorizations (or waivers) of any Regulatory Authority that are necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of a Product in any country or jurisdiction.

**1.68** "**Regulatory Authority**" means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given jurisdiction, including the FDA and MHLW, or any successor agency of the foregoing having regulatory jurisdiction over the manufacture, distribution, and sale of drugs in the Collaborator Territory, and any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

**1.69** "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product other than patents, including, without limitation, rights conferred in the U.S. under the Hatch-Waxman Act

or the FDA Modernization Act of 1997 (including pediatric exclusivity), or rights similar thereto in the Collaborator Territory.

**1.70** "**Regulatory Filing**" means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the testing, Development, manufacture, or Commercialization of any Product made to or received from any Regulatory Authority in a given country, including any INDs and MAAs.

**1.71** "**Safety Data**" means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities. Safety Data also includes "adverse events", "adverse drug reactions", and "unexpected adverse drug reactions" as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

**1.72** "**Supplied Product**" has the meaning set forth in Section 1.24.

**1.73** "**SEC**" means the U.S. Securities and Exchange Commission, or any successor entity or its foreign equivalent in the Collaborator Territory, as applicable.

**1.74** "**Specifications**" means all the attributes, acceptance criteria, tests, analytical methods, and/or limits, and the results thereof, as applicable, for which the raw materials, bulk active, intermediates, or process of making the Drug Product must conform to in order for the Drug Product or Finished Product, as the case may be, to be acceptable for clinical use or commercial use, as applicable, as may be modified as set forth in this Agreement or the applicable Supply Agreement.

**1.75** "**Sponsor**" means the Party that takes the ultimate responsibility for the initiation, performance and management of, including financing or arranging the financing for, the appropriate Clinical Trial.

**1.76** "**Sublicensee**" means a Third Party to whom Collaborator grants a sublicense to Develop, use, import, promote, offer for sale, sell or otherwise Commercialize any Product in the Field in the Collaborator Territory, beyond the mere right to purchase Products from Collaborator and its Affiliates, and excluding wholesalers, full-service distributors that do not promote the sale of the Product, and other similar physical distributors. In no event shall Exelixis or any of its Affiliates be deemed a Sublicensee.

**1.77** "**Third Party**" means any entity other than Exelixis or Collaborator or an Affiliate of Exelixis or Collaborator.

**1.78** "**Tier 1 Indication**" means [ * ].

**1.79** "**Tier 2 Indication**" means [ * ].

**1.80** "**U.S.**" means the United States of America, including its territories and possessions (including Puerto Rico).

**1.81** "**Valid Claim**" means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a pending patent application that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken and that has not been pending for more than [ * ].

**1.82 Additional Definitions.** The following table identifies the location of definitions set forth in various Sections of the Agreement:

| **Defined Terms** | **Section** |
|---|---|
| Acquisition Transaction | 16.8(b) |
| Alliance Manager | 3.7 |
| Allowable Increases | 4.5(a) |
| Auditor | 9.4 |
| Beneficial Party | 8.2(d) |
| Budget Cap | 4.5(a) |
| Claim | 12.3 |
| Collaborative Work | 4.5(a) |
| Collaborator Data | 10.1(a) |
| Collaborator Indemnitee | 12.1 |
| Collaborator Local Development Work | 4.5(c) |
| Commercialization Plan | 6.2 |
| Competing Program | 2.8(a) |
| Compound Invention | 10.1(b)(i) |
| Development Budget | 4.2(b) |
| Developing Party | 4.3 |
| Disputed Matter | 15.2 |
| Divest | 2.8(b) |
| Exelixis Data | 10.1(a) |
| Exelixis Entity | 16.8(a)(i)(1) |
| Exelixis Indemnitee | 12.2 |
| Exelixis Local Development Work | 4.5(c) |
| First Full Calendar Year | 6.3(b) |
| First Generic Entry | 2.8(a) |
| Global Development Plan or GDP | 4.2(a) |

| | |
|---|---|
| Indemnitee | 12.3 |
| Indemnitor | 12.3 |
| Independent Work | 4.3 |
| Independent Work Cost | 8.2(b) |
| Injunctive Relief | 15.3(b) |
| Joint Commercialization Committee or JCC | 3.3 |
| Joint Development Committee or JDC | 3.2 |
| Joint Executive Committee or JEC | 3.1 |
| Joint Inventions | 10.1(b)(ii) |
| Joint Patents | 10.1(b)(ii) |
| Local Regulatory Requirement | 3.5(b)(i)(2) |
| Losses | 12.1 |
| Materials | 4.14 |
| Minimum Commercial Performance | 6.3(b) |
| Minimum Commercial Performance Period | 6.3(b) |
| Newly-Proposed Development | 4.3 |
| Non-Developing Party | 4.3 |
| PV Costs | 5.5(c) |
| Pharmacovigilance Agreement | 5.5(a) |
| Previously Achieved Sales Milestone | 8.4(a) |
| Product Infringement | 10.4(a) |
| Product Marks | 10.8(a) |
| Promotional Materials | 6.4(c) |
| Proposal | 4.3 |
| Quality Agreement | 7.1 |
| Recall | 5.9 |
| Regulatory Meeting | 5.3 |
| Remaining Royalty Term | 8.5(d) |
| Responding Party | 13.4(a) |
| Royalty Term | 8.5(c) |
| Rules | 15.3(a) |
| Sole Inventions | 10.1(b)(ii) |
| Standstill Period | 16.8(a) |
| Submitting Party | 13.4(a) |
| Sunshine Reporting Laws | 5.10 |
| Supply Agreement | 7.1 |
| Supply Contacts | 3.8 |
| Term | 14.1(a) |
| Unaffiliated Third Party | 2.8(a) |
| Withholding Tax Action | 9.3(c) |

## 2. Grant of Licenses

**2.1 Licenses Granted to Collaborator**. Subject to the terms and conditions of this Agreement, Exelixis hereby grants to Collaborator, during the Term:

**(a)** an exclusive (even as to Exelixis, except as expressly set forth in Section 2.3), royalty-bearing license, with the right to grant sublicenses solely as provided in Section 2.2, under the Exelixis Technology to use, sell, offer for sale, import, and otherwise Commercialize (but not to make or have made) the Products in the Field and in the Collaborator Territory;

**(b)** to the extent Exelixis supplies to Collaborator Compound or Drug Product and not Finished Product, an exclusive (even as to Exelixis), royalty-bearing license, with the right to grant sublicenses as provided in Section 2.2, under the Exelixis Technology to conduct or have conducted Finished Manufacture in the Collaborator Territory for use in the Development and Commercialization of the Products in the Field in the Collaborator Territory; and

**(c)** a co-exclusive license, together solely with Exelixis and its other licensee(s) of the Product, with the right to grant sublicenses solely as provided in Section 2.2, under the Exelixis Technology to Develop (but not to make or have made) the Products in the Collaborator Territory under the GDP, and to use the Products for that purpose.

**2.2 Sublicensees/Contractors**. Collaborator shall not have the right to grant sublicenses under the licenses granted in Section 2.1 without Exelixis' express prior written consent. All sublicenses granted under the licenses granted in Section 2.1 with Exelixis' consent shall be expressed in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement and shall provide that any such Sublicensee (for clarity, excluding any wholesale distributor) shall not further sublicense except with the consent of Collaborator and Exelixis. Collaborator shall ensure that each agreement with a Sublicensee grants Exelixis all rights with respect to Data, Inventions, and Regulatory Filings made or generated by such Sublicensee as if such Data, Inventions, and Regulatory Filings were made or generated by Collaborator. Collaborator shall be responsible for the compliance of its Affiliates involved in the Development or Commercialization of the Compound and Products and Sublicensees (for clarity, excluding any wholesale distributor) and subcontractors with the terms and conditions of this Agreement. Within [ * ] after execution, Collaborator shall provide Exelixis with a copy of each agreement granting a sublicense under the license granted in Section 2.1. Unless otherwise set forth in this Agreement, Collaborator may contract with any of its Affiliates or Third Party contractors (e.g., contract research organization, contract sales organization, contract manufacturing organization, or regulatory agent) to conduct any of its activities contemplated hereunder without the prior written consent of Exelixis; provided, however, that Collaborator shall impose on each such contractor the same obligations that Collaborator undertakes hereunder and Collaborator shall remain responsible to Exelixis for the performance of such obligations by each such contractor.

**2.3 Reserved Rights**. Subject to the terms and conditions of this Agreement, Exelixis hereby expressly reserves:

**(a)** the right under the Exelixis Technology to exercise its rights and perform its obligations under this Agreement, whether directly or through one or more licensees or subcontractors, including the right to Develop the Compound and Products in the Collaborator Territory under the GDP; and

**(b)** subject to Section 2.8, all rights to practice, and to grant licenses under, the Exelixis Technology outside of the scope of the licenses granted in Section 2.1, including the exclusive right to make and have made the Compound and Products anywhere in the world, and the exclusive rights to practice the Exelixis Patents and Exelixis Know-How with respect to compounds and products other than Compound and Products.

**2.4 Licenses Granted to Exelixis**. Subject to the terms and conditions of this Agreement, Collaborator hereby grants to Exelixis, during the Term:

**(a)** an exclusive (even as to Collaborator), royalty-free, fully-paid, and irrevocable license, with the right to sublicense through multiple tiers, under the Collaborator Technology to use, sell, offer for sale, import, and otherwise Commercialize the Products in the Field in the Exelixis Territory as long as such Collaborator Technology is those actually applied and/or used in the Product Developed or Commercialized by Collaborator;

**(b)** a co-exclusive (with Collaborator), royalty-free, fully-paid, and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Collaborator Technology to Develop the Compound and Products on a worldwide basis under the GDP as long as such Collaborator Technology is those actually applied and/or used in the Product Developed or Commercialized by Collaborator; and

**(c)** an exclusive (even as to Collaborator), royalty-free, fully-paid, and irrevocable license, with the right to sublicense through multiple tiers, under the Collaborator Technology to make and have made the Compound and Products anywhere in the world as long as such Collaborator Technology is those actually applied and/or used in the Product Developed or Commercialized by Collaborator.

For the avoidance of any doubt, a scope of the license under the Collaborator Technology granted to Exelixis under this Section 2.4 shall be limited only to each purpose of license explicitly provided in the above (a) through (c), and Collaborator may reserve the rights to use or grant a license under the Collaborator Technology freely for outside of such scope of Exelixis' exclusive license set forth above. For the avoidance of any doubt, any such use by Collaborator of the Collaborator Technology outside of the scope of Exelixis' exclusive license set forth above shall be subject to the conditions under Section 2.8 (Exclusivity).

**2.5 No Implied Licenses; Negative Covenant**. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by

implication or otherwise, under or to any Patents, Know-How, or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement. Without limitation of the foregoing, each Party acknowledges the restrictions on its activities set forth in Section 4.13 and Collaborator agrees that such activities are outside the scope of the licenses granted to it herein.

**2.6 Disclosure of Know-How**. For as long as the Parties are conducting Development activities under the GDP, Exelixis shall, without additional compensation, disclose and make available to Collaborator, in electronic form where possible, all Exelixis Know-How that comes into existence after the Effective Date and that was not previously provided to Collaborator, promptly after the development, making, conception, or reduction to practice of such Exelixis Know-How. For as long as the Parties are conducting Development activities under the GDP, Collaborator shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Exelixis, in electronic form where possible, any Collaborator Know-How not previously provided to Exelixis, and promptly after the earlier of the development, making, conception, or reduction to practice of such Collaborator Know-How. The JDC and JCC shall each establish a mechanism for the reciprocal disclosure of Know-How within its respective area of responsibility.

**2.7 Third Party Licenses**.

**(a)** If Exelixis enters into any agreement with a Third Party after the Effective Date that includes a license from such Third Party to Exelixis under any Patents that would be infringed, absent a license or other right to practice granted under such Patents, by the Development, use, Manufacture, sales, offer for sale, import, or Commercialization of the Product in the Field and in the Collaborator Territory (including as contemplated in Section 10.5), then Exelixis shall notify Collaborator and identify for Collaborator the relevant Patents. Such Patents, to the extent falling within the definition of Exelixis Patents, will be sublicensed to Collaborator if Collaborator provides Exelixis with written notice in which (i) Collaborator consents to adding such Patents to the definition of Exelixis Patents, (ii) Exelixis and Collaborator shall [ * ] of the payments that would be owed by Exelixis under such Third Party license agreement as a result of Exelixis granting a sublicense to Collaborator or Collaborator's practice thereunder, including Collaborator's and its Affiliates' and Sublicensees' Development, use, Manufacture, sale, offer for sale, importation, and Commercialization of the Compound and Products in the Field in the Collaborator Territory, and such payments would be reasonably allocated proportionately to Collaborator Territory in the case such Third Party license agreement covers multiple countries including the Collaborator Territory, and to make all payments when due and provide all reports required under such license agreement; and (iii) Collaborator acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement.

**(b)** Collaborator shall promptly notify Exelixis if it becomes aware of any Third Party's Patents that are necessary or reasonably useful to Develop, make, have made, use,

sell, offer for sale, import or Commercialize the Compound and Products in the Field in the Collaborator Territory, and shall give Exelixis the first right to negotiate and obtain a license from such Third Party under such Patents. Except with the prior written consent of Exelixis, Collaborator shall not obtain a license to Third Party's Patents that is necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale, import or Commercialize the Products in either Party's territory, unless it obtains the right to sublicense such rights to Exelixis.

**2.8 Exclusivity**.

**(a)** Subject to Section 2.8(b) below, (i) for the period starting from the Effective Date until the earlier of either of (1) eight (8) years after the First Commercial Sale of any Product in the Collaborator Territory or (2) the first commercial sale in the Collaborator Territory by an Unaffiliated Third Party of a Generic Product for which such Third Party has obtained National Health Insurance pricing from the MHLW ("**First Generic Entry**"), neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), develop [ * ] any Competing Product for any use in the Competitive Field in the Collaborator Territory (a "**Competing Program**"), and (ii) for the period starting from the Effective Date and continuing until two (2) years following the First Generic Entry, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), commercialize any Competing Product for any use in the Competitive Field in the Collaborator Territory. For purposes of this Section 2.8, "**Unaffiliated Third Party**" means a Third Party that is not a Sublicensee and did not purchase the applicable Generic Product in a chain of distribution that included any of Exelixis, Collaborator, or their respective Affiliates, licensees, or sublicensees.

**(b)** In the event that a Third Party becomes an assignee of this Agreement, or an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation, or other similar transaction, and such Third Party, as of the closing date of such transaction, is engaged in the development [ * ] or commercialization of a Competing Program:

**(i)** if such transaction arises with respect to [ * ], then such assignee or new Affiliate (as the case may be) shall have the right to continue the Competing Program and such continuation shall not constitute a breach of [ * ] exclusivity obligations set forth above; provided that such assignee or new Affiliate (as the case may be) conducts the Competing Program independently of the activities of this Agreement and does not use any [ * ] in the conduct of the Competing Program and provided further that [ * ] shall continue to Develop [ * ] the Product for the Collaborator Territory in accordance with the terms of this Agreement [ * ] as if the Competing Program was not acquired;

**(ii)** if such transaction arises with respect to [ * ], then such assignee or new Affiliate (as the case may be; in either case, referred to as [ * ] for the remainder of this Section 2.8(b)(ii)) shall continue to Develop and Commercialize the Product [ * ] that assumes as if the Competing Program was not acquired, provided that, within [ * ] after the closing of such transaction, [ * ] shall either: (a) Divest the Competing Program to a Third Party, or (b) discontinue the Competing Program. For clarity, if the closing of such transaction occurs after

the earlier of 2.8(a)(i)(1) or 2.8(a)(i)(2), [ * ] may continue the development of such Competing Program [ * ], but shall in no event be permitted to commercialize such Competing Program in the Competitive Field in the Collaborator Territory until two (2) years after the First Generic Entry, as set forth in Section 2.8(a)(ii). For the avoidance of any doubt, during such [ * ] period, [ * ] shall continue to fulfill its obligations under this Agreement in all respects, shall conduct Competing Program activities independently of the activities pursuant to this Agreement, shall not use any [ * ] in the conduct of the Competing Program, and shall not initiate or launch any new Competing Program activities. Notwithstanding the foregoing, in the event that [ * ] reasonably anticipates that it will require more than [ * ] to complete any then-ongoing clinical trials or studies with respect to the Competing Program, then [ * ] shall notify Exelixis via the JEC and the JEC shall discuss and determine in good faith any necessary extension to such [ * ] period to permit [ * ] solely to complete and not to interrupt such ongoing clinical trials and studies with respect to the Competing Program, and [ * ] shall not withhold its consent to any such necessary extension. For clarity, if [ * ] completely winds down the Competing Program within such [ * ] time period plus the period of time of the extension, if any, [ * ] shall be allowed to Divest the Competing Program later, provided that it does not restart any Competing Program activities. For the purpose of this Section 2.8(b)(ii), an "ongoing clinical trial or study" shall be any clinical trial or study for which [ * ] as of the closing of such transaction.

As used in this Section 2.8(b), "**Divest**" means the sale or transfer of all rights to the Competing Program to a Third Party without receiving any contractual mechanism for Collaborator to provide involvement in or support of any diligence or performance obligations of such Third Party with respect to the Competing Program, or to perform or be involved in any development or commercial activities with respect to such Competing Program ("**Divesture**" has a correlative meaning). For the avoidance of any doubt, "Divest" does not mean the renouncement nor waiver of any right to receive payment from the Third Party involved in the development and commercial activities with respect to the Competing Program and to the extent that [ * ].

**(c)** During the Term of this Agreement, to the extent permitted by Applicable Law, for the legitimate and proportionate purpose and means for the protection of Confidential Information and Know-How and for the lifecycle management of the Product, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), commercialize any Generic Product of any Product in the other Party's territory; provided, however, that the foregoing restriction shall apply to [ * ] only until [ * ].

**2.9 Authorized Generics and Off Patent Products**.

**(a) Authorized Generics**. The Parties acknowledge that it may become in the Parties' mutual interest to create an authorized generic of the Product either during or after the Royalty Term for such Product in the Collaborator Territory. If and when [ * ] believes that creating such an authorized generic for commercialization in the Collaborator Territory would be mutually beneficial to the Parties, [ * ] shall notify [ * ] and the Parties shall discuss whether to create such an authorized generic for commercialization in the Collaborator Territory. In the

event that the Parties determine to create an authorized generic version of the Product, the Parties shall negotiate the commercially reasonable terms and conditions of manufacturing and commercializing such authorized generic in the Collaborator Territory and either amend this Agreement or enter into a separate agreement with respect thereto, as appropriate.

**(b) Off Patent Products**. The Parties acknowledge that it may be in the Parties' mutual interest and wishes to continue to commercialize the Product for patients in the Collaborator Territory by using Exelixis supplied API, Compound, or Product even after the [ * ] for such Product. If Collaborator desires to purchase the API, Compound, and/or Product of the Collaborator Territory after the [ * ] for such Product, Collaborator shall notify Exelixis up to [ * ] prior to the expiration of the [ * ] and the Parties shall discuss in good faith with the intent to determine commercially reasonable terms and conditions for the continued supply of the API, Compound, and/or Product (in the form then-currently supplied to Collaborator by Exelixis and which supply price shall include a reasonable margin) and a license under the Product Marks for use in connection with the Commercialization of the Product.

## 3. Governance

**3.1 Joint Executive Committee**. As of the Effective Date, the Parties have established a joint executive committee (the "**Joint Executive Committee**" or the "**JEC**"), composed of an equal number of up to [ * ] senior officers/representatives of each Party, to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The JEC shall act as a joint consultative body and to the extent expressly provided herein, a joint decision-making body. The JEC in particular shall:

**(a)** review the overall status of the Development and Commercialization of the Compound and Products in the Exelixis Territory and the Collaborator Territory, as presented by the JDC and JCC;

**(b)** review and approve any proposed amendments to the GDP, including corresponding budgets, following recommendation by the JDC;

**(c)** review and approve the Commercialization Plans for the Collaborator Territory, including proposed amendments, following recommendation by the JCC;

**(d)** review and approve Minimum Commercial Performance thresholds pursuant to Section 6.3(b), following recommendation by the JCC;

**(e)** review the status and strategy of manufacturing and supply, following recommendation by the JDC or JCC;

**(f)** resolve any disputed matter submitted to it by the JDC or JCC;

**(g)** establish additional Committees as it deems necessary or advisable to further the purpose of this Agreement; and

**(h)** perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or allocated to it by the Parties' written agreement, including providing financial oversight of the activities conducted pursuant to this Agreement.

For clarity, any information sharing of Commercialization matters regarding the Exelixis Territory shall be solely for purposes of the coordination of the Parties' activities, and Exelixis shall retain all decision making authority with respect to such matters without requiring any approvals except as expressly provided in Sections 13.4 and 13.5.

**3.2 Joint Development Committee.** As of the Effective Date, the Parties have established a joint Development, Medical Affairs, and regulatory committee (the "**Joint Development Committee**" or the "**JDC**"), composed of up to [ * ] representatives of each Party, to monitor and coordinate the Development of, and Medical Affairs Activities connected with, the Compound and Products at the operational level. Each JDC representative shall have knowledge and expertise in the clinical development of products similar to the Products. The JDC shall in particular:

**(a)** coordinate and monitor the Development activities of the Parties under the GDP and oversee implementation of the GDP, and report to the JEC on all significant Development activities in the Collaborator Territory;

**(b)** provide a forum for and facilitate communications between the Parties with respect to the Development of Products in the Collaborator Territory and the Exelixis Territory, including sharing of Development information and Data in accordance with Section 4.7;

**(c)** review and approve for the Collaborator Territory Clinical Trial protocols, including investigator-initiated and cooperative group clinical trial plans and protocols, and statistical analysis plans for Clinical Trials (and any amendments thereto);

**(d)** define areas of permissible scientific and medical inquiry and parameters for Phase 4 Clinical Trials in the Collaborator Territory;

**(e)** review Data resulting from Clinical Trials to determine if progression to additional Clinical Trials or submission of Regulatory Filings in the Collaborator Territory is warranted in terms of regulatory and scientific point of view;

**(f)** review and recommend amendments to the GDP (including the Development Budget) and propose the recommendation to JEC;

**(g)** provide a forum for Exelixis to provide Collaborator with a status report, at each regularly-scheduled meeting of the JDC, of any significant potential or proposed change(s) in any of Exelixis' or its other Product licensee's Development plans and activities that may

result in or require an amendment to the GDP, including any global clinical trial or study of the Product in which Collaborator may wish to participate;

**(h)** review the status of Product manufacturing and supply activities and strategies associated with Development;

**(i)** provide a forum for evaluation of Japanese regulatory actions, communications and submissions for the Compound and Products under the GDP, and pharmacovigilance and safety matters worldwide;

**(j)** establish joint working groups (such as clinical, regulatory and safety working groups) as it deems necessary or appropriate to oversee the day-to-day management of different aspects of the Development work under the GDP;

**(k)** oversee and coordinate the material Medical Affairs Activities for the Product in all indications, which shall be subject to a Medical Affairs portion of the GDP and may be coordinated through a Medical Affairs working group established and overseen by the JDC;

**(l)** review and coordinate decisions related to research or Development of Products for new indications, characterization, and Development of [ * ] (if any); and

**(m)** perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Development of Products, including endeavoring to resolve any disputes between the Parties arising from the deliberations of the JDC, or as otherwise directed by the JEC.

**3.3 Joint Commercialization Committee.** As of the Effective Date, the Parties have established a joint commercialization committee (the "**Joint Commercialization Committee**" or the "**JCC**"), composed of up to [ * ] representatives of each Party, to monitor and discuss the Commercialization of Products at the operational level. Each JCC representative shall have knowledge and expertise in the commercialization of products similar to Products. The JCC shall in particular:

**(a)** review and recommend the Commercialization Plans and related activities with respect to the Commercialization of Products in the Collaborator Territory, and report to the JEC on all significant Commercialization activities in the Collaborator Territory;

**(b)** provide a forum for and facilitate communications and coordination between the Parties with respect to the Commercialization of Products in the Collaborator Territory and the Exelixis Territory;

**(c)** on an annual basis, discuss and establish Collaborator's Minimum Commercial Performance thresholds pursuant to Section 6.3(b) and propose recommendation to JEC;

**(d)** review the status of material Product manufacturing and supply activities and strategies associated with Commercialization;

**(e)** review and discuss the major findings of Collaborator's market research with respect to any Product in the Collaborator Territory, if any;

**(f)** review and oversee the branding and product positioning strategy for Products in the Collaborator Territory and evaluate Collaborator's brand strategy for the Product in the Collaborator Territory for consistency with the then-current global brand strategy for the Product;

**(g)** discuss Product list price and status of reimbursement in the Collaborator Territory; and

**(h)** perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Commercialization of Products, including endeavoring to resolve any disputes between the Parties arising from the deliberations of the JCC, or as otherwise directed by the JEC.

**3.4 Committee Membership and Meetings**.

**(a) Committee Members.** Each Committee representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the applicable Committee's responsibilities. Each Party may replace its representatives on any Committee on written notice to the other Party, but each Party shall strive to maintain continuity in the representation of its Committee members. The [ * ]. [ * ]. The chairperson shall have Alliance Manager prepare and circulate agendas and any background materials to be discussed at the Committee to Committee members at least [ * ] before each Committee meeting and shall direct the preparation of reasonably detailed minutes for each Committee meeting, which shall be approved by the chairperson and circulated to Committee members within [ * ] of such meeting. The initial members of each of the JEC, JCC, and JDC shall be determined by the Parties promptly following the Effective Date.

**(b) Meetings**. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall meetings of the JDC be held less frequently than once every [ * ] during the first [ * ] following the Effective Date; meetings of the JCC be held less frequently than once every [ * ] during the [ * ] in the Collaborator Territory and [ * ]; and meetings of the JEC once every [ * ] during the first [ * ] following the Effective Date and once every [ * ] during the [ * ] in the Collaborator Territory; provided, the Parties may decide to reduce the frequency of the Committee meetings. The first JEC meeting, first JDC meeting, and first JCC meeting shall be held within [ * ] after the Effective Date, at which meetings the dates for the first Calendar Year shall be set. Meetings of any Committee may be held in person, or by audio or video teleconference; provided that unless otherwise agreed, at least one (1) meeting per year of each Committee shall be held in person. In-person Committees shall be held at locations alternately selected by the Parties and Collaborator shall select the location of the first meeting.

Each Party shall be responsible for all of its own expenses of participating in any Committee meetings. No action taken at any meeting of a Committee shall be effective unless at least [ * ] of each Party is participating. In addition, upon written notice to the other Party, either Party may request that a special *ad hoc* meeting of the (i) JEC be convened for the purpose of resolving disputes or for the purpose of reviewing or making decisions pertaining to material subject-matter, the review or resolution of which cannot be reasonably postponed until the following scheduled JEC meeting, and (ii) JDC be convened for the purpose of addressing or resolving (on an expedited basis) any dispute with respect to any Local Regulatory Requirement. Such *ad hoc* meeting shall be convened at such time as may be mutually agreed by the Parties, but no later than [ * ] following the notification date of request that such meeting be held.

**(c) Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the Committee meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide reasonable prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, delayed, or conditioned. Such Party shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

**3.5 Decision-Making**.

**(a)** All decisions of each Committee shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before a Committee, the representatives of the Parties cannot reach an agreement as to such matter within [ * ] after such matter was brought to such Committee for resolution, then, except as provided in Section 3.5(c), if such disagreement arose within the JDC or JCC, it shall be referred to the JEC for resolution. If the JEC cannot resolve such matter within [ * ], or if the disagreement first arose within the JEC, then either Party at any time may refer such issue to the Executive Officers for resolution.

**(b)** If the Executive Officers cannot resolve such matter within [ * ] after such matter has been referred to them, then:

**(i)** Exelixis shall have the final decision making authority, which shall be exercised in its reasonable discretion, with respect to Development and regulatory matters that may be reasonably expected to affect the Exelixis Territory, except for:

**(1)** the [ * ], the costs of which would be [ * ];

**(2)** any material modification to a [ * ]. For clarity, the foregoing shall include any material modification to [ * ]. As used in this clause, "material modification" means any material changes to the agreed upon [ * ];

**(3)** any modification to the Development Budget, the costs of which would be [ * ]; and/or

**(4)** the addition or inclusion of [ * ], whether the Parties [ * ] or not.

**(ii)** Notwithstanding Section 3.5(b)(i), Collaborator shall have the final decision making authority, which shall be exercised in its reasonable discretion, with respect to (1) Commercialization in the Collaborator Territory (except for [ * ]), (2) regulatory matters in the Collaborator Territory that are reasonably expected not to directly affect the Exelixis Territory (including, [ * ]), and (3) immediate treatment that is reasonably necessary to protect patient safety in any Development activities held in the Collaborator Territory; in each case provided that Collaborator's decision shall be consistent with the terms and conditions of this Agreement.

**(iii)** Neither Party shall have the final decision making authority with respect to the matters in Sections 3.5(b)(i)(1), 3.5(b)(i)(2), 3.5(b)(i)(3), and 3.5(b)(i)(4) and the status quo shall persist with respect to such matter unless and until the Parties mutually agree; provided, however, that with respect to any material modification in order to fulfill a [ * ] in Section 3.5(b)(i)(2), Exelixis' consent through the JDC shall not be unreasonably withheld, delayed, or conditioned.

**(c)** Notwithstanding Section 3.5(a) and (b), [ * ] representative shall have the deciding vote on all tactical or strategic [ * ] matters for the Products in Collaborator Territory ([ * ]), and such matter shall not be subject to escalation to [ * ]; provided that such decision is reasonably expected not to directly affect [ * ] and such decision shall be consistent with the terms and conditions of this Agreement.

**3.6 Limitations on Authority.** Each Committee shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, no Committee will have the power to amend this Agreement, and no decision of a Committee may be in contravention of any terms and conditions of this Agreement.

**3.7 Alliance Managers.** Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. The Alliance Manager will ensure communication to the JEC of all relevant matters raised at the JDC, the JCC, and at any joint subcommittees and project teams (if any). Each Alliance Manager shall be permitted to attend meetings of the JEC and other Committees as appropriate as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written

notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JEC and its subcommittees. Each Party shall bear its own costs of its Alliance Manager, which costs shall be excluded from the Parties' respective Development and manufacturing costs (i.e., Development Costs and Cost of Goods).

**3.8 Supply Contacts**. Each Party shall designate one (1) qualified and experienced supply chain professional to serve as that Party's primary supply contact regarding the supply of Compound and Products within this Agreement ("**Supply Contacts**") and under the direction of the JCC. Each Party may replace its Supply Contact with an alternative representative at any time with prior written notice to the other Party. Supply Contacts shall be responsible for facilitating information exchange and discussion between the Parties regarding the supply of Compound and Products under this Agreement. [ * ]. Each Party shall bear its own costs of its Supply Contact, which costs shall be excluded from the Parties' respective Development and Cost of Goods.

## 4. Development

**4.1 Overview**. Subject to the terms and conditions of this Agreement, the Parties will collaborate with respect to the Development of the Compound and Products and share the Data resulting from such collaboration to facilitate the Development of the Compound and Products throughout the Collaborator Territory and the Exelixis Territory.

**4.2 Development Plan**.

**(a)** The Development of the Compound and Products under this Agreement (including the development of the Compound and any Product as a combination product or combination therapy with another product and/or therapy), including Independent Work and Local Development Work, shall be conducted only pursuant to a comprehensive written global Development plan which shall be updated at least [ * ] through the JDC subject to the JEC's approval during the Term (the "**Global Development Plan**" or "**GDP**"). The GDP shall be incorporated by reference as part of this Agreement. As of the Effective Date, the Parties have agreed upon an initial GDP, including an initial Development Budget, attached to this Agreement as **Exhibit 4.2**. If the terms of the then-current GDP contradicts, or creates inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

**(b)** The GDP shall set forth the timeline and details (including line of therapy, tumor type, primary endpoints, approximate patient size, combination agents, and comparator agents) of all preclinical and clinical Development activities to be conducted by the Parties as necessary to generate Data sufficient to meet the common requirements of both the FDA and PMDA for MAA Approval of the Compound and Products for RCC (1st line and 2nd line), HCC (2nd line), and other indications agreed upon by the Parties. The GDP shall also include (i) any other Development activities approved by the JDC, including parameters for permissible

scientific inquiry in Phase 4 Clinical Trials or Expanded Access Program; (ii) Clinical Trials that the Parties are committed to conducting; (iii) any modification to the Clinical Trials set forth in GDP that will be decided by the JDC based on requirement from a Regulatory Authority or any local or regional IRB (Institutional Review Board)/ethics committee or reasonably necessary to protect patient safety; and (iv) Clinical Trials that will be decided by the JDC based on Data and results obtained after the Effective Date and the Parties' review of the future competitive landscape. The GDP shall include a coordinated Development and regulatory strategy, including the Parties' respective roles in the Development of the registration dossier and Regulatory Filings for the Products and the countries in which Development of the Products will occur. The GDP shall also set forth the detailed budget of the anticipated costs for such Development activities (the "**Development Budget**") on a study-by-study or Clinical Trial-by-Clinical Trial basis. For clarity, the Development Budget shall not include any Development Costs associated with Collaborator Local Development Work or Exelixis Local Development Work.

**(c)** If upon the determination by the JDC, any modification to the then-current GDP, including any non-clinical or Clinical Trials not included in the GDP, (i) is required in order to obtain and/or maintain MAA Approval for a Product in the Collaborator Territory or in one or more of the countries of the Exelixis Territory, (ii) is otherwise recommended or suggested by the PMDA in the Collaborator Territory or the FDA or other Regulatory Authority in the Exelixis Territory, (iii) is required by any local or regional IRB/ethics committee or (iv) is reasonably deemed necessary to protect patient safety, then the JDC shall prepare an amendment to the GDP reflecting such required, recommended or suggested modification, including associated Development Budget. The costs of such additional studies shall be borne by the Parties as provided in Section 4.5(a).

**4.3 Independent Work**. If either Party is interested in pursuing additional Development work on a Product (the "**Developing Party**") for the benefit of the Exelixis Territory (in the case of Exelixis) or the Collaborator Territory (in the case of Collaborator) beyond what is set forth in the then-current GDP, then such Party shall provide the other Party with a written detailed plan and budget for such additional work (the "**Proposal**"). Within [ * ] of receipt of the Proposal, the JDC or delegated team shall meet to review the Proposal and to permit the other Party (the "**Non-Developing Party**") an opportunity to ask questions and request additional information from the Developing Party related to the Proposal, including whether such Proposal is reasonably likely to have a material and adverse effect on the Product in the Non-Developing Party's territory. No additional Development work shall proceed without the approval of the JDC, and following each such approval such additional Development work and corresponding budget shall be incorporated into the GDP by the JDC (the "**Newly-Proposed Development)**. For any Newly-Proposed Development work, the Non-Developing Party that did not propose such work originally may elect, at its discretion, to share the Development Costs with respect to such Development work under Section 8.2(b). For clarity, for any Newly-Proposed Development by Exelixis, if Collaborator elects to share the Development Costs with respect to such Development work in accordance with Section 8.2(b), Collaborator shall have the option to [ * ]. If the Non-Developing Party does not decide to pursue the Newly-Proposed Development work jointly with the Developing Party or does not share the Development Costs

with respect to such Newly-Proposed Development work, in which event such Development work shall be deemed "**Independent Work**" and the Developing Party may pursue such work in the Field in its respective territory and the Development Costs with respect thereto shall be deemed Independent Work Costs and subject to Sections 4.5(b) and 8.2(b). Notwithstanding the foregoing, following the approval of the Independent Work by the JDC, the Party proposing the Independent Work may conduct such Independent Work, provided that: (A) it shall do so in accordance with the amended GDP; (B) such Independent Work shall be conducted under the oversight of the JDC; and (C) neither Party shall conduct Independent Work in a manner that would have a material adverse effect on any Product(s) in either Party's territory. For the purpose of clarification, the Development activities conducted by Exelixis for RCC (1st line and 2nd line) and HCC (2nd line) before the Effective Date shall not be treated as Independent Work.

**4.4 Annual Update to Development Budget**. The JDC shall discuss and agree, without a casting vote by either Party with respect to costs that would be shared by the Parties, upon the subsequent year's Development Budget on an annual basis no later than [ * ] of each year. The JDC shall report any significant changes in the annual budgets to the JEC at the next regularly-scheduled JEC meeting.

**4.5 Development Cost**.

**(a) Collaborative Work Cost**. Exelixis shall be responsible for eighty percent (80%) and Collaborator shall be responsible for twenty percent (20%) of all Development Costs for any Development activities (including Clinical Trials) set forth in the GDP other than Independent Work, Collaborator Local Development Work and/or Exelixis Local Development Work (the "**Collaborative Work**"). For the avoidance of any doubt, such Development Costs with respect to the Collaborative Work shall include work performed by temporary workers and contractors on applicable activities and all Allowable Increases. For the purpose of this Section 4.5(a), "**Allowable Increases**" are defined as increased Development Costs in connection with the Collaborative Work resulting from (i) changes in study design after the Effective Date that are approved by the JDC [ * ] (up to the amount of a mutually-agreed budget increase), (ii) changes in regulatory requirements arising after the Effective Date (including changes required or recommended by Regulatory Authorities, but excluding changes required or recommended specifically by a Regulatory Authority of the Exelixis Territory solely for the benefit of the Exelixis Territory), or (iii) extensions in the duration of Clinical Trials resulting from a lower than anticipated patient accrual rate, rate of clinical events, or higher rates of survival. The Parties' foregoing Development Cost obligations with respect to the Collaborative Work (including Allowable Increases, if any) are subject to a maximum payment obligation of [ * ] of the amount specified in the Development Budget (the "**Budget Cap**"). For clarification, notwithstanding Section 3.2(f), in the event that the Collaborative Work is conducted in accordance with the GDP and within the Budget Cap, no amendment of the Development Budget shall be required. In the event that Development Costs are expected or anticipated to exceed the Budget Cap, the Party conducting the applicable Clinical Trial shall notify the other Party and the JDC shall meet to discuss amending the Development Budget.

**(b) Independent Work Cost**. Notwithstanding Section 4.5(a), the Party conducting the Independent Work approved by the JDC under Section 4.3 shall be solely responsible for the Development Costs with respect to such Independent Work, subject to Section 8.2(b).

**(c) Local Development Work**. Notwithstanding Section 4.5(a), each Party shall be solely responsible for all Development Costs with respect to Development activities that are exclusively for the benefit of the country(ies) within such Party's territory, including: (i) any and all country-specific activities (e.g., a Canada only trial for Exelixis, a Japan only trial for Collaborator, or an Expanded Access Program); (ii) all Phase 4 Clinical Trials solely benefiting such Party's territory; (iii) any and all Development activities required for any pricing and/or reimbursement approvals in such Party's territory (but are not required for the MAA Approval in such territory); and (iv) any and all indirect manufacturing overhead costs solely benefiting such Party's territory. The Development work set forth in this Section 4.5(c) pertaining to Collaborator shall be deemed the "**Collaborator Local Development Work**" and the Development work set forth in this Section 4.5(c) pertaining to Exelixis shall be deemed the "**Exelixis Local Development Work**". For clarity, only studies that are exclusively for the benefit of the Collaborator Territory shall be deemed local Development activities which constitute Collaborator Local Development Work; all other studies under the GDP, including studies with portions conducted in the Collaborator Territory, shall constitute global Development activities subject to Section 4.5(a). All planned and in-process Collaborator Local Development Work and Exelixis Local Development Work shall be included in and conducted in accordance with the GDP, to be performed reasonably and subject to the oversight of the JDC.

**4.6 Development Responsibilities**. The JDC shall reasonably allocate Development responsibilities of the Compound and Products under the GDP between the Parties and such allocation shall be set forth in the GDP, provided that: (a) Exelixis or its designee shall be the Sponsor and have the operational responsibility for all Development work under the GDP that is ongoing as of the Effective Date; (b) each Party shall have the operational responsibility for its own Independent Work in its Territory; and (c) Collaborator shall be the Sponsor and have the operational responsibility for the Collaborator Local Development Work and Exelixis or its designee shall be the Sponsor and have the operational responsibility for the Exelixis Local Development Work.

**4.7 Data Exchange and Use.**

**(a) General.** In addition to its adverse event and Safety Data reporting obligations pursuant to Section 5.5, each Party shall promptly provide the other Party with (i) [ * ] status reports on trial recruitment and other metrics consistent with the performing Party's internal reporting for clinical studies and Development activities, provided however that in case of unexpected events that may have any impact on safety, (such case will be elaborated and defined in Pharmacovigilance Agreement), each Party shall inform the other Party within [ * ] from knowledge of the occurrence of such event; (ii) supporting documentation (e.g. protocols, case report forms, analysis plans, etc.); (iii) preliminary and final Data, and interim, preliminary,

and final results and reports; and (iv) output from advisory committees and investigator meetings, any and all such documentation generated by each Party (including by any Sublicensee or licensee) from its Development activities under this Agreement as such documentation could reasonably be deemed to affect the Development or Commercialization activities of the Product in each Party's territory. As time may be of the essence, each Party shall collaborate in good faith in the exchange of any such Data set forth in this Section within [ * ] of receipt. The Parties shall cooperate on a secure website to facilitate the sharing of reports, Data, and other information on a routine basis. Except as set forth in Section 4.7(b) below, each Party shall have the right to use and reference, without additional consideration, any and all Data generated by or on behalf of the other Party (including by any Sublicensee or other licensee) under this Agreement for obtaining and maintaining Regulatory Approval for the Products and otherwise Commercializing the Products in its territory in accordance with the terms of this Agreement. For clarity, this Section 4.7(a) shall apply to any and all Data generated in the Development under the GDP, including Independent Work (but subject to Section 4.7(b) below), Exelixis Local Development Work, and Collaborator Local Development Work. Notwithstanding the foregoing, should either Party fail to obtain such use and reference rights entirely from any Sublicensee or other licensee, such Party shall not have the right to grant use and access or rights to such Sublicensee or other licensee to any corresponding documentation for which such Party failed to obtain such right listed in this Section 4.7(a) generated by or on behalf of the other Party.

**(b) Independent Work.** Notwithstanding the foregoing, the Party receiving Data resulting from the other Party's Independent Work shall have the right to use such Data only to the extent reasonably necessary for the receiving Party to comply with its regulatory reporting and compliance obligations, including safety reporting obligations, but shall not have the right to use such Data to support its own Development, Regulatory Approval, or Commercialization except pursuant to Section 8.2(b).

**4.8 Diligence**. Each Party shall use Commercially Reasonable Efforts to perform the Development activities assigned to such Party under and in accordance with the GDP. In addition, consistent with the GDP, Collaborator shall use Commercially Reasonable Efforts to perform Collaborator Local Development Work and any Collaborator Independent Work, file MAAs and seek and maintain Regulatory Approval (including Pricing and Reimbursement Approval, as applicable) for the Products in the Collaborator Territory.

**4.9 Compliance**. Each Party shall Develop the Compound and Products in compliance with all Applicable Laws, including good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

**4.10 Development Records**. Each Party shall maintain complete, current, and accurate records of all Development activities conducted by it hereunder, and all Data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-

clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH, cGCP, cGLP, and cGMP).

**4.11 Development Reports.** At [ * ] JDC meeting, each Party shall provide the JDC with regular reports detailing its Development activities for the Products under this Agreement, and the results of such activities. In addition, after the completion of any Clinical Trial or other study of the Products, the Party responsible for the conduct of such Clinical Trial or study shall provide the other Party with a data package consisting of, at a minimum, tables, lists, and figures, as well as any other Data specified in the GDP or otherwise agreed by the Parties, within [ * ] following the completion of such data package. The Parties shall discuss the status, progress, and results of each Party's Development activities under this Agreement at such JDC meetings.

**4.12 Use of Subcontractors.** Each Party may perform its Development activities under this Agreement through one or more subcontractors, provided that (a) such Party will remain responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself; (b) each subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 13, and (c) each subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work to such Party (or, in the event such assignment is not feasible, a license to such intellectual property with the right to sublicense to such other Party). The Parties may also subcontract work on terms other than those set forth in this Section 4.12 with the prior written approval of the JDC.

**4.13 Restrictions**. After the Effective Date and during the Term, neither Party nor any of its Affiliates or (sub)licensees shall, directly or through any Third Party, sponsor, conduct, or cause to be conducted, otherwise assist in, supply any Product for use in connection with, or otherwise fund: (a) any Development of any Product outside the scope of the GDP; or (b) comparative studies of its product versus the Product outside the scope of the GDP. For clarity and without limiting the foregoing, except as expressly approved by the JDC and included in the GDP, Collaborator shall not perform or sponsor any study or test on the Compound or Products, including any pre-clinical or non-clinical study, toxicology study, or CMC-related study, or seek to modify or create the Compound or any analog thereof.

**4.14 Materials Transfer**. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain biological materials or chemical compounds Controlled by the supplying Party (collectively, "**Materials**") for use by the other Party in furtherance of such Development activities. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except to subcontractors permitted in Section 4.12, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used with prudence and appropriate

caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

## 5. Regulatory Activities

### 5.1 Regulatory Responsibilities.

**(a) General.**

**(i)** The GDP shall set forth the regulatory strategy for seeking Regulatory Approval for the Compound and Products by the appropriate Regulatory Authorities in the Collaborator Territory and Exelixis Territory. Unless otherwise necessary for global registration requirements, Collaborator shall apply for and hold Regulatory Filings in the Collaborator Territory with respect to the conduct of Development activities. Subject to the direction and oversight of the JDC, each Party shall be responsible for implementing such regulatory strategy in its territory. Except as otherwise provided herein or required by Applicable Law, each Party shall be responsible for the preparation and submission of any and all Product registrations and marketing approvals in its territory and shall own and hold all such Regulatory Filings (including Regulatory Approvals), and neither Party shall submit any application for Product registration or marketing approval in the other Party's territory.

**(ii)** Each Party shall be responsible for the cost and expense of all regulatory activities in connection with obtaining or maintaining Regulatory Approval of Products in its territory.

**(iii)** Collaborator acknowledges that Exelixis may be required to communicate with Regulatory Authorities in the Collaborator Territory as a result of manufacturing activities for the Collaborator Territory. Exelixis shall notify Collaborator as soon as reasonably possible of such communication with Regulatory Authorities and seek to incorporate input from Collaborator in preparation for such communication. Exelixis shall then keep Collaborator informed of any such communications.

**(b) Transfer of Regulatory Filings**. Exelixis shall provide, promptly after the execution of this Agreement, to Collaborator a copy of all the IND for the Product for the Collaborator Territory submitted to the PMDA, which IND the Parties acknowledge is, as of the Effective Date, closed and inactive in the Collaborator Territory. Collaborator shall have a right to use and/or reference such IND in connection with Collaborator's Development and regulatory activities under this Agreement.

**5.2 Regulatory Information Sharing**. To the extent that such Regulatory Filings that relate to the activities in the requesting Party's territory, each Party shall, upon the other Party's reasonable request, promptly provide the other Party (but in no event more than [ * ]) with copies of Regulatory Filings prepared (including any drafts and supporting information), submitted or received by such Party in the Exelixis Territory including the U.S. and the Collaborator Territory pertaining to the Compound and Products, and such other Party shall have the right to review and comment on drafts of such Regulatory Filings, provided that such review and comment shall not delay the submission of any Regulatory Filings. The sharing of Regulatory Filings shall include any communications/correspondence with the Regulatory Authority regarding label changes, IND annual reports and cover letters, and documents related to regulatory milestones and dates (e.g., submissions and validations). If any Regulatory Filing to be provided under this Section 5.2 was originally created in a language other than the English language, then at the receiving Party's request and to the extent already existing and readily available, the providing Party shall provide an English translation along with the original document to the receiving Party. The Parties acknowledge that it is their intent to collaborate in good faith in the exchange of such Regulatory communications including with any Sublicensee or other Exelixis licensee. Each of Collaborator and Exelixis shall reasonably endeavor to grant access and rights for the other Party to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee or other Exelixis licensee, respectively. For clarity, a Party's provision to the other Party of copies of Regulatory Filings prepared, submitted, or received in each Party's territory is expressly conditioned upon the receiving Party granting to the providing Party the right to share with the providing Party's own licensee for its territory copies of any and all Regulatory Filings prepared, submitted, or received by the receiving Party in its territory. Should either Party fail to obtain such access and rights from any Sublicensee or Exelixis licensee, such Party shall not have the right to grant access or rights to such Sublicensee or other Exelixis licensee to any such communications with any Regulatory Authority generated by or on behalf of the other Party.

**5.3 Meetings with Regulatory Authorities**. On a current and ongoing basis, each Party shall provide the other Party with a list and schedule of any significant in-person meeting or teleconference with the Regulatory Authorities (or related advisory committees) in the Collaborator Territory planned for the next [ * ] that relates to the Development of the Compound and Products under the GDP in the Collaborator Territory (each, a "**Regulatory Meeting**"). In addition, each Party shall notify the other Party as soon as reasonably practicable if such Party becomes aware of any additional Regulatory Meetings that become scheduled for such [ * ] and will keep the other Party informed of any significant interface or communication with any Regulatory Authority which is reasonably expected to affect efforts to obtain Regulatory Approval for the Product in its respective territory. Collaborator shall be solely responsible for any communications with the Regulatory Authorities occurring or required in connection with performing its regulatory responsibilities set forth in this Article 5 with respect to the Product in the Collaborator Territory, and Exelixis shall have the right to provide input in preparation for all Regulatory Meetings and the right, but not the obligation, to have its representatives attend (but, unless otherwise requested by Collaborator, not participate in) the Regulatory Meetings. Collaborator shall have these same rights with respect to any such

Regulatory Meetings in the Collaborator Territory before such Regulatory Filings are transferred to Collaborator under Section 5.1(b).

**5.4 Regulatory Inspections**. Collaborator shall permit the Regulatory Authority(ies) in the Exelixis Territory to conduct inspections of Collaborator, its Affiliates, Sublicensees, or subcontractors (including Clinical Trial sites) relating to Product Development under the GDP or the Finished Manufacture of the Finished Product, and shall ensure that such Affiliates, Sublicensees, and subcontractors permit such inspections. In addition, Collaborator shall promptly notify Exelixis of any such inspection and shall supply Exelixis with all information pertinent thereto. Exelixis shall have the right, but not the obligation, to attend any such inspection with the presence of Collaborator. Exelixis shall permit the Regulatory Authority(ies) in the Collaborator Territory to conduct inspections of Exelixis, its Affiliates, and its sublicensees or subcontractors (including Clinical Trial sites) relating to Product Development under the GDP for the Collaborator Territory, and shall ensure that such Affiliates, sublicensees, and subcontractors permit such inspections. In addition, Exelixis shall promptly notify Collaborator of any such inspection and shall supply Collaborator with all information pertinent thereto. Collaborator shall have the right, but not the obligation, to attend any such inspection with the presence of Exelixis.

**5.5 Pharmacovigilance and Adverse Event Reporting**.

**(a) Pharmacovigilance Agreement**. Within [ * ] after the Effective Date, but in any case prior to the Initiation of a Clinical Trial for the Product in the Collaborator Territory, the Parties shall enter into a pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for and responsibilities of the Parties with respect to the Products, such as Safety Data sharing, adverse events reporting, and safety signal and risk management (the "**Pharmacovigilance Agreement**"), which agreement shall be amended by the Parties [ * ] to comply with any changes in Applicable Laws or any guidance received from Regulatory Authorities. Such procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws.

**(b) Global Safety Database**. Exelixis has established and shall continue to hold, at its expense, the Product global safety database, and shall maintain such global safety database for so long as such Product is under Development and/or Commercialization hereunder. Exelixis will ensure that each Party is able to access the Safety Data, if necessary indirectly, from the global safety database in order to meet legal and regulatory obligations. For the Collaborator Territory, the Parties will agree on data cut points for periodic aggregate safety reports, Exelixis will author such reports, including the integrated data sets, the Parties will jointly review and approve such reports, and Collaborator will generate final versions of the reports for submission in accordance with regulatory requirements in the Collaborator Territory. If the PMDA requires any additional reports, Collaborator shall prepare such reports for submission to the PMDA, consulting with Exelixis as practicable and appropriate and, upon Exelixis' reasonable request, providing to Exelixis a copy (in English) of any such report.

**(c) PV Costs**. As between the Parties, Exelixis shall be responsible for the cost and expense incurred by Exelixis for establishing and maintaining such global safety database and the preparation of periodic aggregate safety reports that are specifically directed (or reasonably allocable) to the Product (the "**PV Costs**") prior to [ * ]. For the period of time commencing upon [ * ] until [ * ], Exelixis shall be responsible for [ * ] of PV Costs and Collaborator shall be responsible for [ * ] of PV Costs. Thereafter, Exelixis shall be responsible for [ * ] of PV Costs and Collaborator shall be responsible for [ * ] of PV Costs.

**(d) PV Governance**. The JDC shall establish a safety subcommittee and all Safety Data, including adverse event reports, shall be submitted to such safety subcommittee and Exelixis concurrently so that Exelixis may update the global safety database accordingly. Such safety subcommittee shall coordinate with respect to any Safety Data reporting for the Product to Regulatory Authorities in the Collaborator Territory, but Collaborator shall be primarily responsible for (i) reporting quality complaints, adverse events, and Safety Data related to the Products, and all case processing of adverse events, to applicable Regulatory Authorities in the Collaborator Territory, and (ii) responding to safety issues and to all requests of Regulatory Authorities in the Collaborator Territory related to the Products, in each case at its own expense. Collaborator shall have the right to use, at its own expense, a safety database owned by Collaborator for the purpose of tracking and reporting quality complaints, adverse events, and Safety Data related to the Products in the Collaborator Territory; provided, however, that such right shall not relieve Collaborator of its obligation to communicate all such information directly to the safety subcommittee and Exelixis. Each Party agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees, and sublicensees to comply with such obligations.

**5.6 No Harmful Actions**. If a Party believes that the other Party is taking or intends to take any action with respect to a Product that could reasonably be expected to have a material adverse impact upon the regulatory status of such Product in the first Party's territory, then such Party may bring the matter to the attention of the JDC and the Parties shall discuss in good faith to resolve such concern.

**5.7 Notification of Threatened Action**. Each Party shall notify the other Party within [ * ] of any information it receives regarding any threatened or pending action, inspection, or communication by any Regulatory Authority, which may affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

**5.8 Right of Reference to Regulatory Materials.** Each Party hereby grants to the other Party the right of reference to all Regulatory Filings pertaining to the Compound and Products submitted by or on behalf of such Party. The receiving Party may use such right of reference solely for the purpose of seeking, obtaining, and maintaining Regulatory Approval of the Products for use in its territory in accordance with this Agreement. Notwithstanding the foregoing, the receiving Party has such right of reference to any Regulatory Filings based on

Data resulting from the other Party's Independent Work only to comply with its safety reporting obligations, unless the receiving Party pays the other Party for such work as set forth in Section 8.2(b).

**5.9 Recalls**. In the event that a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's territory is required by a Regulatory Authority of competent jurisdiction, or if any Regulatory Authority requires or advises either Party or such Party's Affiliates or sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product in a Party's territory, or if a recall, withdraw, or correction of a Product in its territory is deemed advisable by such Party in its sole discretion, such Party shall so notify the other Party no later than [ * ] in advance of the earlier of (i) initiation of a recall, withdrawal, or correction; or (ii) the submission of plans for such an action to a Regulatory Authority. Any such recall, withdrawal, correction, or dissemination of information (e.g., "Dear Doctor" letter) shall be referred to herein as a "**Recall**". Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party. All costs and expenses in connection with a Recall in a Party's territory shall be paid by such Party, including without limitation the costs and expenses related to the dissemination of relevant information. Each Party shall handle exclusively the organization and implementation of all Recalls of Products in its territory. Notwithstanding the foregoing, any Recall related to the manufacture and supply of the Product by Exelixis to Collaborator shall be governed by the terms and conditions of the Parties' applicable Supply Agreement and the Quality Agreement.

**5.10 Sunshine Reporting Laws**. Each Party acknowledges that the other Party may be subject to federal, state, local, international, industrial and internal laws, regulations, rules and guidelines related to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities (collectively, "**Sunshine Reporting Laws**"), and agrees to provide the other Party with all information regarding such payments or transfers of value by such Party as necessary for such other Party to comply in a timely manner with its reporting obligations under the Sunshine Reporting Law.

## 6. Commercialization

**6.1 General.** Subject to the terms and conditions of this Article 6, Collaborator shall have the sole and exclusive responsibility, at its own expense, for all aspects of the Commercialization of the Products in the Collaborator Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities and other payors regarding the price and reimbursement status of the Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing, and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Applicable Laws relating to the promotion, sales and marketing, access, and distribution of the Products.

**6.2 Commercialization Plan.** No later than [ * ], Collaborator shall prepare and present to the JCC a Commercialization plan for Products in the Collaborator Territory, including a reasonably detailed description and an anticipated timeline for Collaborator's significant Commercialization activities for the Products for the next [ * ] the plan will include, at a minimum, a reasonably detailed description of the activities contemplated by Sections 6.4 through 6.7 (the "**Commercialization Plan**"). Collaborator shall update and amend the Commercialization Plan periodically ([ * ]) and shall present such updates and amendments to the JCC for review and discussion. Without limiting the provisions of this Section 6.2, through the JCC, Collaborator shall consult with and provide updates to Exelixis regarding strategy and tactics for Commercialization of Products in the Collaborator Territory. Subject to the provisions of this Agreement and compliance with the Commercialization Plan, Collaborator shall have full control and authority with respect to the day-to-day Commercialization of the Products and implementation of the Commercialization Plan.

**6.3 Diligence**.

**(a) General**. During the Term, Collaborator shall use Commercially Reasonable Efforts to Commercialize the Products for all indications that have received or will receive Regulatory Approval throughout the Collaborator Territory. In addition, and without limitation of the foregoing, Collaborator shall, as soon as possible following each MAA Approval(s), launch the Product for such indication and obtain all necessary Price and Reimbursement Approvals. Thereafter, Collaborator shall utilize Commercially Reasonable Efforts in the ongoing support for the Product in the Collaborator Territory.

**(b) Minimum Commercial Performance**. In addition to the foregoing general commitments, Collaborator shall also achieve for the first six (6) full Calendar Years following the First Commercial Sale of the Product in the Collaborator Territory (the "**Minimum Commercial Performance Period**") (i) a minimum annual sale volume based on the aggregate sales forecast for the Collaborator Territory, and (ii) minimum annual promotional and sales force requirements for the Collaborator Territory, for each Calendar Year as set forth in the table below ((i) and (ii) collectively, the "**Minimum Commercial Performance**"). The Minimum Commercial Performance for the First Full Calendar Year shall be determined by [ * ], and set forth in the first Commercialization Plan. Thereafter during the Minimum Commercial Performance Period, the Minimum Commercial Performance will be updated [ * ], to reflect any changes in the timing of Regulatory Approvals and the First Commercial Sale of a Product for each approved indication in the Collaborator Territory as well as actual experience and competitive conditions then prevailing.

| Full Calendar Year | Sales Volume Minimum | Promotional Efforts Minimum |
|---|---|---|
| 1 | [ * ] | [ * ] |
| 2 | [ * ] | [ * ] |
| 3 | [ * ] | [ * ] |
| 4 | [ * ] | [ * ] |
| 5 | [ * ] | [ * ] |
| 6 | [ * ] | [ * ] |

For clarity, for the [ * ], the sales volume and promotional effort minimums set forth in the table above will be non-binding and solely for planning purposes and of no effect under this Agreement. For the [ * ], Collaborator shall be required to achieve either the sales volume minimum or the promotional efforts minimum, but not both. For the [ * ], Collaborator shall be required to achieve the sales volume minimum only. Collaborator's failure to achieve Minimum Commercial Performance for any [ * ] Calendar Years during the Minimum Commercial Performance Period (excluding the [ * ]) shall be considered a material breach of this Agreement, giving rise to Exelixis' right to terminate the Agreement pursuant to Section 14.2(a) as a sole and exclusive remedy for Exelixis regarding such material breach of Collaborator. For the purpose of this Section 6.3(b), "**First Full Calendar Year**" means the period commencing on the January 1st following the date of the First Commercial Sale of the Product in the Collaborator Territory and ending on December 31st of such Calendar Year. For example, if the First Commercial Sale of the Product occurs in August 2021, the First Full Calendar Year begins on January 1, 2022 and ends on December 31, 2022.

**(c) Commercial Updates**. Collaborator shall update the JCC on a [ * ] basis regarding its Commercialization activities with respect to the Products in the Collaborator Territory. Each such update shall be in a form to be agreed by the JCC and shall summarize Collaborator's, its Affiliates', and Sublicensees' significant Commercialization activities with respect to the Products in the Collaborator Territory, and shall contain at least such information at such level of detail reasonably required by Exelixis to determine Collaborator's compliance with its diligence obligations set forth herein. Such updates shall include Collaborator's sales activities, marketing activities, and Medical Affairs Activities.

**6.4 Coordination of Commercialization Activities**.

**(a) Generally**. The Parties recognize that their collaboration may benefit from the coordination of certain activities in support of the Commercialization of Products in both the Collaborator Territory and the Exelixis Territory. As such, the JCC shall review Collaborator's Commercialization strategies for the Product in the Collaborator Territory (e.g., branding and messaging, international congresses, national- or global-level advisory boards) in order to provide input and drive consistency with those Commercialization strategies for the Product in the Exelixis Territory that have proven successful. For clarity, (i) the foregoing sentence shall not be construed as limiting Collaborator's rights under Section 3.5, and (ii) Exelixis shall not be obligated to seek Collaborator's consent in connection with the

establishment and/or implementation of any sales, marketing, or medical affairs practices in the Exelixis Territory.

**(b) List Price and Pricing for Combination Products**. Collaborator shall keep Exelixis timely informed on the status of any application for Pricing and Reimbursement Approval or material updates to an existing Pricing and Reimbursement Approval in the Collaborator Territory, including any discussion with a Regulatory Authority with respect thereto, via the JCC. Collaborator and its Affiliates and Sublicensees shall not sell any Product [ * ], as part of [ * ], or as [ * ], or offer [ * ] to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product [ * ]. For clarification, should Collaborator derive direct economic benefit from the sale of another pharmaceutical product that is approved to be used in combination with the Product, [ * ].

**(c) Sharing of Promotional Materials**. Collaborator shall, at its own expense, prepare, develop, produce, or otherwise obtain and utilize sales, promotional, advertising, marketing, website, educational, and training materials (the "**Promotional Materials**") to support its Commercialization activities in the Collaborator Territory. The Parties shall share samples of Promotional Materials (including English translation, if such materials are not in the English language) with respect to and for use in the Commercialization of the Products with one another. Additional materials, including medical education and medical information, sales force and sales force training materials, will be made available to the other Party upon reasonable request.

**(d) Commercialization in Exelixis Territory**. Subject to the terms and conditions of this Agreement, Exelixis shall have the exclusive right to Commercialize the Product in the Exelixis Territory at its own cost and expense, with or without Third Party(ies).

**6.5 Detailing and Promotion**.

**(a)** Collaborator shall have the right to engage Third Party contract sales representatives to help with the promotion of the Product in the Collaborator Territory without prior written JCC approval, provided that in no event shall the total number of such contract sales representatives exceed [ * ] of the total sales representatives provided in support of the Product in the Collaborator Territory at any given [ * ] during the Royalty Term without prior written JCC approval. If Collaborator elects to engage Third Party contract sales representatives in accordance with this Section 6.5(a), it shall inform the JCC in reasonable detail of the number of contract sales representatives to be provided. All Third Party contract sales representatives engaged by Collaborator shall have at least, but in no event less than, the same or similar level of experience, capabilities, and training as Collaborator's in-house sales representatives for the Product.

**(b)** Collaborator shall not use the same sales force to promote or detail the Product and a separate product that is [ * ] (except in the case [ * ]). If Collaborator desires to use the same sales force to promote or detail the Product and a separate product that is [ * ], Collaborator shall indicate such desire to Exelixis and Exelixis shall, in its sole discretion,

determine whether to permit such sales force to promote or detail both the Product and such other product.

**6.6 Medical Affairs Activities**.

**(a)** Collaborator shall lead and conduct all Medical Affairs Activities for the Product in the Collaborator Territory in accordance with the medical affairs portion of the GDP, provided, however, that medical affairs publications and medical information activities shall be subject to Section 13.4. Exelixis will not undertake any Medical Affairs Activities in the Collaborator Territory without prior coordination with and consent of Collaborator, such consent not to be unreasonably withheld.

**(b)** To the extent practicable, Collaborator shall provide Exelixis with written notice at least [ * ] in advance of any national-level advisory panel meetings with key opinion leaders regarding the Development or Commercialization of the Products in the Collaborator Territory. If requested by Exelixis, Collaborator shall provide Exelixis with a written summary (in English) of such meetings.

**6.7 Diversion**. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its sublicensees not to, directly or indirectly, promote, market, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receives any order for a Product for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product for use in the other Party's territory.

## 7. Manufacture and Supply.

**7.1 Manufacture and Supply.** Exelixis, through one or more Third Party contract manufacturers, will provide all Supplied Product for use in the Development and Commercialization of the Products under this Agreement. All Supplied Product supplied by Exelixis to Collaborator shall be at a price equal to [ * ]. During the Term, Exelixis shall use Commercially Reasonable Efforts to [ * ]. If [ * ] for particular Supplied Product is reasonably expected to exceed [ * ] per tablet of any dose strength, Exelixis shall inform Collaborator promptly, and discuss with Collaborator in good faith a reasonable mitigation plan to reduce [ * ]. Exelixis (through one or more Third Party contract manufacturers) shall be exclusively responsible for the supply of Supplied Product to Collaborator and Collaborator shall be exclusively responsible, at its expense, for the Finished Manufacture of the Finished Product.

[ * ] of the Supplied Product used in the Development work under the GDP shall be included in the Development Cost and shared by the Parties in accordance with Section 4.5. Exelixis shall source such Supplied Product supply for both Parties either from a facility owned by Exelixis or from a reputable, qualified, and certified Third Party and, in the event that Collaborator is responsible for conducting any Clinical Studies pursuant to Section 4.2 or 4.3, Exelixis shall provide such supply to Collaborator for such Clinical Studies in accordance with the GDP. As soon as reasonably practicable after the Effective Date, but in any event prior to the initial supply of the Supplied Product to Collaborator for use in Development work, the Parties shall enter into supply agreements for the manufacture and supply of the Supplied Product to Collaborator for use in Development or Commercialization activities (each, a "**Supply Agreement**"), and a Quality Agreement setting forth in detail the quality assurance arrangements and procedures for Exelixis' manufacture of Supplied Product (the "**Quality Agreement**"). Exelixis shall, upon Collaborator's reasonable request, allow Collaborator to access Exelixis and/or its manufacturing facility of the Supplied Product, as applicable, for the purpose of regulatory and Collaborator's reasonable in-house auditing.

## 8. Financial Provisions

**8.1 Upfront Payment.** Collaborator shall make a one-time, non-refundable, non-creditable upfront payment to Exelixis of fifty million U.S. dollars ($50,000,000) within five (5) Business Days after the Effective Date.

**8.2 Sharing/Reimbursements of Development Costs and PV Costs**.

**(a) Future Development Costs**. No later than [ * ] after the beginning of each Calendar Quarter during which a Party will perform any Collaborative Work in such Calendar Quarter pursuant to the GDP, such Party shall submit to the other Party a statement setting forth the Development Costs incurred, including the other Party's share (calculated in accordance with Section 4.5) of (i) estimated Development Costs for the then current quarter; (ii) variances from prior invoiced estimates and actual Development Costs; and (iii) Development Costs incurred by or on account of such Party in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such Development Costs, including supporting documents. To the extent provided in Section 4.5, the other Party shall pay the amount invoiced within [ * ] after the receipt of the invoice. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 9.4, which remain in full force and effect. If both Parties will perform Development activities under the GDP in such Calendar Quarter, the Parties shall consolidate the payments for such Calendar Quarter into a single payment from one Party to the other Party.

**(b) Independent Work.** Subject to Section 4.7(b), and except as set forth below in this Section 8.2(b), each Party shall bear all the internal (calculated on an FTE basis using the then current FTE Rate) and reasonable out-of-pocket expenses incurred by or on account of such Party in performing its own Independent Work (the "**Independent Work Costs**"). After the completion of such Independent Work, such Party shall provide the other

Party with a report of such Independent Work Costs. If a Party desires to submit any portion of the Data resulting from any Independent Work conducted by the other Party and related Regulatory Filings generated by the other Party to support Regulatory Approval in its territory, then such Party shall notify the other Party in writing at any time upon the completion of such Independent Work. Within [ * ] after its receipt of such notice, the Party conducting or having conducted such Independent Work shall submit to the other Party a reasonably detailed invoice setting forth [ * ] of the Independent Work Costs that would have been incurred by or on account of such other Party in connection with the generation of such Data under Section 8.2(b) as if such Independent Work Costs were Development Costs with respect to Collaborative Work. If the Party seeking to use such Data decides to use such Data to support Regulatory Approval in its territory, then such Party shall notify the other Party in writing and pay the amount invoiced (i.e., if Collaborator seeks to use the Data resulting from Exelixis' Independent Work, twenty percent (20%) of [ * ] of the Independent Work Costs) within [ * ] after the receipt of such invoice. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 9.4, which remain in full force and effect.

**(c) Internal Development Cost.** Each Party shall record and calculate its internal Development Costs with respect to Collaborative Work and/or its Independent Work on an FTE basis at the FTE Rate.

**(d) Development Cost for Products in Combination.** If the Parties agree to Develop a Product under this Agreement in combination with [ * ] (the "**Beneficial Party**"), either as a combination product or combination therapy, then such Development work shall be conducted in accordance with the GDP and the Development Costs with respect to such Development shall be included in the Development Budget, provided that only [ * ] of the Development Cost with respect to such Development shall be subject to the Parties' cost sharing under Section 8.2(b) and the Beneficial Party shall be solely responsible for the other [ * ] of the Development Costs.

**(e) PV Costs Following Initiation of Clinical Trials**. Following the Initiation of the first Clinical Trial in the Collaborator Territory, no later than [ * ] after the beginning of each Calendar Quarter, Exelixis shall submit to Collaborator a statement setting forth the PV Costs incurred, including Collaborator's share (calculated in accordance with Section 5.5) of (i) estimated PV Costs for the then current quarter; (ii) variances from prior invoiced estimates and actual PV Costs; and (iii) PV Costs incurred by or on account of Exelixis in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such PV Costs, including supporting documents. To the extent provided in Section 5.5, Collaborator shall pay the amount invoiced within [ * ] after the receipt of the invoice. For clarity, making such a payment does not preempt Collaborator's audit rights under Section 9.4, which remain in full force and effect.

**8.3 Development Milestone Payments**.

**(a) Development Milestones.** Subject to the remainder of this Section 8.3, Collaborator shall pay to Exelixis the non-refundable, non-creditable payment set forth in the table below upon the achievement of the applicable milestone event (whether by or on behalf of Collaborator, Exelixis, or their Affiliates, licensee(s) of Exelixis, or Sublicensees):

| **Milestone Event** | **Milestone Payments** | | | | |
|---|---|---|---|---|---|
| | For RCC ($2^{nd}$ line) | For RCC ($1^{st}$ line) | For HCC ($2^{nd}$ line) | Tier 1 Indications | Tier 2 Indications |
| Milestone #1: Upon [ * ] the first Phase 3 Clinical Trial for the Product in the Collaborator Territory | [ * ] | $[ * ] | [ * ] | $[ * ] | $[ * ] |
| Milestone #2: Upon [ * ] the first MAA for the Product in the Collaborator Territory | $[ * ] | $[ * ] | $[ * ] | $[ * ] | $[ * ] |
| Milestone #3: Upon First Commercial Sales for the Product in the relevant indication in the Collaborator Territory | $[ * ] | $[ * ] | $[ * ] | $[ * ] | $[ * ] |

**(i)** For RCC ($2^{nd}$ line), RCC ($1^{st}$ line), and HCC ($2^{nd}$ line), each milestone payment shall be paid only once for the first applicable events described above for each different applicable Product.

**(ii)** Milestone #1 shall be deemed achieved and payable, if not already achieved, upon achievement of any of Milestone #2 and/or Milestone #3 for the same indication. Milestone #2 shall be deemed achieved and payable, if not already achieved, upon achievement of Milestone #3 for the same indication.

**(iii)** Without limiting the foregoing, with respect to RCC ($1^{st}$ line) and RCC ($2^{nd}$ line), if Milestone #3 is achieved for RCC ($1^{st}$ line) prior to being achieved for RCC ($2^{nd}$ line), then Milestone #3 for RCC ($2^{nd}$ line) shall be deemed achieved and payable upon achievement of Milestone #3 for RCC ($1^{st}$ line), except if Collaborator is, at the time of such achievement, diligently engaged in the performance of Development or regulatory activities with respect to Products for the express purpose of achieving Milestone #3 for both RCC ($1^{st}$ line) and RCC ($2^{nd}$ line), in which case Milestone #3 for RCC ($2^{nd}$ line) shall not be deemed achieved and payable unless and until achieved by a Product for RCC ($2^{nd}$ line).

**(b) Notice and Payment.** Each Party shall notify the other Party in writing within [ * ] after the achievement of any milestone set forth in this Section 8.3 by such Party, its

Affiliates, licensee(s) of Exelixis, or Sublicensees. Collaborator shall pay to Exelixis the applicable development milestone payments within [ * ] after the delivery or receipt of such notice.

**8.4 Sales-Based Milestones Payments.**

**(a) Sales Milestones.** Collaborator shall pay to Exelixis the one-time, non-refundable, non-creditable payments set forth in the table below when the aggregated Net Sales of all Products in the Collaborator Territory in any period of four (4) consecutive Calendar Quarters first reach the values indicated in the table below. Once one of the values indicated in the table below is first reached and the corresponding Milestone Payment is paid by Collaborator under this Section 8.4 (the "**Previously Achieved Sales Milestone**"), the period of four (4) consecutive Calendar Quarters to be applied to determine the reaching of a subsequent Net Sales amount in the table below shall only start at the Calendar Quarter immediately following the fourth ($4^{th}$) Calendar Quarter which served as the period to determine the reaching of the Net Sales amount triggering the Previously Achieved Sales Milestone. For the avoidance of any doubt, each payment in this Section 8.4(a) shall be payable once only, regardless of the number of times such milestone is achieved.

| Aggregate Net Sales of all Products in the Collaborator Territory in any 4 consecutive Calendar Quarters | Sales Milestone Payments |
|---|---|
| Equal or exceed$[ * ] | $[ * ] |
| Equal or exceed$[ * ] | $[ * ] |
| Equal or exceed $[ * ] | $[ * ] |
| Equal or exceed $[ * ] | $[ * ] |

**(b) Notice and Payment.** As part of the report in Section 9.1, Collaborator shall provide written notice to Exelixis upon the aggregated Net Sales of all Products in the Collaborator Territory in any four (4) consecutive Calendar Quarters first reaching the values set forth in Section 8.4(a) above, and Collaborator shall pay to Exelixis the corresponding sales milestone payment within [ * ] after the end of the Calendar Quarter.

**(c) Cumulative Net Sales Milestones**. Collaborator shall pay to Exelixis the one-time, non-refundable, non-creditable payments set forth in the table below when the cumulative Net Sales of all Products in the Collaborator Territory first reach the values indicated in the table below.

| Cumulative Net Sales of all Products in the Collaborator Territory | Cumulative Net Sales Milestone Payments |
|---|---|
| Exceed$[ * ] | $[ * ] |
| Exceed$[ * ] | $[ * ] |

**(d) Notice and Payment.** As part of the report in Section 9.1, Collaborator shall provide written notice to Exelixis upon the cumulative Net Sales of all Products in the

Collaborator Territory first reaching the values set forth in Section 8.4(c) above, and Collaborator shall pay to Exelixis the corresponding cumulative Net Sales milestone payment within [ * ] after the end of the Calendar Quarter.

**8.5 Royalty Payments**.

**(a) Royalty Rate.** Subject to the other terms of this Section 8.5, during the Royalty Term, Collaborator shall make quarterly, non-refundable, non-creditable royalty payments to Exelixis on the annual Net Sales of all Products sold in the Collaborator Territory at the applicable rate set forth in the table below. For clarity, if the threshold in Section 8.5(b) is achieved in any Calendar Year, then the Net Sales for purposes of this Section 8.5(a) will commence on the date after which such threshold is achieved.

| **Annual Net Sales of all Products in the Collaborator Territory** | **Royalty Rate** |
|---|---|
| Tier 1: Portion less than or equal to $[ * ] | 20% |
| Tier 2: Portion greater than $[ * ] and less than or equal to $[ * ] | [ * ]% |
| Tier 3: Portion greater than $[ * ] and less than or equal to $[ * ] | [ * ]% |
| Tier 4: Portion greater than $[ * ] and less than or equal to $[ * ] | [ * ]% |
| Tier 5: Portion greater than $[ * ] | 30% |

**(b) Initial Royalty Rate Adjustment Period.** Notwithstanding Section 8.5(a), for the first three hundred million dollars ($300,000,000) of cumulative Net Sales of all Products sold in the Collaborator Territory, Collaborator shall make quarterly, non-refundable, non-creditable royalty payments to Exelixis on the Net Sales of all Products sold in the Collaborator Territory at the rates set forth in the table below. Thereafter, the royalty rate for all Net Sales shall be at the applicable rate set forth in Section 8.5(a).

| **Cumulative Net Sales of all Products in the Collaborator Territory** | **Royalty Rate** |
|---|---|
| Tier 1: Portion less than or equal to $[ * ] | 15% |
| Tier 2: Portion greater than $[ * ] and less than or equal to $[ * ] | [ * ]% |
| Tier 3: Portion greater than $[ * ] and less than or equal to $[ * ] | [ * ]% |
| Tier 4: Portion greater than $[ * ] and less than or equal to $[ * ] | 24% |

**(c) Royalty Term.** Royalties shall be paid on a Product-by-Product basis in the Collaborator Territory from the First Commercial Sale of such Product by or on behalf of Collaborator, its Affiliates, or Sublicensees, until the earlier of (i) two (2) years after the First Generic Entry with respect to such Product, and (ii) the later of (A) expiration of the last-to-expire Valid Claim of the Exelixis Patents, Joint Patents, and Collaborator Patents and (B) expiration of any Regulatory Exclusivity covering such Product in the Collaborator Territory (the "**Royalty Term**").

**(d) Royalty Rate Adjustment for Collaborator Patents**. If the Royalty Term extends beyond the expiration of the last-to-expire Valid Claim of the [ * ] Patents, and any Regulatory Exclusivity [ * ] (the "**Remaining Royalty Term**"), the royalty rates to be paid by Collaborator to Exelixis during the Remaining Royalty Term shall be reduced by [ * ] of the amounts otherwise applicable under Section 8.5(a).

**(e) Basis of Payment**. This Section 8.5 is intended to provide for royalty payments to Exelixis equal to the percentages of Net Sales set forth in this Section 8.5 for the entire duration of the Royalty Term. In establishing this payment structure, Collaborator recognizes and acknowledges the substantial value of the various actions and investments that Exelixis has taken and will undertake under this Agreement, as well as the fact that the value of the license granted hereunder resides substantially in the Know-How. Therefore, Collaborator agrees that the royalty payments set forth above are appropriate for the entire duration of such payment obligation. The Parties have agreed to the payment structure set forth herein as a convenient and fair mechanism for both Parties to be compensated for the value of their actions and investments under this Agreement.

**8.6 Exelixis Payments to Third Party.** Exelixis shall be solely responsible for all payments, including royalties and milestone payments, due with respect to Compound and Products pursuant to any Third Party agreement that Exelixis entered into prior to or as of the Effective Date, including any obligations [ * ].

**8.7 Supply Payments**. Collaborator shall pay Exelixis for Compound, Drug Product, or Finished Product, as the case may be, Exelixis supplies to Collaborator an amount equal to [ * ], as applicable, all as provided in the applicable Supply Agreement.

## 9. Payment; Records; Audits

**9.1 Payment; Reports**. Royalty payments due by Collaborator to Exelixis under Section 8.5 shall be calculated and reported for each Calendar Quarter during the Royalty Term. Within [ * ] after the end of each month during the Royalty Term, Collaborator shall provide to Exelixis a preliminary report setting forth the gross amount of sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory during such month. Within [ * ] after the end of each Calendar Quarter during the Royalty Term, Collaborator shall provide to Exelixis a preliminary report setting forth the estimated Net Sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory during such

Calendar Quarter. Within [ * ] after the end of each Calendar Quarter, Collaborator shall deliver to Exelixis all royalty payments due under Section 8.5. Each such payment shall be accompanied by a final report setting forth the Net Sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory in such Calendar Quarter in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including the number of Products sold, the gross sales and Net Sales of Products, including the deductions from gross sales to arrive at Net Sales, the royalties payable, the method used to calculate the royalties, the exchange rates used, and whether any commercial milestone under Section 8.4 has been achieved. Collaborator shall submit a single report for all Net Sales during the Calendar Quarter, including all of Collaborator's and its Affiliates' and Sublicensees' Net Sales, but shall separately identify the Net Sales and other information applicable to each entity.

**9.2 Exchange Rate; Manner and Place of Payment**. All references to dollars and "$" herein shall refer to U.S. dollars. All payments hereunder shall be payable in U.S. dollars. With respect to conversion of Net Sales in Japanese yen to U.S. dollars, such conversion shall be at the exchange rate equal to the U.S. dollar conversion rate for the Japanese yen as published by [ * ]. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Exelixis, unless otherwise specified in writing by Exelixis.

**9.3 Taxes.**

**(a) Taxes on Income.** Except as otherwise provided in this Section 9.3, each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

**(b) Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding, transfer taxes, or similar obligations with respect to milestone payments, royalty payments, and other payments made by Collaborator to Exelixis under this Agreement. To the extent Collaborator is required by Applicable Laws to deduct and withhold taxes on any payment to Exelixis, Collaborator shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Exelixis an official tax certificate or other evidence of such payment sufficient to enable Exelixis to claim such payment of taxes. Exelixis shall provide Collaborator any tax forms that may be reasonably necessary in order for Collaborator to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, to the extent legally able to do so. Exelixis shall use reasonable efforts to provide any such tax forms to Collaborator in advance of the due date provided that Exelixis may direct Collaborator to temporarily hold a payment otherwise payable in order to avoid withholding taxes if Exelixis is waiting for a required tax form to be issued by a Governmental Authority. Collaborator shall provide Exelixis with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, transfer taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Exelixis. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or

treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

**(c) Taxes Resulting From Collaborator's Action**. Collaborator represents and warrants that, as of the Effective Date, (i) Collaborator is not required by Applicable Law to deduct or withhold taxes on the upfront payment, milestone payments, royalty payments, and other payments payable to Exelixis under this Agreement and (ii) no transfer taxes will be imposed on the foregoing payments under the laws of Japan. If a Party takes any action of its own discretion (i.e., not required by a Regulatory Authority), including any assignment, sublicense, change of place of incorporation, or failure to comply with Applicable Laws or filing or record retention requirements, which results in a withholding or deduction obligation or a transfer tax (the "**Withholding Tax Action**"), then such Party shall pay the sum associated with such Withholding Tax Action. For clarity, if Collaborator undertakes a Withholding Tax Action, then the sum payable by Collaborator (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Exelixis receives a sum equal to the sum that it would have received had no such Withholding Tax Action occurred. Otherwise, the sum payable by Collaborator (in respect of which such deduction or withholding is required to be made) shall be made to Exelixis after deduction of the amount required to be so withheld or deducted. If a change in Applicable Laws results in a withholding or deduction obligation absent either Party taking a Withholding Tax Action, then the amount of such withholding or deduction obligation shall be paid by Collaborator to the applicable Governmental Authority on behalf of Exelixis in accordance with the provisions of Section 9.3(b). The Parties shall use commercially reasonable efforts to invoke the application of any applicable bilateral income tax treaty that would reduce or eliminate otherwise applicable taxes with respect to payments payable pursuant to this Agreement.

**9.4 Records; Audit.** Each Party shall maintain complete and accurate records in sufficient detail in relation to this Agreement to permit the other Party to confirm the accuracy of the amount of Development Costs and the Cost of Goods to be reimbursed or shared, achievement of commercial milestones, and the amount of royalty and other payments under this Agreement. Each Party will keep such books and records for [ * ] following the Calendar Year to which they pertain, or such longer period of time as may be required by Applicable Laws. Upon reasonable prior notice, such records shall be inspected during regular business hours at such place or places where such records are customarily kept by an independent certified public accountant (the "**Auditor**") selected by the auditing Party and reasonably acceptable to the audited Party for the sole purpose of verifying for the auditing Party the accuracy of the financial reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by or to the audited Party pursuant to this Agreement. Before beginning its audit, the Auditor shall execute an undertaking acceptable to each Party by which the Auditor agrees to keep confidential all information reviewed during the audit. Such audits shall be limited to once each Calendar Year and once with respect to records covering any specific period of time. Such auditor shall not disclose the audited Party's Confidential Information to the auditing Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments to or by the audited

Party under this Agreement. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment, the underpaid or overpaid amount shall be settled within [ * ] after the Auditor's report. The auditing Party shall bear the full cost of such audit unless such audit reveals an underpayment of more than [ * ] by the audited Party, in which case the audited Party shall reimburse the auditing Party for the costs of such audit.

**9.5 Late Payments.** In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at [ * ]; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

## 10. Intellectual Property

### 10.1 Ownership.

**(a) Data.** All Data generated in connection with any Development or Commercial activities with respect to any Product conducted by or on behalf of Exelixis and its Affiliates and licensees (other than Collaborator) (the "**Exelixis Data**") shall be the sole and exclusive property of Exelixis or its Affiliates or licensees, as applicable. All Data generated in connection with any Development or Commercial activities with respect to any Product conducted by or on behalf of Collaborator or its Affiliates or Sublicensees (the "**Collaborator Data**") shall be the sole and exclusive property of Collaborator or of its Affiliates or Sublicensees, as applicable. For clarity, each Party shall have access to and the right to use and reference the other Party's Data as and to the extent set forth in this Agreement.

**(b) Inventions.** Inventorship of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. The Parties will work together to resolve any issues regarding inventorship or ownership of Inventions. Ownership of Inventions will be allocated as follows:

**(i)** Exelixis will solely own all data, Inventions, and Patents claiming such Inventions that relate to the composition, manufacture, or use of any Compound, or any improvement of any such composition, manufacture, or use, or are necessary for use in any combination therapy with the Compound produced by either Party or jointly during the Term and in the course of Development or Commercialization of the Product (each, a "**Compound Invention**"). All Compound Inventions will be included in the Exelixis Know-How, and Patents in the Collaborator Territory claiming such Inventions will be included in the Exelixis Patents. To the extent any Compound Invention is made by or on behalf of Collaborator, whether solely or jointly with Exelixis, Collaborator shall, and hereby does, transfer and assign to Exelixis, without additional consideration, all of its interest in such Compound Invention. To effectuate the foregoing assignment by Collaborator to Exelixis, Collaborator shall ensure that its Affiliates and Sublicensees are obligated to assign all such Compound Inventions to Collaborator. In

addition, Exelixis hereby grants to Collaborator a non-exclusive, fully-paid, perpetual, and irrevocable license under such Compound Inventions in the Collaborator Territory for any purpose other than to Develop, use, manufacture, sell, offer for sale, import, or otherwise Commercialize the Compound or Product.

**(ii)** Except for Compound Inventions, each Party shall solely own any Inventions made solely by its and its Affiliates' employees, agents, or independent contractors (the "**Sole Inventions**"), and the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party or its Affiliates together with employees, agents, or independent contractors of the other Party or its Affiliates (the "**Joint Inventions**"). All Patents claiming patentable Joint Inventions shall be referred to herein as "**Joint Patents.**" Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign, and otherwise exploit its interest under the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party.

**10.2 Patent Prosecution and Maintenance**.

**(a) Exelixis Patents.**

**(i)** Subject to this Section 10.2(a), Exelixis shall have the sole right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of the Exelixis Patents (other than Joint Patents) worldwide, using counsel of its own choice in the Exelixis Territory and counsel mutually agreed to by the Parties in the Collaborator Territory. Collaborator shall reimburse Exelixis for all costs and expenses incurred with respect to the preparation, filing, prosecution, and maintenance of Exelixis Patents in the Collaborator Territory after the Effective Date and until the expiration or termination of this Agreement as provided in Section 14.1(a), within [ * ] from the date of invoice for such costs and expenses provided by Exelixis. In the event that Collaborator does not reimburse Exelixis for such costs and expenses for any Exelixis Patent or notifies Exelixis in writing that it elects to cease reimbursing Exelixis for such costs and expenses for any Exelixis Patent, such Patent shall cease to be an Exelixis Patent and shall no longer be subject to the licenses and other rights granted by Exelixis to Collaborator under this Agreement. Exelixis shall keep Collaborator informed of material progress with regard to the preparation, filing, prosecution, and maintenance of Exelixis Patents in the Collaborator Territory, sufficiently in advance for Collaborator to be able to review any material documents, including content, timing, and jurisdiction of the filing of such Exelixis Patents in the Collaborator Territory, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Collaborator with respect to strategies for filing, prosecuting, and defending, if any, Exelixis Patents in the Collaborator Territory.

**(ii)** In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Exelixis Patent in the Collaborator Territory during the Term, Exelixis shall provide reasonable prior written notice to Collaborator of such intention to abandon (which notice shall, to the extent possible, be given no later than [ * ] prior to the next deadline for any action that must be taken with respect to any such Exelixis Patent in the relevant patent office). In such case, upon Collaborator's written election provided no later than [ * ] after such notice from Exelixis, Exelixis shall continue prosecution and maintenance of such Exelixis Patent at Collaborator's direction and expense. If Collaborator does not provide such election within [ * ] after such notice from Exelixis, Exelixis may, in its sole discretion, continue prosecution and maintenance of such Exelixis Patent or discontinue prosecution and maintenance of such Exelixis Patent.

**(b) Collaborator Patents.**

**(i)** Subject to this Section 10.2(b), Collaborator shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings and defense of validity or enforceability challenges) of all Collaborator Patents (other than Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice in the Collaborator Territory and by counsel mutually agreed to by the Parties in the Exelixis Territory. Collaborator shall keep Exelixis informed of the status of filing, prosecution, maintenance and defense, if any, of the Collaborator Patents, and Collaborator shall consult with, and consider in good faith the requests and suggestions of, Exelixis with respect to strategies for filing, prosecuting and defending, if any, Collaborator Patents.

**(ii)** In the event that Collaborator desires to abandon or cease prosecution or maintenance of any Collaborator Patent during the Term, Collaborator shall provide reasonable prior written notice to Exelixis of such intention to abandon (which notice shall, to the extent possible, be given no later than [ * ] prior to the next deadline for any action that must be taken with respect to any such Collaborator Patent in the relevant patent office). In such case, upon Exelixis' written election provided no later than [ * ] after such notice from Collaborator, Exelixis shall have the right to assume prosecution and maintenance of such Collaborator Patent at Exelixis' expense and Collaborator shall assign to Exelixis all of its rights, title, and interest in and to such Collaborator Patent. If Exelixis does not provide such election within [ * ] after such notice from Collaborator, Collaborator may, in its sole discretion, continue prosecution and maintenance of such Collaborator Patent or discontinue prosecution and maintenance of such Collaborator Patent.

**(c) Joint Patents.**

**(i)** Subject to this Section 10.2(c), Exelixis shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary

protection certificates, oppositions, invalidation proceedings and defense of validity or enforceability challenges) Joint Patents using a patent counsel selected by Exelixis in the Exelixis Territory and counsel mutually agreed to by the Parties in the Collaborator Territory. Collaborator shall reimburse Exelixis for all costs and expenses incurred with respect to the preparation, filing, prosecution, and maintenance of Joint Patents in the Collaborator Territory, within [ * ] from the date of invoice for such costs and expenses provided by Exelixis. In the event that Collaborator does not reimburse Exelixis for such costs and expense for any Joint Patent or notifies Exelixis in writing that it elects to cease reimbursing Exelixis for such costs and expense for any Joint Patent, Collaborator shall execute such documents and perform such acts, at Collaborator's expense, as may be reasonably necessary to effect an assignment of Collaborator's entire right, title, and interest in and to such Joint Patent to Exelixis, and such Patent shall cease to be either a Joint Patent or an Exelixis Patent and shall no longer be subject to the licenses and other rights granted by Exelixis to Collaborator under this Agreement. Exelixis shall keep Collaborator informed of material progress with regard to the preparation, filing, prosecution, maintenance, and defense, if any, of Joint Patents, including content, timing, and jurisdiction of the filing of such Joint Patents, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Collaborator with respect to filing, prosecuting and defending, if any, Joint Patents in the Collaborator Territory.

**(ii)** In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Joint Patent in the Collaborator Territory, Exelixis shall provide reasonable prior written notice to Collaborator of such intention to abandon (which notice shall, to the extent possible, be given no later than [ * ] prior to the next deadline for any action that must be taken with respect to any such Joint Patent in the relevant patent office). In such case, at Collaborator's sole discretion, upon written notice from Collaborator to Exelixis, Collaborator may elect to continue prosecution or maintenance of any such Joint Patent at its own expense, and Exelixis shall execute such documents and perform such acts, at Collaborator's expense, as may be reasonably necessary to allow Collaborator to continue the prosecution and maintenance of such Joint Patent in the Collaborator Territory. Any such assignment shall be completed in a timely manner to allow Collaborator to continue prosecution and maintenance of any such Joint Patent and any such Patent so assigned shall cease to be either a Joint Patent or a Collaborator Patent and shall no longer be subject to the licenses and other rights granted by Collaborator to Exelixis under this Agreement.

**(d) Cooperation.** Each Party agrees to cooperate fully in the preparation, filing, prosecution, maintenance, and defense, if any, of Patents under Section 10.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, and their equivalent with respect thereto, at its own cost (except as expressly set forth otherwise in this Article 10). Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 10.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent



[ * ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

application and the obtaining of any patent term extensions, supplementary protection certificates, and their equivalent.

**10.3 Patent Term Extensions in the Collaborator Territory**. The JEC will discuss and recommend for which, if any, of the Patents within the Exelixis Patents, Collaborator Patents, or Joint Patents the Parties should seek patent term extensions in the Collaborator Territory. Exelixis in the case of the Exelixis Patents or any Joint Patents, and Collaborator in the case of the Collaborator Patents, shall have the final decision-making authority with respect to applying for any such patent term extension in the Collaborator Territory, and will act with reasonable promptness in light of the development stage of the Product to apply for any such patent term extension, where it so elects; provided, however, that if in the Collaborator Territory only one such Patent can obtain a patent term extension, then the Parties will consult in good faith to determine which such Patent(s) should be the subject of efforts to obtain a patent term extension. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, for example and without limitation, making available all required regulatory Data and information and executing any required authorizations to apply for such patent term extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks patent term extensions pursuant to this Section 10.3 shall be the sole responsibility of such Party.

**10.4 Patent Enforcement**.

**(a) Notice.** Each Party shall notify the other within [ * ] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Exelixis Patents (including Joint Patents) in the Collaborator Territory, which infringement adversely affects or is expected to adversely affect any Product, including any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement of any of the Exelixis Patents (collectively "**Product Infringement**").

**(b) Enforcement Right.** Exelixis shall have the first right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate. If Exelixis (i) decides not to bring such legal action against a Product Infringement (the decision of which Exelixis shall inform Collaborator promptly) or (ii) Exelixis otherwise fails to bring such legal action against a Product Infringement within [ * ] of first becoming aware of such Product Infringement, Collaborator shall have the right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate after consultation with Exelixis.

**(c) Collaboration.** Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including to be named in such action if required by Applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts, including determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its

own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

**(d) Expense and Recovery.**

**(i)** Except as set forth in clause (ii) below, the enforcing Party shall be solely responsible for any expenses incurred by such Party as a result of such enforcement action. If such Party recovers monetary damages in such enforcement action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the enforcing Party in such enforcement action, second to the reimbursement of any expenses incurred by the other Party in such enforcement action, and any remaining amounts shall be retained by the enforcing Party.

**(ii)** Notwithstanding the foregoing, if Exelixis is the enforcing Party against a Product Infringement in the Collaborator Territory, Collaborator shall have the option to share [ * ] of the expense incurred by Exelixis in such enforcement action, which option may be exercised by Collaborator by providing written notice to Exelixis within [ * ] after receiving a notice from Exelixis that Exelixis decides to bring such action. If Collaborator exercises such option, then (1) Collaborator shall reimburse Exelixis for [ * ] of all expenses incurred by Exelixis in such enforcement action, within [ * ] from the date of invoice for such expenses provided by Exelixis; and (2) If Exelixis recovers any monetary damages in such enforcement action, such recovery shall be allocated [ * ] to Exelixis and [ * ] to Collaborator.

**(e) Other Infringement.** Except for Product Infringement as set forth above, each Party shall have the exclusive right to enforce its own Patent against any infringement anywhere in the world. For clarity, Exelixis shall have the exclusive right to enforce (i) the Exelixis Patents against any infringement in the Collaborator Territory that is not a Product Infringement, and (ii) the Exelixis Patents and Joint Patents against any infringement in the Exelixis Territory, in each case at its own expense as it reasonably determines appropriate. The Parties shall discuss global enforcement strategy for the Exelixis Patents and Collaborator Patents, including the defense of validity and enforceability challenges arising from any enforcement action.

**10.5 Infringement of Third Party Rights.** If any Product used or sold by Collaborator, its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any intellectual property rights in a jurisdiction within the Collaborator Territory, Collaborator shall promptly notify Exelixis and the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Absent any agreement to the contrary, and subject to claims for indemnification under Article 13, each Party shall defend itself from any such Third Party claim at its own cost and expense, provided, however, that the provisions of Section 10.3 shall govern the right of Collaborator to assert a counterclaim of infringement of any Exelixis Patents.

**10.6 Patent Marking.** Collaborator shall, and shall require its Affiliates and Sublicensees, to mark the Products sold by it hereunder (in a reasonable manner consistent with industry custom and practice) with appropriate Patent numbers or indicia to the extent permitted by Applicable Laws; provided, however, that Collaborator shall only be required to so mark such Products to the extent such markings or such notices would impact recoveries of damages or equitable remedies available under Applicable Laws with respect to infringements of Patents in the Collaborator Territory.

**10.7 Patents Licensed From Third Parties**. Each Party's rights under this Article 10 with respect to the prosecution and enforcement of any Exelixis Patent and Collaborator Patent shall be subject to the rights: (a) retained by any upstream licensor to prosecute and enforce such Patent Right, if such Patent Right is subject to an upstream license agreement; and (b) granted to any Third Party prior to such Patent Right becoming subject to the license grant under this Agreement.

**10.8 Trademarks.**

**(a) Product Trademarks.** Exelixis shall develop and adopt trademarks, including trade names, trade dresses, branding, and logos, to be used for the Products (the "**Product Marks**"). Exelixis shall own the Product Marks throughout the world and all goodwill in the Product Marks shall accrue to Exelixis. To the extent permitted by Applicable Laws, the Parties shall use CABOMETYX®, or an equivalent trademark in Japanese, for all indications. Exelixis shall be responsible for the registration, maintenance, defense, and enforcement of the Product Marks using counsel of its own choice in the Exelixis Territory and counsel mutually agreed to by the Parties in the Collaborator Territory. Collaborator shall reimburse Exelixis for all costs and expenses incurred with respect to the registration and maintenance of the Product Marks after the Effective Date in the Collaborator Territory, within [ * ] from the date of invoice for such costs and expenses provided by Exelixis. Exelixis shall keep Collaborator informed of material progress with regard to the registration, prosecution, maintenance, and defense, if any, of Product Marks in the Collaborator Territory, including content and timing of the filing of such Product Marks in the Collaborator Territory, sufficiently in advance for Collaborator to be able to review any material documents, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Collaborator with respect to strategies for filing, prosecuting, and defending, if any, the Product Marks in the Collaborator Territory.

**(b) Trademark License.** Collaborator shall use the Product Marks selected by Exelixis to Commercialize the Product in the Collaborator Territory. Where use of the Product Mark is not permitted by Applicable Laws, the Parties shall agree on an alternative product trademark and such alternative product trademark shall be included as a Product Mark. In addition, unless prohibited by Applicable Laws, Collaborator shall include Exelixis' corporate trademark on the packaging and product information (i.e., SmPC) of the Products sold in the Collaborator Territory to indicate that the Product is licensed from Exelixis. Exelixis hereby grants to Collaborator a limited royalty-free license to use such Product Marks and Exelixis' corporate trademark solely in connection with the Commercialization of the Product in the

Collaborator Territory during the Royalty Term under this Agreement. All use of the Product Marks and Exelixis' corporate trademark shall comply with Applicable Laws and regulations and shall be subject to Exelixis' review and approval. For clarity, Collaborator shall also include its (or its Affiliate's or Sublicensee's) corporate logo in the Product sold in the Collaborator Territory.

## 11. Representations and Warranties

**11.1 Mutual Representations and Warranties**. Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it, and (d) it has the right to grant the licenses granted by it under this Agreement.

**11.2 Covenants**.

**(a) Employees, Consultants, and Contractors**. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign (or, in the case of contractor, grant a license under) Inventions in a manner consistent with the provisions of this Agreement.

**(b) Debarment**. Each Party represents, warrants, and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Sublicensees, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

**(c) Compliance**. Each Party covenants as follows:

**(i)** In the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws.

**(ii)** Each Party and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including such Party (and each Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered, or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift, or hospitality or other illegal or unethical benefit to a Public Official or other entity or any other person in connection with the performance of such Party's obligations under this Agreement, and each Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

**(iii)** Each Party and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not cause its Indemnitees to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws or otherwise cause any reputational harm to the other Party.

**(iv)** Each Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of this Agreement or the Development, manufacture, or Commercialization of any Product.

**(v)** In connection with the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with such Party's own anti-corruption and anti-bribery policy, a copy of which has been provided to the other Party prior to the Effective Date.

**(vi)** Each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to conduct, at its own expense, inspections of and to audit the other Party's books and records in the event of a suspected violation or to ensure compliance with the representations, warranties, or covenants of this Section 11.2(c); provided, however, that in the absence of good cause for such inspections and audits, such Party may only exercise this right on an annual basis.

**(vii)** In the event that either Party has violated or been suspected of violating any of the representations, warranties, or covenants in this Section 11.2(c), the other Party will cause its or its Affiliates' personnel or others working under its direction or control to

submit to periodic training that such violating Party will provide on anti-corruption law compliance.

**(viii)** Either Party will, at the other Party's request, annually certify to the other Party in writing such Party's compliance, in connection with the performance of its obligations under this Agreement, with the representations, warranties, or covenants in this Section 11.2(c), which certification shall be issued by such Party's commercial head of its respective territory.

**(ix)** Each Party shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that the other Party, its Affiliates, or its Sublicensees, in connection with performance of the other Party's obligations under this Agreement, has violated the FCPA.

**11.3 Additional Exelixis Representations, Warranties, and Covenants.** Exelixis represents, warrants, and covenants, as applicable, to Collaborator that, as of the Effective Date:

**(a)** **Exhibit 1.31** lists all Patents Controlled by Exelixis in the Collaborator Territory as of the Effective Date that claim the composition of matter or use of the Compound;

**(b)** Exelixis has the right to grant all rights and licenses it purports to grant to Collaborator with respect to the Exelixis Technology under this Agreement;

**(c)** Exelixis has not granted any liens or security interests on the Exelixis Technology;

**(d)** Exelixis has not received any written notice from a Third Party that the Development of any Product conducted by Exelixis prior to the Effective Date has infringed any Patents of any Third Party;

**(e)** Exelixis has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the Exelixis Technology that would conflict with the rights granted to Collaborator hereunder;

**(f)** no claim or action has been brought or, to Exelixis' knowledge, threatened in writing, by any Third Party alleging that the Exelixis Patents are invalid or unenforceable, and no Exelixis Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

**(g)** to Exelixis' knowledge, no Third Party is infringing or misappropriating or has infringed or misappropriated the Exelixis Technology in the Collaborator Territory;

**(h)** Exelixis has disclosed to Collaborator all clinical and non-clinical data in the Control of Exelixis that is necessary and/or material to the evaluation of the safety, efficacy and manufacturing process of the Product; and

**(i)** to Exelixis' knowledge, there are no issues or information, which to Exelixis' knowledge and reasonable opinion, are reasonably likely to have a material impact on the Development of the Product that have not been fully disclosed to Collaborator in the course of Collaborator's due diligence.

**11.4 Additional Representations, Warranties and Covenants.** Collaborator represents, warrants, and covenants to Exelixis that, as of the Effective Date, Collaborator has not granted, and will not grant during the Term, any right to any Third Party under the Collaborator Technology that would conflict with the rights granted to Exelixis hereunder. Collaborator further represents, warrants, and covenants to Exelixis that, as of the Effective Date, Collaborator does not own or control any Collaborator Patents.

**11.5 Disclaimer.** Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or warrants that any data obtained from conducting Clinical Trials in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted by it pursuant to this Agreement, or the safety or usefulness for any purpose of the technology it provides hereunder.

## 12. Indemnification

**12.1 Indemnification by Exelixis.** Exelixis hereby agrees to defend, indemnify, and hold harmless Collaborator and its Affiliates and their respective directors, officers, employees and agents (each, a "**Collaborator Indemnitee**") from and against any and all liabilities, expenses, and losses, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any Collaborator Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the manufacturing, Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Exelixis or its Affiliates or licensees or the contractors of any of them (excluding any activities by or on behalf of Collaborator or its Affiliates or Sublicensees), (b) the negligence or willful misconduct of any Exelixis Indemnitee, or (c) the breach by Exelixis of any warranty, representation, covenant, or agreement made by Exelixis in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Sections 12.2(a)-(c) for which Collaborator is obligated to indemnify the Exelixis Indemnitee under Section 12.2.

**12.2 Indemnification by Collaborator.** Collaborator hereby agrees to defend, indemnify, and hold harmless Exelixis, its Affiliates, and licensees and their respective directors, officers, employees, and agents (each, an "**Exelixis Indemnitee**") from and against any and all Losses to which any Exelixis Indemnitee may become subject as a result of any claim, demand, action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the manufacturing, Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Collaborator, its Affiliates, or Sublicensees or the contractor of any of them, (b) the negligence or willful misconduct of any Collaborator Indemnitee, or (c) the breach by Collaborator of any warranty, representation, covenant, or agreement made by Collaborator in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Sections 12.1(a)-(c) for which Exelixis is obligated to indemnify the Collaborator Indemnitee under Section 12.1.

**12.3 Procedure.** A party that intends to claim indemnification under this Article 12 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party claim, demand, action, or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate, at its expense and using its own counsel, in the Indemnitor's defense of and settlement negotiations for any Claim. The indemnity arrangement in this Article 12 shall not apply to amounts paid in settlement of any action with respect to a Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 12 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

**12.4 Insurance**. During the Term, each Party, at its own expense, shall maintain commercial general liability insurance, including public and product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

**12.5 Limitation of Liability**. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 13, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, LOST PROFIT OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that the foregoing limitation shall not apply with respect to any amounts that may become payable as a result of Losses arising from a Third Party Claim.

## 13. Confidentiality

**13.1 Confidential Information**. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [ * ] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to Sections 13.2 and 13.3 and 13.4, shall not publish or otherwise disclose the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own of similar nature (but no less than reasonable care) to ensure that its officers, directors, employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

**13.2 Exceptions.** The obligations of confidentiality and restriction on use under Section 13.1 will not apply to any information that the receiving Party can prove by competent evidence: (a) is as of the Effective Date, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public; (b) is known by the receiving Party or its Affiliate at the time of receiving such information hereunder, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the receiving Party or its Affiliate without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by or on behalf of the receiving Party or its Affiliate without the use of Confidential Information belonging to the disclosing Party.

**13.3 Authorized Disclosure.** Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

**(a)** filing, prosecuting, or maintaining Patents as permitted by this Agreement;

**(b)** filing Regulatory Filings for Products that such Party has a license or right to Develop and Commercialize hereunder in a given country or jurisdiction;

**(c)** prosecuting or defending litigation as permitted by this Agreement;

**(d)** complying with Applicable Laws or regulations (including regulations promulgated by securities exchanges) or orders from a court having competent jurisdiction or administrative orders;



[ * ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**(e)** disclosure to potential and actual investors, acquirors, licensees, and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and

**(f)** disclosure to its and its Affiliates' officers, directors, employees, consultants, contractors, and agents, to its licensees and sublicensees, in each case on a need-to-know basis in connection with the Development, manufacture, or Commercialization of the Compound and Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein. For the avoidance of any doubt, Collaborator shall not be permitted to disclose, for any reason, any Confidential Information of Exelixis to [ * ] or [ * ] without Exelixis' prior written consent.

Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 13.3(c) or 13.3(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 13.3(c) or 13.3(d) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 13.

**13.4 Publications.**

**(a)** Each Party shall have the right to review and comment on any material proposed for disclosure or publication by the other Party regarding results of and other information regarding the other Party's Development activities with respect to the [ * ], whether by oral presentation, manuscript, or abstract. Before any such material is submitted for publication, or presentation of any such material is made, the Party disclosing or submitting the proposed publication (the "**Submitting Party**") shall deliver a complete copy of the material proposed for disclosure to the other Party (the "**Responding Party**"), to the extent reasonably practicable, at least [ * ] (for oral presentations or abstracts) or [ * ] (for manuscripts) prior to submitting the material to a publisher or initiating any other disclosure. The Responding Party shall review any such material and give its comments to the Submitting Party within [ * ] (for oral presentations or abstracts) or [ * ] (for manuscripts) of the receipt of such material. Notwithstanding the foregoing, the Parties acknowledge that each Party may require expedited review with respect to oral presentation materials, abstracts, and manuscripts; accordingly, the Responding Party shall make reasonable efforts to expedite review of such materials, abstracts, and manuscripts, and shall return such items as soon as practicable to the Submitting Party with appropriate comments, if any. Following the expiration of the applicable time period for review, the Submitting Party shall be free to submit such proposed publication for publication or otherwise disclose to the public such information, subject to the procedures set forth in Section 13.4(b).

**(b)** If the Responding Party believes that the subject matter of the proposed publication or other disclosure contains Confidential Information or a patentable invention of the Responding Party, then prior to the expiration of the applicable time period for review, the Responding Party shall notify the Submitting Party in writing of its determination that such proposed publication or other disclosure, as applicable, contains such information or subject matter for which patent protection should be sought. Upon receipt of such written notice from the Responding Party, the Submitting Party shall delay public disclosure of such information or submission of the proposed publication for an additional period of [ * ] (or such other time period mutually agreed by the Parties in writing) to permit preparation and filing of a patent application on the disclosed subject matter. The Submitting Party shall thereafter provide the Responding Party with a copy of final version of publication materials and be free to publish or disclose such information, except that the Submitting Party may not disclose any Confidential Information of the Responding Party in violation of Section 13.1.

**13.5 Publicity; Public Disclosures.** The Parties agree to issue a joint press release substantially in a form agreed by the Parties and attached to this Agreement as **Exhibit 13.5** announcing the signature of this Agreement at or shortly after the Effective Date within the time-period required by applicable securities laws. It is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases prior to the issuance thereof, to the extent practicable, provided that a Party may not unreasonably withhold, condition, or delay consent to such releases by more than [ * ], and that either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, as reasonably necessary to comply with laws or regulations or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following the initial joint press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party, and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

**13.6 Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 13. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 13.



[ * ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## 14. Term and Termination

### 14.1 Term.

**(a)** This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 14 or by mutual written agreement of the Parties, shall continue until the expiration of the Royalty Term in the Collaborator Territory (the "**Term**").

**(b)** Notwithstanding anything herein, on a Product-by-Product basis, upon the expiration of the Royalty Term (i.e., all royalty payment obligations for a Product in the Collaborator Territory), the licenses granted to Collaborator in Section 2.1 shall be deemed to be perpetual and fully paid-up with respect to such Product in the Collaborator Territory, but thereafter shall be on a non-exclusive basis.

**(c)** Notwithstanding anything herein, on a Product-by-Product basis, upon the expiration of the Royalty Term the licenses granted to Exelixis in Section 2.4 shall become perpetual and non-exclusive.

### 14.2 Termination for Cause.

**(a) Material Breach**. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach to the reasonable satisfaction of the other Party within [ * ] ([ * ] with respect to any payment breach) after notice of such breach from the non-breaching Party. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such alleged breaching Party provides the other Party notice of such dispute within [ * ], then the other Party shall not have the right to terminate this Agreement under this Section 14.2(a) unless and until an arbitral panel, in accordance with Article 15, has determined that the alleged breaching Party has materially breached the Agreement and that such Party fails to cure such breach within the applicable cure period set forth above following such decision. In the event Exelixis commences an arbitration alleging material breach by Collaborator and Collaborator later delivers notice of voluntary termination under Section 14.3, then, at the election of Exelixis, the period of time set forth in Section 14.3 shall be reduced by an amount of time equal to the duration of time from the commencement of the arbitration to the delivery of such notice, [ * ].

**(b) Bankruptcy**. Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee, or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type

described above and such proceeding is not dismissed within [ * ] after the commencement thereof.

**(c) Patent Challenge**. Exelixis shall have the right to terminate this Agreement immediately in its entirety upon written notice to Collaborator if Collaborator or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Exelixis Patent.

**(d) Safety Reasons**. Either Party shall have the right to terminate this Agreement upon written notice to the other Party if the terminating Party reasonably determines, based upon additional information that becomes available or an analysis of the existing information at any time, that the medical risk/benefit of such Product is so unfavorable that it would be incompatible with the welfare of patients to Develop or Commercialize or to continue to Develop or Commercialize such Product. Prior to any such termination, the terminating Party shall comply with such internal review and management approval processes as it would normally follow in connection with the termination of the development and commercialization of its own products for safety reasons. The terminating Party shall document the decisions of such committees or members of management and the basis therefor and shall make such minutes and documentation available to the other Party promptly upon written request.

**(e) Discontinuation of Clinical Trials.** Collaborator may terminate this Agreement upon [ * ] advance written notice to Exelixis, if substantially all ongoing Clinical Trials of the Product are ordered or required to be terminated by the FDA or the MHLW.

**14.3 Termination without Cause**.

**(a) Prior to Commercial Launch**. At any time prior to August 1, 2023, the Parties may mutually agree that the PMDA is unlikely to grant approval of the MAA for the Product in any cancer indication in the Collaborator Territory. In such event, the Parties may agree to terminate this Agreement by mutual written agreement, such agreement to include a mutually acceptable plan to wind down and terminate the Agreement. Commencing on August 1, 2023, Collaborator shall have the right to terminate the Agreement without cause upon [ * ] prior written notice to Exelixis if the PMDA has not granted approval of the MAA for the Product in any cancer indication in the Collaborator Territory. For the purpose of this Section 14.3(a), if the PMDA grants such MAA Approval conditioned on the performance of additional Phase 3b or other studies, then the PMDA shall be deemed to have granted approval of such MAA. For clarification, this Section 14.3(a) shall not be construed as limiting a right of termination under Section 14.2.

**(b) After Commercial Launch**. Collaborator shall have the right to terminate this Agreement in its entirety without cause upon twelve (12) months' prior written notice after the First Commercial Sale of a Product in the Collaborator Territory; provided, however, that Collaborator may not terminate this Agreement pursuant to this Section 14.3(b)

prior to the third (3rd) anniversary of the First Commercial Sale of such Product in the Collaborator Territory.

**14.4 Effects of Termination (Except By Reason Of Exelixis Material Breach).** Upon any termination of this Agreement by either Party for any reason other than termination under Section 14.2(a) resulting from a material breach of this Agreement by Exelixis, the following will apply: For clarity, during the pendency of any dispute regarding material breach and/or any termination notice period, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

**(a) Licenses**. All licenses granted by Exelixis to Collaborator will automatically terminate, including all sublicenses granted by Collaborator to any Sublicensee. All licenses granted by Collaborator to Exelixis shall survive such termination and shall automatically become worldwide and perpetual.

**(b) Regulatory Materials; Data.** Within [ * ] of the effective date of termination of this Agreement, Collaborator shall transfer and assign to Exelixis, at no cost to Exelixis, all Regulatory Filings and Regulatory Approvals for the Products, Data from all preclinical, non-clinical and clinical studies conducted by or on behalf of Collaborator, its Affiliates, or Sublicensees on the Products, and all pharmacovigilance data (including any adverse events database) on the Products. In the event any Regulatory Filings and/or Regulatory Approval for a Product cannot be transferred to Exelixis within such [ * ] period, Collaborator shall continue to maintain such Regulatory Fillings and/or Regulatory Approval until such time as Collaborator is permitted to transfer such Regulatory Filing or Regulatory Approval to Exelixis. In addition, at Exelixis' request, Collaborator shall provide Exelixis with reasonable assistance with any inquiries and correspondence with Regulatory Filings and Regulatory Authorities regarding the Product in the Collaborator Territory for a period of [ * ] after such termination. Exelixis shall be responsible for Collaborator's reasonable costs incurred directly in connection with any such Exelixis request.

**(c) Development Wind-Down**. Collaborator shall either, as directed by Exelixis, (i) wind-down any ongoing Development activities (including any Clinical Trials) of Collaborator and its Affiliates and Sublicensees with respect to any Product in the Collaborator Territory in an orderly fashion, or (ii) promptly transfer such Development activities to Exelixis or its designee, in compliance with all Applicable Laws.

**(d) Cost of Ongoing Trials.** If there is any ongoing Clinical Trial of the Product under the GDP for which Collaborator has committed to share the costs or be fully responsible for funding, then Collaborator shall continue to share the non-cancelable costs of or fund such Clinical Trial, as the case may be, until [ * ].

**(e) Commercial Wind-Down**. Collaborator shall, as directed by Exelixis, (i) continue certain ongoing Commercial activities of Collaborator and its Affiliates and Sublicensees with respect to any Product in the Collaborator Territory for a period of up to [ * ]

as determined by Exelixis, and (ii) handoff such Commercial activities to Exelixis or its designee, on a timetable to be set by Exelixis, not to exceed [ * ], and in compliance with all Applicable Laws. During such commercial wind-down period, Collaborator shall continue to book sales and pay royalties to Exelixis in accordance with Section 8.5. Except as necessary to conduct the foregoing activities as directed by Exelixis, Collaborator shall immediately discontinue its (and shall ensure that its Affiliates and Sublicensees immediately discontinue their) promotion, marketing, offering for sale, and servicing of the Product and its use of all Product Marks. In addition, Collaborator shall immediately deliver to Exelixis (at Collaborator's expense) all samples, demonstration equipment, sales materials, catalogs, and literature of Exelixis in Collaborator's possession or control.

**(f) Transition Assistance.** Collaborator shall use Commercially Reasonable Efforts to seek an orderly transition of the Development and Commercialization of the Compound and Products to Exelixis or its designee for so long as is necessary to ensure patient safety, including ensuring continuity of supply to any patients. Collaborator shall, at no cost to Exelixis, provide reasonable consultation and assistance for a period of no more than [ * ] after termination for the purpose of transferring or transitioning to Exelixis all Collaborator Know-How not already in Exelixis' possession and, at Exelixis' request, all then-existing commercial arrangements relating to the Products that Collaborator is able, using Commercially Reasonable Efforts, to transfer or transition to Exelixis or its designee, in each case, to the extent reasonably necessary or useful for Exelixis to continue the Development and/or Commercialization of the Compound and Products in the Collaborator Territory. If any such contract between Collaborator and a Third Party is not assignable to Exelixis or its designee (whether by such contract's terms or because such contract does not relate specifically to the Products) but is otherwise reasonably necessary or useful for Exelixis to continue the Development and/or Commercialization of the Compound and Products in the Collaborator Territory, or if Collaborator is performing such work for the Compound and Product itself (and thus there is no contract to assign), then Collaborator shall reasonably cooperate with Exelixis to negotiate for the continuation of such services for Exelixis from such entity, or Collaborator shall continue to perform such work for Exelixis, as applicable, for a reasonable period (not to exceed [ * ]) after termination at Exelixis' cost until Exelixis establishes an alternate, validated source of such services.

**(g) Remaining Inventories.** Exelixis shall have the right, at its discretion, to purchase from Collaborator any or all of the inventory of the Products held by Collaborator as of the date of termination at a price equal to the transfer price paid by Collaborator to acquire such inventory from Exelixis. Exelixis shall notify Collaborator within [ * ] after the date of termination whether Exelixis elects to exercise such right.

**(h) Non-Compete**. Following any termination of this Agreement by Collaborator pursuant to Section 14.3(b), or by Exelixis pursuant to Section 14.2, neither Collaborator nor any of its Affiliates shall (directly or indirectly, either with or without a bona fide Collaborator or any other Third Party) (i) develop any Competing Product in the Collaborator Territory for a period of [ * ] following the effective date of such termination, or (ii)

commercialize any Competing Product in the Collaborator Territory for a period of [ * ] following the effective date of such termination.

**(i) No Generic Product.** Following any termination of this Agreement by Collaborator pursuant to Section 14.3(b) or by Exelixis pursuant to Section 14.2, neither Collaborator nor any of its Affiliates shall (directly or indirectly, either with or without a bona fide Collaborator or any other Third Party) (i) develop any Generic Product in the Collaborator Territory for a period of [ * ] following the effective date of such termination or (ii) commercialize any Generic Product in the Collaborator Territory for a period of [ * ] following the effective date of such termination.

**14.5 Effect of Termination (Material Breach by Exelixis).** Upon any termination of this Agreement by Collaborator pursuant to Section 14.2(a) resulting from a material breach of this Agreement by Exelixis, then all of the provisions of Section 14.4 shall apply, except that (1) Sections 14.4 (d), (h) and (i) shall have no effect, and (2) to the extent Exelixis requests Collaborator's performance under any of the provisions of Sections 14.4 (b), (c), (e), (f) or (g), Exelixis shall reimburse Collaborator for all costs incurred by Collaborator in connection with such performance, including both its external costs plus its internal costs calculated on a reasonable FTE basis. For clarity, while Collaborator shall not be subject to Section 14.4(d) in such event, it shall remain subject to Section 14.4(c) subject to the reimbursement of costs by Exelixis.

**14.6 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

**14.7 Confidential Information.** Upon expiration or termination of this Agreement in its entirety, except to the extent that a Party obtains or retains the right to use the other Party's Confidential Information, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential

Information of the other Party; provided that a Party may keep one copy of such materials for archival purposes subject to continuing confidentiality obligations and other copies to the extent necessary for complying with Applicable Laws. All Collaborator Data and Regulatory Filings assigned to Exelixis upon termination of this Agreement will be deemed Exelixis' Confidential Information and no longer Collaborator's Confidential Information.

**14.8 Additional Remedies.** In case of termination by reason of either Party's material breach, unless otherwise expressly provided in the Agreement, the termination under this Article 14 will not be an exclusive remedy for the terminating Party, and will not preclude, limit, nor be in lieu of any other remedies available to the terminating Party under this Agreement or Applicable Laws as a result of any material breach by the other Party.

**14.9 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement to the extent that the subject matter of such provision exists: Article 1 (Definitions); Article 9 (Payments, Records, Audits); Article 12 (Indemnification); Article 15 (Dispute Resolution); Article 16 (General Provisions); Section 2.5 (No Implied Licenses; Negative Covenant); Section 5.10 (Sunshine Reporting Laws); Section 10.1 (IP Ownership); Section 10.2(c) (Joint Patent Prosecution); Sections 13.1, 13.2, 13.3 and 13.6 (Confidentiality); Sections 14.1(b) and (c) (Term; in each case to the extent applicable); Sections 14.4 and 14.5 (Effects of Termination, in each case to the extent applicable); Section 14.6 (Rights in Bankruptcy; to the extent applicable); Section 14.7 (Confidentiality); Section 14.8 (Additional Remedies); and Section 14.9 (Survival).

## 15. Dispute Resolution

**15.1 Objective.** The Parties recognize that disputes as to matters arising under, in connection with or relating to this Agreement or either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient and amicable manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 15 to resolve any such dispute if and when it arises.

**15.2 Executive Mediation**. The Parties will try to settle any dispute, controversy, or claim that arises out of, in connection with or relates to, any provision of the Agreement ("**Disputed Matter**") by first referring the Disputed Matter to the Parties' Executive Officers. Either Party may initiate such informal dispute resolution by sending written notice of the Disputed Matter to the other Party, and, within [ * ] after such notice, the Executive Officers (or their respective designees having the authority to settle such Disputed Matter) of the Parties will meet for attempted resolution by good faith negotiations. If the Executive Officers (or their respective designees) are unable to resolve such dispute within [ * ] of their first meeting for such negotiations, either Party may seek to have such dispute resolved in accordance with Section 15.3 below.

**15.3 Dispute Resolution.**

**(a)** If the Parties are unable to resolve a Disputed Matter using the process described in Section 15.2, then a Party seeking further resolution of the Disputed Matter will submit the Disputed Matter to resolution by final and binding arbitration. Whenever a Party will decide to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in [ * ], and administered by the International Chamber of Commerce pursuant to its ICC International Arbitration Rules then in effect (the "**Rules**"), except as otherwise provided herein and applying the substantive law specified in Section 16.1. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with the Rules; provided that each Party will, within [ * ] after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within [ * ], select a third (3rd) arbitrator as the chairman of the arbitration panel. Each arbitrator must have significant business or legal experience in the pharmaceutical business. If the two (2) initial arbitrators are unable to select a third (3rd) arbitrator within such [ * ] period, the third (3rd) arbitrator will be appointed in accordance with Rules. In addition to the authority conferred by the Rules, the Parties hereby agree to engage in discovery of information and evidence that is or might be relevant to the claims, defenses, and issues in the dispute, including by means of discovery in the form of [ * ], subject to [ * ] being permitted by the panel of arbitrators on a showing of good cause. The Parties further agree to the ability, right, and power to subpoena Third Party witnesses for both discovery and hearing purposes. After conducting any hearing and taking any evidence deemed appropriate for consideration, the arbitrators will render their opinion within [ * ] of the final arbitration hearing. The panel of arbitrators will not have the power to award damages excluded pursuant to Section 12.5 under this Agreement and any arbitral award that purports to award such damages is expressly prohibited and void ab initio. Decisions of the panel of arbitrators that conform to the terms of this Section 15.3 will be final and binding on the Parties and judgment on the award so rendered may be entered in any court of competent jurisdiction. The losing Party, as determined by the panel of arbitrators, will pay all of the ICC administrative costs and fees of the arbitration and the fees and costs of the arbitrators, and the arbitrators will be directed to provide for payment or reimbursement of such fees and costs by the losing Party. If the panel of arbitrators determines that there is no losing Party, the Parties will each be responsible for one-half of those costs and fees and the arbitrators' award will so provide. Notwithstanding the foregoing, each Party shall be responsible for its own attorneys' fees, expert or witness fees, and any other fees and costs, and no such fees or costs will be shifted to the other Party.

**(b)** Notwithstanding the terms of and procedures set forth in Section 15.2 or 15.3, any applications, motions, or orders to show cause seeking temporary restraining orders, preliminary injunctions or other similar preliminary or temporary legal or equitable relief ("**Injunctive Relief**") concerning a Disputed Matter (including, but not limited to, Disputed Matters arising out of a potential or actual breach of the confidentiality and non-use provisions in Article 13) may immediately be brought in the first instance and without invocation or exhaustion of the procedures set forth in subsections (a) and (b) for hearing and resolution in and by a court of competent jurisdiction. Alternatively, a party seeking Injunctive Relief may

immediately institute arbitral proceedings without invocation or exhaustion of the procedures set forth in subsections (a) and (b), and any such Injunctive Relief proceedings will be administered by the ICC pursuant to its ICC emergency arbitration procedures then in effect and applying the substantive law specified in Section 16.1. In either event, once the Injunctive Relief proceedings have been conducted and a decision rendered thereon by the court or arbitral forum, the Parties will, if the Disputed Matter is not finally resolved by the Injunctive Relief, proceed to resolve the Disputed Matter in accordance with the terms of Section 15.2 and 15.3.

**(c)** Notwithstanding the foregoing, this Section 15.3 shall not apply to any dispute, controversy, or claim that concerns (i) the validity, enforceability, or infringement of a patent, trademark, or copyright; or (ii) any antitrust, anti-monopoly, or competition law or regulation, whether or not statutory.

## 16. General Provisions

**16.1 Governing Law.** This Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, United States, without reference to its conflicts of law principles.

**16.2 Entire Agreement; Modification.** This Agreement, including the exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

**16.3 Relationship Between the Parties.** The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

**16.4 Waiver.** The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. Any waiver by a Party of a particular term or condition will be effective only if set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition.

**16.5 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably

withheld); provided, however, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent:

**(a)** in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to the Compound and Products to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets, or otherwise, provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring Party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder; or

**(b)** to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 16.5. Any assignment not in accordance with this Section 16.5 shall be null and void and of no legal force or effect.

**16.6 Severability.** If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. The Parties will in such an instance use their best efforts to replace the invalid, unenforceable, or illegal provision(s) with valid, enforceable, and legal provision(s) that implement the purposes of this Agreement.

**16.7 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) overnight courier by FedEx or DHL, or (b) facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this Section 16.7. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of delivery; or (ii) if sent by facsimile, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next Business Day.

If to Collaborator, notices must be addressed to:

Takeda Pharmaceutical Company Limited
12-10, Nihonbashi 2-chome, Chuo-ku
Tokyo 103-8668, JAPAN
Attention: [ * ]
Facsimile: +[ * ]



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with a copy to:

Takeda Pharmaceutical Company Limited
12-10, Nihonbashi 2-chome, Chuo-ku
Tokyo 103-8668, JAPAN
Attention: [ * ]
Facsimile: +[ * ]

Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN
Attention: [ * ]

If to Exelixis, notices must be addressed to:

Exelixis, Inc.
210 East Grand Avenue,
So. San Francisco, CA 94080
USA
Attention: General Counsel
Facsimile: +[ * ]

**16.8 Standstill.**

**(a)** Commencing the Effective Date and expiring on the fifth ($5^{th}$) anniversary date of the Effective Date, unless such provision is terminated earlier by mutual written agreement of the Parties (the "**Standstill Period**"), neither Collaborator nor any of its Affiliates, without the prior consent of Exelixis or except as provided for in this Agreement or in any agreement referred to herein, or in any agreement executed after the Effective Date by Exelixis with Collaborator or any of its Affiliates, will:

**(i)** make, effect, initiate, cause or participate in:

**(1)** any acquisition of beneficial ownership of any securities of Exelixis or any securities of any subsidiary or other Affiliate of Exelixis (each, a "**Exelixis Entity**") such that following any such acquisition, Collaborator and its Affiliates then own more than [ * ] of the securities of such Exelixis Entity;

**(2)** any acquisition of any assets of any Exelixis Entity;

**(3)** any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving an Exelixis Entity, or involving any securities or assets of a Exelixis Entity; or

**(4)** any "solicitation" of "proxies" (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of an Exelixis Entity;

**(ii)** form, join, or participate in a "group" (as defined in the Securities Exchange Act of 1934 and the rules promulgated thereunder) with respect to the beneficial ownership of any securities of an Exelixis Entity;

**(iii)** act, alone or in concert with others, to seek to control or influence the management, board of directors, or policies of an Exelixis Entity;

**(iv)** take any action that might require an Exelixis Entity to make a public announcement regarding any of the types of matters set forth in clause "(i)" of this Section 16.8(a);

**(v)** agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in clause "(i)", "(ii)", "(iii)" or "(iv)" of this Section 16.8(a);

**(vi)** assist, induce or encourage any other person or entity to take any action of the type referred to in clause "(i)", "(ii)", "(iii)", "(iv)" or "(v)" of this Section 16.8(a); or

**(vii)** enter into any discussions, negotiations, arrangement, or agreement with any other person or entity relating to any of the foregoing.

For clarity, the expiration of the Standstill Period will not terminate or otherwise affect any of the other provisions of this Agreement.

**(b)** Notwithstanding the foregoing provisions, Collaborator or its Affiliates will not be subject to any of the restrictions set forth in this Section 16.8 with respect to an Exelixis Entity if either:

**(i)** such Exelixis Entity publicly announces its intention to pursue a proposed Acquisition Transaction (as defined below);

**(ii)** such Exelixis Entity shall have entered into an agreement in principle or definitive agreement providing for an Acquisition Transaction;

**(iii)** the board of directors of such Exelixis Entity shall have adopted a formal plan of liquidation or dissolution;

**(iv)** if a Third Party commences a tender or exchange offer or bid which, if successful, would result in such Third Party beneficially owning not less than [ * ] of the voting securities or equity interest in such Exelixis Entity; or

**(v)** if a Third Party makes a public announcement of a bona fide takeover bid to acquire the outstanding voting securities or equity interest in such Exelixis Entity.

"**Acquisition Transaction**" means (A) any direct or indirect acquisition or purchase of assets of the applicable Exelixis Entity at a purchase price representing [ * ] of the voting securities of or equity interest in such Exelixis Entity by any person or "group"; (B) any tender offer or exchange offer that if consummated would result in any person or "group" beneficially owning [ * ] or more of any class of equity securities of such Exelixis Entity; or (C) any merger, consolidation, business combination, sale of assets, recapitalization, or similar transaction involving such Exelixis Entity representing more than [ * ] of the market capitalization of such Exelixis Entity.

**(c)** Notwithstanding the foregoing, the Parties agree that Collaborator or its Affiliates shall not be prohibited from (i) initiating private discussions with, and submitting confidential private proposals to, the management or Chief Executive Officer of any Exelixis Entity; or (ii) proposing other collaborative research agreements or other commercial license agreements to Exelixis.

**16.9 Force Majeure.** Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control, including Acts of God, fire, flood, explosion, earthquake, tsunami, pandemic flu, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of electricity, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [ * ] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

**16.10 Interpretation.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to

exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

**16.11 Counterparts; Electronic or Facsimile Signatures.** This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

**{Signature Page Follows}**



[ * ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**In Witness Whereof,** the Parties hereto have caused this **COLLABORATION AND LICENSE AGREEMENT** to be executed and entered into by their duly authorized representatives as of the Effective Date.

| **EXELIXIS, INC.** | **TAKEDA PHARMACEUTICAL COMPANY LIMITED** |
|---|---|
| By: /s/ Michael M. Morrissey | By: /s/ Tsudoi Miyoshi |
| Name: Michael M. Morrissey, Ph.D. | Name: Tsudoi Miyoshi |
| Title: President and Chief Executive Officer | Title: Head of Japan Oncology Business Unit |



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**List of Exhibits:**

**Exhibit 1.2: Chemical Structure of cabozantinib**

**Exhibit 1.31: Exelixis Patents**

**Exhibit 4.2: Initial Global Development Plan and Budget**

**Exhibit 13.5: Press Release**



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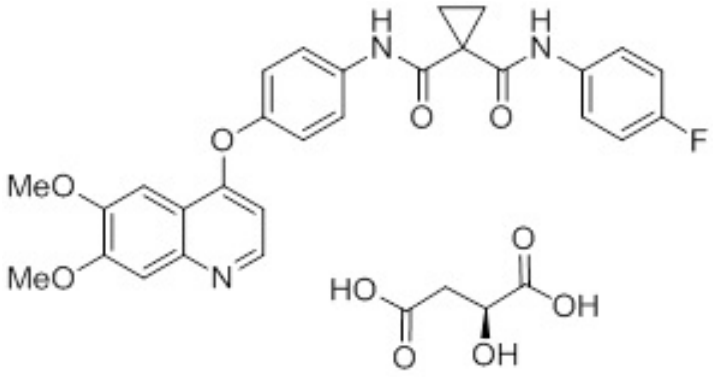
**Exhibit 1.2**
**Chemical Structure of cabozantinib**




**Cabozantinib (*S*)-malate salt**



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**Exhibit 1.31**
**Exelixis Patents**

{Redacted content comprises approximately 4 pages}
**[ * ]**


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**Exhibit 4.2**
**Initial Global Development Plan and Budget**

{Redacted content comprises approximately 6 pages}

**[ * ]**



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**Press Release**

**EXELIXIS AND TAKEDA ENTER INTO EXCLUSIVE LICENSING AGREEMENT TO COMMERCIALIZE AND DEVELOP NOVEL CANCER THERAPY CABOZANTINIB IN JAPAN**

***– Takeda's Rights to Include all Potential Indications for Cabozantinib, which is Marketed in the U.S. and European Union for Renal Cell Carcinoma and Medullary Thyroid Carcinoma –***
***– Exelixis Receives $50 Million Upfront Payment and is Eligible for Future Regulatory and Commercial Milestones –***

**South San Francisco, Calif., Cambridge, Mass. and Osaka, Japan – January 30 (PST) and (EST/JST), 2017 –** Exelixis, Inc. (NASDAQ: EXEL) and Takeda Pharmaceutical Company Limited (TSE:4502) today announced an exclusive licensing agreement for the commercialization and further clinical development in Japan of cabozantinib, Exelixis' lead oncology medicine. With the signing of the agreement, Takeda gains exclusive commercial rights for all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma (RCC), for which cabozantinib is marketed in the United States and European Union as CABOMETYX™ tablets. The two companies will collaborate on the future clinical development of cabozantinib in Japan.

Under the terms of the agreement, Exelixis will receive a $50 million upfront payment. Exelixis is eligible to receive development, regulatory, and first-sales milestones of $95 million for the first three planned indications. In addition, Exelixis will be eligible to receive royalties on sales by Takeda.

"As an organization with a strong focus on oncology innovation, our agreement with Exelixis brings a promising and well-studied solid-tumor therapy to our pipeline that may help patients in Japan suffering from RCC and potentially other equally devastating cancers," said Tsudoi Miyoshi, Head of Japan Oncology Business Unit of Takeda. "We intend to pursue regulatory approval for RCC indications as soon as we're able, and look forward to commencing the local clinical trial program to further strengthen the clinical profile of cabozantinib."

Exelixis and Takeda will partner on cabozantinib's clinical development in Japan and on translating existing and forthcoming clinical data for potential regulatory filings in the country. In the METEOR pivotal trial, cabozantinib demonstrated statistically significant improvements in overall survival, progression-free survival and objective response rate, meaningfully differentiating it from other therapies to treat advanced renal cell carcinoma following prior therapy. In addition to advanced RCC, future indications could include advanced hepatocellular cancer (HCC), the subject of the CELESTIAL global pivotal trial for which results are anticipated in 2017. Additional earlier-stage studies are under way through Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program, and its ongoing Investigator-Sponsored Trial program. Through these two programs, there are more than 45 ongoing or planned studies including trials in advanced RCC, bladder cancer, colorectal cancer, non-small cell lung cancer, and endometrial cancer.

"Takeda is the ideal partner to advance cabozantinib in Japan and deliver this important treatment option to Japanese patients with cancer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Takeda is widely respected for both its clinical development and commercial expertise. We look



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forward to supporting our new partner as it pursues Japanese regulatory approval for cabozantinib, while simultaneously working together to plan the next steps for clinical development in the country. This agreement further propels the global progress for cabozantinib development and commercialization, which now includes the recent first commercial sale of CABOMETYX in the United Kingdom, triggering a $10 million milestone payment from Ipsen to Exelixis."

Cabozantinib is not approved for use in Japan. Previously, Exelixis and its collaborators conducted early-stage clinical trials in Japan, including a phase 1 trial in advanced solid tumors. Data from this trial were presented at the European Society for Medical Oncology 2012 Congress and the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

Exelixis maintains its exclusive rights to develop and commercialize cabozantinib in the United States, and its partner Ipsen maintains its exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States and Japan.

**About CABOMETYX™ (cabozantinib) Tablets**
CABOMETYX is the tablet formulation of cabozantinib. Its targets include MET, AXL, and VEGFR-1, -2 and -3. In preclinical models, cabozantinib has been shown to inhibit the activity of these receptors, which are involved in normal cellular function and pathologic processes such as tumor angiogenesis, invasiveness, metastasis, and drug resistance.

CABOMETYX is available in 20 mg, 40 mg or 60 mg doses. The recommended dose is 60 mg orally, once daily.

On April 25, 2016, the FDA approved CABOMETYX tablets for the treatment of patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy. On September 9, 2016, the European Commission approved CABOMETYX tablets for the treatment of advanced renal cell carcinoma in adults who have received prior vascular endothelial growth factor (VEGF)-targeted therapy in the European Union, Norway and Iceland. On February 29, 2016, Exelixis and Ipsen jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib indications outside of the United States, Canada and Japan. On December 20, 2016, Exelixis and Ipsen jointly announced an amendment to their exclusive licensing agreement for the commercialization and development of cabozantinib to include Canada.

**U.S. Important Safety Information**

**Hemorrhage**: Severe hemorrhage occurred with CABOMETYX. The incidence of Grade ≥3 hemorrhagic events was 2.1% in CABOMETYX-treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETYX to patients that have or are at risk for severe hemorrhage.

**Gastrointestinal (GI) Perforations and Fistulas:** Fistulas were reported in 1.2% (including 0.6% anal fistula) of CABOMETYX-treated patients and 0% of everolimus-treated patients. GI perforations were reported in 0.9% of CABOMETYX-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms of fistulas and perforations. Discontinue CABOMETYX in patients who experience a fistula that cannot be appropriately managed or a GI perforation.


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**Thrombotic Events:** CABOMETYX treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

**Hypertension and Hypertensive Crisis:** CABOMETYX treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥3) of CABOMETYX-treated patients and 7.1% (3.1% Grade ≥3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

**Diarrhea:** Diarrhea occurred in 74% of patients treated with CABOMETYX and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of CABOMETYX-treated patients and in 2% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 diarrhea or Grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

**Palmar-Plantar Erythrodysesthesia Syndrome (PPES):** Palmar-plantar erythrodysesthesia syndrome (PPES) occurred in 42% of patients treated with CABOMETYX and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX-treated patients and in <1% of everolimus-treated patients. Withhold CABOMETYX in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume CABOMETYX at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS):** RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

**Embryo-fetal Toxicity:** CABOMETYX can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the last dose.

**Adverse Reactions:** The most commonly reported (≥25%) adverse reactions are: diarrhea, fatigue, nausea, decreased appetite, PPES, hypertension, vomiting, weight decreased, and constipation.

**Drug Interactions: Strong CYP3A4 inhibitors and inducers:** Reduce the dosage of CABOMETYX if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Increase the dosage of CABOMETYX if concomitant use with strong CYP3A4 inducers cannot be avoided.

**Lactation:** Advise a lactating woman not to breastfeed during treatment with CABOMETYX and for 4 months after the final dose.

**Reproductive Potential: Contraception—**Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX and for 4 months after the final dose. Infertility —CABOMETYX may impair fertility in females and males of reproductive potential.

**Hepatic Impairment:** Reduce the CABOMETYX dose in patients with mild (Child-Pugh score [ * ] A) or moderate (C-P B) hepatic impairment. CABOMETYX is not recommended for use in patients with severe hepatic impairment.

**Please see full Prescribing Information at https://cabometyx.com/downloads/cabometyxuspi.pdf.**

**About Takeda Pharmaceutical Company**
Takeda Pharmaceutical Company Limited is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its R&D efforts on oncology, gastroenterology and central nervous system therapeutic areas plus vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as our presence in Emerging Markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Oncology, the brand for the global oncology business unit of Takeda Pharmaceutical Company Limited, is available through its website, www.takedaoncology.com.

**About Exelixis**
Exelixis, Inc. (Nasdaq: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S. and EU) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

**Exelixis Forward-Looking Statements**
This press release contains forward-looking statements, including, without limitation, statements related to: the future clinical development of cabozantinib by Exelixis and Takeda in Japan; Exelixis' receipt of a $50 million upfront payment; Exelixis' eligibility to receive development, regulatory and first-sales milestones of $95 million for the first three planned indications; Exelixis' eligibility to receive royalties on sales of cabozantinib by Takeda; the clinical and therapeutic potential of cabozantinib for patients in Japan suffering from RCC and potentially other cancers; Takeda's intent to pursue regulatory approval for cabozantinib in RCC indications and commence a local clinical trial program; Exelixis' and Takeda's plan to translate existing and forthcoming clinical data for potential regulatory filings in Japan; advanced HCC as a potential future



[ * ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

commercial indication; the timing of anticipated results from CELESTIAL; the continued development of cabozantinib through Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program, and its ongoing Investigator-Sponsored Trial program; Exelixis' intent to support Takeda as it pursues Japanese regulatory approval for cabozantinib, while simultaneously working together to plan the next steps for clinical development in Japan; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "potential," "further," "will," "eligible," "planned," "may," "intend," "look forward," "future," "could," "anticipated," "next," "committed," "focused," or other similar expressions identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the complexities and challenges associated with regulatory review and approval processes; Exelixis' dependence on its relationship with Takeda, including, the level of Takeda's investment in the resources necessary to successfully commercialize cabozantinib in Japan; the degree of market acceptance of CABOMETYX and the availability of coverage and reimbursement for CABOMETYX; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationship with other collaborators, including Ipsen with respect to cabozantinib in territories outside of the United States and Japan and Genentech/Roche with respect to cobimetinib; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; changes in economic and business conditions, and other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 3, 2016, and in Exelixis' future filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.


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[ * ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Exhibit 31.1**

**CERTIFICATION**

I, Michael M. Morrissey, Ph.D., certify that:

1. I have reviewed this Form 10-Q/A of Exelixis, Inc.; 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.

/s/ MICHAEL M. MORRISSEY

**Michael M. Morrissey, Ph.D.**

President and Chief Executive Officer
(Principal Executive Officer)

Date: July 14, 2017

**Exhibit 31.2**

**CERTIFICATION**

I, Christopher J. Senner, certify that:

1. I have reviewed this Form 10-Q/A of Exelixis, Inc.; 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.

/s/ CHRISTOPHER J. SENNER

**Christopher J. Senner**

Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: July 14, 2017