Licensing agreement for PI3K-delta research and development program, including XL499

Merck and Co
Exelixis

Dec 21 2011
Licensing agreement for PI3K-delta research and development program, including XL499

Companies:  
Merck and Co  
Exelixis

Announcement date:  
Dec 21 2011

Deal value, US$m:  
251.0 : sum of upfront and milestone payments

Details

Financials

Deal value, US$m:  
251.0 : sum of upfront and milestone payments

Upfront, US$m:  
12.0 : upfront payment

Milestones, US$m:  
239.0 : eligible for potential development and regulatory milestone payments for multiple indications

n/d : eligible for potential combined sales performance milestones

Royalty rates, %:  
n/d : royalties on net-sales of products emerging from the agreement

Termsheet

Exelixis has granted to Merck an exclusive worldwide license to its PI3K-delta research and development program, including XL499, the company’s most advanced preclinical PI3K-delta inhibitor and other related compounds.

Merck will have a worldwide exclusive license and have sole responsibility to research, develop, and commercialize compounds originating from the program.

Merck will make an upfront payment of $12 million to Exelixis and Exelixis will be eligible for potential development and regulatory milestone payments for multiple indications of up to $239 million.
Exelixis will also be eligible for potential combined sales performance milestones and royalties on net-sales of products emerging from the agreement.

Milestones and royalties are payable on compounds emerging from Exelixis’ PI3K-delta program or from certain compounds that arise from Merck’s internal discovery efforts targeting PI3K-delta during a certain period.

**Press Release**

Exelixis Licenses PI3K-Delta Program to Merck

Exelixis to receive $12M upfront payment and be eligible for potential development, regulatory and commercial milestones, plus royalties

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Exelixis, Inc. (NASDAQ:EXEL) today announced that it has granted to Merck, known as MSD outside of the United States and Canada, an exclusive worldwide license to its PI3K-delta research and development program, including XL499, the company’s most advanced preclinical PI3K-delta inhibitor and other related compounds. Under the agreement, Merck will have a worldwide exclusive license and have sole responsibility to research, develop, and commercialize compounds originating from the program.

Merck will make an upfront payment of $12 million to Exelixis and Exelixis will be eligible for potential development and regulatory milestone payments for multiple indications of up to $239 million. Exelixis will also be eligible for potential combined sales performance milestones and royalties on net-sales of products emerging from the agreement. Milestones and royalties are payable on compounds emerging from Exelixis’ PI3K-delta program or from certain compounds that arise from Merck’s internal discovery efforts targeting PI3K-delta during a certain period.

“PI3K-delta is an interesting target with potential utility in a number of therapeutic areas, including inflammation and oncology,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “Our PI3K-delta program builds on our prior interest in the PI3K family, which led to the advancement of pan-PI3K inhibitors into clinical development for cancer. Merck’s global presence and significant resources make it the ideal organization to carry the PI3K-delta program forward. At the same time, this agreement provides Exelixis with resources for the continued development and potential commercialization of our lead compound, cabozantinib, which is in late-stage development for medullary thyroid and prostate cancers.”

“Exelixis has established a strong reputation for innovation in the development of targeted kinase inhibitors,” said Don Nicholson, Ph.D., Vice President and Head of Worldwide Discovery, Respiratory and Immunology Franchise, Merck Research Laboratories. “Collaborations like this are an important part of our strategy as we seek new ways to address unmet needs in inflammatory disease and oncology.”

PI3K-delta is a member of the Class 1 family of phosphoinositide-3 kinases and is predominantly expressed in cells of the immune system. Activation of PI3K-delta occurs in response to a variety of immune cell stimuli, and inappropriate PI3K-delta activation is thought to contribute to multiple inflammatory and allergic disorders, including rheumatoid arthritis and allergic asthma. Selectively targeting PI3K-delta has also shown potential in the treatment of certain lymphomas.

About Exelixis

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapeutics for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on cabozantinib, its most advanced solely-owned product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis believes cabozantinib has the potential to be a high-quality, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs. For more information, please visit the company’s web site at www.exelixis.com.

Filing Data

10K abstract - 2013

In December 2011, we entered into an agreement with Merck pursuant to which we granted Merck an exclusive worldwide license to our PI3K-delta, or PI3K-d, program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck has sole responsibility to research, develop, and commercialize compounds from our PI3K-d program. The agreement became effective in December 2011.

Merck paid us an upfront cash payment of $12.0 million in January 2012 in connection with the agreement. We will be eligible to receive payments associated with the successful achievement of potential development and regulatory milestones for multiple indications of up to $239.0 million. We will also be eligible to receive payments for combined sales performance milestones and royalties on net-sales of products emerging from the agreement. Contingent payments associated with milestones achieved by Merck and royalties are payable on compounds emerging from our PI3K-d program or from certain compounds that arise from Merck’s internal discovery efforts targeting PI3K-d during a certain period.

Merck may at any time, upon specified prior notice to us, terminate the license. In addition, either party may terminate the agreement for the other party’s uncured material breach. In the event of termination by Merck at will or by us for Merck’s uncured material breach, the license
granted to Merck would terminate. In the event of a termination by us for Merck’s uncured material breach, we would receive a royalty-free license from Merck to develop and commercialize certain joint products. In the event of termination by Merck for our uncured material breach, Merck would retain the licenses from us, and we would receive reduced royalties from Merck on commercial sales of products.

**Contract**

EXCLUSIVE LICENSE AGREEMENT

between

MERCK SHARP & DOHME CORP.

and

EXELIXIS, INC.

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EXCLUSIVE LICENSE AGREEMENT

THIS AGREEMENT is effective as of December 21, 2011 (the “Effective Date”) between Merck Sharp & Dohme Corp., a corporation organized and existing under the laws of New Jersey (“MERCK”), and Exelixis, Inc., a corporation organized and existing under the laws of Delaware (“EXELIXIS”).

RECITALS:

WHEREAS, EXELIXIS has developed EXELIXIS Technology (as hereinafter defined) and has rights to EXELIXIS Technology; and

WHEREAS, MERCK desires to obtain a license under the EXELIXIS Technology, upon the terms and conditions set forth herein, and EXELIXIS desires to grant such a license;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

1. DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 “Affiliate” shall mean: (a) any corporation or business entity of which fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by MERCK or EXELIXIS; or (b) any corporation or business entity which, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of MERCK or EXELIXIS; provided that “Affiliates” of EXELIXIS shall not include the Change of Control Group upon completion of a Change of Control of EXELIXIS, so long as such Change of Control Group has agreed to the restrictions specified in Section 2.1(c).

1.2 “Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.3 “Calendar Year” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.4 “Change of Control” shall be deemed to occur if a Party is involved in a merger, reorganization or consolidation, or if there is a sale of all or substantially all of such Party’s assets or business relating to this Agreement, or if a person or group other than the current Controlling person or group shall effectively acquire Control of the management and policies of such Party.

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

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1.6 “Clinical Trial” shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or Post-approval Clinical Trial.

1.7 “Combination Product” shall mean a Product that contains one or more therapeutically active ingredients (other than Royalty Compound) in a fixed dose combination with a Royalty Compound. Each Combination Product shall be deemed to be a Royalty Product for all purposes of the Agreement.

1.8 “Compound” shall mean any EXELIXIS Compound, Joint Compound or MERCK Compound and in all cases including [*].

1.9 “Control”, “Controls” or “Controlled by” shall mean with respect to any item of or right under EXELIXIS Technology, MERCK Patent Rights, or other intellectual property rights, the possession of (whether by ownership or license, other than pursuant to this Agreement) or the ability of a Party and/or its Affiliates, as the case may be, to grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party and/or its Affiliates would be required hereunder to grant the other Party such access or license or sublicense.

1.10 “Diligent Effort” shall mean that effort customarily exerted by MERCK with respect to its own products of similar scientific merit and commercial potential, taking into account, [*], and also including the timing and promptness with which such efforts and resources would be applied. The efforts required by MERCK necessary to constitute Diligent Efforts will not be reduced by consideration of the fact in and of itself, that MERCK has an interest in developing or commercializing pharmaceuticals other than the Royalty Compounds and Royalty Products, that may be marketed for the same therapeutic indications as such Royalty Compounds and Royalty Products. Diligent Efforts are [*].

1.11 “EMEA” shall mean the European Medicines Agency (a cross-national Regulatory Authority in the European Union) and any successor governmental authority having substantially the same function.

1.12 “EXELIXIS Compound” shall mean: (a) any PI3Kdelta Specific Compound that is Controlled by EXELIXIS as of the effective date of the Agreement and is listed on Schedule B; (b) any PI3Kdelta Specific Compound that is claimed or covered by the EXELIXIS Patent Rights listed on Schedule A; and/or (c) any small molecule compound that is listed on Schedule C, which consists of compounds that are [*] from EXELIXIS’ PI3Kdelta program that are [*]. For clarity, any PI3Kdelta Specific Compounds that are [*] shall [*].

1.13 “EXELIXIS Know-How” shall mean:
(a) PI3Kdelta specific [*] and other know-how Controlled by EXELIXIS that is not generally known, and is necessary or useful to MERCK to research, develop, make, have made, use, import, export, sell and/or offer for sale Compounds and Products in the Territory for use in the Field, including but not limited to, those items listed in Schedule D;
(b) all [*] listed on Schedule C; and
(c) those [*] that are related [*] and that are listed in Schedule E.

[*] = 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.

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For avoidance of doubt and without limiting the foregoing, to the extent it is legally able to do so, EXELIXIS shall provide to MERCK [*] regarding PI3K activity developed by EXELIXIS as of the Effective Date with respect to the EXELIXIS Compounds and the compounds listed on Schedule C (such [*] shall be provided as part of the know-how disclosure described in Section 2.4).

1.14 “EXELIXIS Patent Rights” shall mean those Patent Rights included in Schedule A and all Patent Rights that are Controlled by EXELIXIS and that claim or cover: (a) any EXELIXIS Compound; (b) PI3Kdelta [*], (c) methods of use of PI3Kdelta Specific Compounds, and/or (d) manufacturing and formulation technology useful for Compound or Product.

1.15 “EXELIXIS Product” shall mean any pharmaceutical product preparation in final form for sale for use in the Field that contains or comprises an EXELIXIS Compound including all dosage forms, formulations and line extensions thereof.

1.16 “EXELIXIS Technology” shall mean EXELIXIS Patent Rights, EXELIXIS Know-How, and EXELIXIS’ interest in Joint Technology.

1.17 “Field” shall mean all therapeutic, diagnostic or prophylactic uses in humans and animals.

1.18 “Filing” of an NDA shall mean the acceptance by a Regulatory Authority of an NDA for filing.
1.19 "First Commercial Sale" shall mean, with respect to any Product, the first sale for end use or consumption of such Product in a country after all required approvals, including Regulatory Approval, have been granted by the Regulatory Authority of such country.

1.20 “IND” shall mean an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.21 “IND-Enabling GLP Toxicology Study” shall mean a genotoxicity, acute toxicology, safety pharmacology or sub-chronic toxicology study, in species that satisfies applicable regulatory requirements, using applicable GLP, and meets the standard necessary for submission as part of an IND filing with a Regulatory Authority.

1.22 “Indication” shall mean [ * ] prophylactic and/or therapeutic purpose for which the Product is developed [ * ] (e.g., [ * ] would be a single Indication, [ * ]. However [ * ] shall be considered a different Indication.

1.23 “Information” shall mean any and all information and data, including without limitation all EXELIXIS Know-How, MERCK Know-How, and all other scientific, preclinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement.

1.24 “Initiates”, “Initiated” or “Initiation” shall mean, with respect to Section 1.35 and/or a milestone event as set forth in Section 4.2, the administration of the first dose to an animal in an IND-Enabling GLP Toxicology Study or, a patient or subject in a Clinical Trial.

1.25 “Joint Compound” shall mean any PI3Kdelta Specific Compounds that are discovered or invented jointly by, or on behalf of, MERCK and EXELIXIS.

[ * ] = 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.

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1.26 “Joint Know-How” shall mean unpatented PI3Kdelta Specific Compound(s) or PI3Kdelta enzyme assays and techniques and other know-how that is discovered or invented jointly by or on behalf of MERCK and EXELIXIS, that is not generally known, and that is necessary or useful to MERCK to develop, make, have made, use, import, export, sell and/or offer for sale Compounds and Products in the Territory for use in the Field.

1.27 “Joint Patent Rights” shall mean all Patent Rights that are Controlled jointly by MERCK and EXELIXIS and that claim or cover: (a) any Joint Compound; (b) PI3Kdelta [ * ]; (c) methods of use of PI3Kdelta Specific Compounds; and/or (d) PI3Kdelta Specific Compound manufacturing and formulation, in each case, that is developed or invented jointly by or on behalf of EXELIXIS and MERCK.

1.28 “Joint Product” shall mean any pharmaceutical product preparation in final form for sale for use in the Field that contains or comprises a Joint Compound including all dosage forms, formulations and line extensions thereof.

1.29 “Joint Technology” shall mean Joint Patent Rights and Joint Know-How.

1.30 “Major European Country” shall mean any one of the following countries: [ * ].

1.31 “MERCK Compound” shall mean any PI3Kdelta Specific Compound that is: (a) Controlled by MERCK during the term of the Agreement; and/or (b) claimed or covered by MERCK Patent Rights; but excluding any [ * ] acquired by [ * ] at any time [ * ].

1.32 “MERCK Compound Period” shall mean the period from [ * ] until [ * ], unless the Agreement is terminated earlier.

1.33 “MERCK Know-How” shall mean any information and materials, including but not limited to, discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including without limitation MERCK’s rights in Joint Technology), know-how and trade secrets, patentable or otherwise, which during the term of this Agreement: (a) are in MERCK’s Control; (b) are not generally known; and (c) are in MERCK’s opinion necessary to EXELIXIS in the performance of its obligations under this Agreement.

1.34 “MERCK Patent Rights” shall mean all Patent Rights Controlled by MERCK that claim or cover: (a) any PI3Kdelta Specific Compound; (b) PI3Kdelta [ * ]; (c) methods of use of PI3Kdelta Specific Compound; and/or (d) PI3Kdelta Specific Compound manufacturing and formulation.

1.35 “MERCK Royalty Compound” shall mean any MERCK Compound for which [ * ].

1.36 “MERCK Royalty Product” shall mean any pharmaceutical product preparation in final form for sale for use in the Field that contains or comprises a MERCK Royalty Compound including all dosage forms, formulations and line extensions thereof.

1.37 “NDA” shall mean a New Drug Application, Worldwide Marketing Application, Marketing Application Authorization, or similar application or submission for Regulatory Approval of a Product filed with a Regulatory Authority to obtain marketing approval for a pharmaceutical or diagnostic product in that country or in that group of countries.

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1.38 “Net Sales” shall mean the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Royalty Product sold by MERCK or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:

(a) trade and quantity discounts other than early pay cash discounts;

(b) returns, rebates, chargebacks and other allowances;

(c) retrospective price reductions that are actually allowed or granted;

(d) a fixed amount equal to [ * ] to cover bad debt, early payment cash discounts, transportation and insurance, custom duties, and other governmental charges; and

(e) if applicable as to the Royalty Product sold, MERCK’s standard inventory cost, using MERCK’s standard internal system for determining such costs across all its products consistently applied, of a Product Delivery Device (as defined below) that is sold with the Royalty Product. A “Product Delivery Device” shall mean a device or delivery system that is used for administering or delivering a Royalty Product (such as a syringe or specialized drug delivery system) and is packaged and sold with such Royalty Product, such as in a sterile kit.

With respect to sales of Combination Products, Net Sales for the purpose of determining royalties owed for sales of such Combination Product shall be calculated by multiplying the total Net Sales of the Combination Product by the fraction A/(A+B), where A is the average gross invoice price in the applicable country in the Territory of the Royalty Product sold separately in the same formulation and dosage, and B is the sum of the average gross invoice prices in the applicable country in the Territory of all other therapeutically active ingredients in the Combination Product sold separately in the same formulation and dosage, during the applicable royalty period, provided that such sales are in arms-length transactions and such gross invoice prices are available. In the event that such gross invoice prices are not available in such period, then Net Sales of the Royalty Product shall be calculated on the basis of the gross invoice price of the Combination Product multiplied by a fraction, the numerator of which shall be [ * ] and the denominator of which shall be [ * ]. The deductions set forth in paragraphs (a) through (e) above will be applied in calculating Net Sales for a Combination Product. In the event that either Party reasonably believes that the calculation carried out with respect to the Combination Product does not fairly reflect the value of the Royalty Compound in the Combination Product relative to the other clinically active components in the Combination Product, the Parties shall negotiate in good faith and agree on another, commercially reasonable means of calculating Net Sales with respect to such Combination Product that fairly reflects the relative contribution, to the total market value of such Combination Product, of the Royalty Compound in the Product.

1.39 “Party” shall mean MERCK and EXELIXIS.

1.40 “Patent Rights” shall mean any and all issued patents and pending patent applications (including any provisional applications, continuations, divisionals, continuations-in-part, re-examinations, reissues, substitutions, confirmations, registrations, re-validations, patents of addition, patent term extensions, supplementary protection certificates and the like, as well as any foreign counterparts of any of the foregoing).

1.41 “Phase I Clinical Trial” shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).

1.42 “Phase II Clinical Trial” shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).

1.43 “Phase III Clinical Trial” shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).

1.44 “PI3K” shall mean Phosphatidylinositol 3-kinases, a family of enzymes that phosphorylate the 3 position hydroxyl group of the inositol ring of phosphatidylinositol. Class 1A kinases are composed of a p85 regulatory chain and a p110 catalytic chain, of which there are three (3) isoforms: PI3Kalpha, PI3Kbeta, PI3Kdelta. Class IB kinase is composed of a p101 regulatory chain and a p110 catalytic chain, of which there is one (1) isoform: PI3Kgamma.

1.45 “PI3Kdelta Specific Compound” shall mean any small molecule compound that meets both of the following requirements: (a) [ * ] inhibits the activity of PI3Kdelta [ * ] in a biochemical assay for PI3Kdelta activity [ * ]; and (b) in a selectivity panel of multiple targets, demonstrates [ * ] selectivity against PI3Kdelta relative to the following targets: [ * ].

1.46 “Product” shall mean any pharmaceutical product preparation in final form for sale for use in the Field that contains or comprises a Compound including all dosage forms, formulations and line extensions thereof.
1.47 “Prosecute” shall mean in relation to any Patent Rights: (a) prepare and file patent applications and represent applicant(s) or assignee(s) before relevant patent offices or other relevant authorities during examination, and in appeal processes, or in any equivalent proceedings, (b) to secure the grant of any Patent Rights arising from such patent applications, (c) to maintain in force any issued Patent Rights (including through payment of any relevant maintenance fees), and (d) to make all decisions with regard to any of the foregoing activities. “Prosecution” has a corresponding meaning.

1.48 “Regulatory Application” shall mean any submission for Regulatory Approval of a Product filed with a Regulatory Authority to obtain marketing approval for a pharmaceutical product in that country or in that group of countries.

1.49 “Regulatory Approval” shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a Product in any country (including without limitation, all applicable pricing and governmental reimbursement approvals even if not legally required to sell Product in a country).

1.50 “Regulatory Authority” shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.

1.51 “Related Party” shall mean MERCK, its Affiliates, and permitted licensees and sublicensees (which term does not include distributors).

1.52 “Royalty Compounds” shall mean MERCK Royalty Compounds, Joint Compounds, and EXELIXIS Compounds.

1.53 “Royalty Products” shall mean MERCK Royalty Products, Joint Products, and EXELIXIS Products.

1.54 “Territory” shall mean all of the countries in the world, and their territories and possessions.

[ * ] = 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.

2. LICENSE; EXCLUSIVITY; DEVELOPMENT AND COMMERCIALIZATION

2.1 Exclusive License Grants

Subject to the terms and conditions of this Agreement:

(a) EXELIXIS hereby grants to MERCK an exclusive, royalty-bearing license, with the right to sublicense, under the EXELIXIS Technology to research, develop, make, have made, import, use, offer for sale and sell Compounds and /or Products in the Territory for use in the Field. Such license grant shall be exclusive even as to EXELIXIS.

(b) EXELIXIS hereby grants to MERCK an exclusive, royalty-free license, with the right to sublicense, under the EXELIXIS Technology for research purposes in order to identify, derivatize, pre-clinically develop, make, have made and use Compounds. For clarity, this research license would allow MERCK to [ * ] for the purpose of identifying, derivatizing, making and having made Compounds.

(c) In order to provide MERCK with the exclusive licenses set forth in this Section 2.1 EXELIXIS will not [ * ], but rather will [ * ] that [ * ] so that [ * ] or [ * ], including without limitation [ * ], [ * ] during the term of the Agreement, provided that [ * ].

2.2 Non-Exclusive License Grant

In the event that the [ * ] would infringe during the term of this Agreement a claim of issued letters patent which [ * ], EXELIXIS hereby grants to MERCK, to the extent EXELIXIS is legally able to do so, a non-exclusive, sublicensable, royalty-free license in the Territory under [ * ] for MERCK and its Related Parties to [ * ].

2.3 Exclusivity

During the term of this Agreement, EXELIXIS and/or its Affiliates shall not (by itself or with any Third Party) [ * ]; provided, however, that if [ * ], and [ * ], EXELIXIS may [ * ].

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2.4 Disclosure of EXELIXIS Know-How

Subject to all applicable provisions of this Agreement, EXELIXIS shall begin disclosing to MERCK, promptly following the Effective Date, all EXELIXIS Know-How existing as of the Effective Date, and

[*] = 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.

EXELIXIS shall complete such disclosure no later than [*] following the Effective Date. All such EXELIXIS Know-How shall be delivered in electronic format, where available, and shall be in English. During such [*] period, EXELIXIS will make its and its Affiliates’ employees and consultants available to MERCK for consultation as reasonably required by MERCK in order to ensure an orderly transition to MERCK of all such EXELIXIS Know-How. No later than [*] after the end of such [*] period, and at MERCK’s reasonable request, there shall be a meeting at EXELIXIS between such MERCK and EXELIXIS representatives for EXELIXIS to answer any additional questions regarding the orderly transition to MERCK of all such EXELIXIS Know-How. Each Party shall bear its own costs in performing any activities pursuant to this Section 2.4.

2.5 Development and Commercialization Diligence

MERCK shall use Diligent Efforts to research, develop and commercialize of at least one Royalty Compound and/or Royalty Product. Beginning [*] after the Effective Date, and every [*] thereafter until the first approval of a Royalty Product in the United States, EMEA or Japan, MERCK shall submit to EXELIXIS a written report in reasonably sufficient detail describing the research, development, manufacturing and commercialization progress performed by or on behalf of MERCK on Royalty Compounds and/or Royalty Products. If reasonably necessary for EXELIXIS to exercise its rights under this Agreement, EXELIXIS may request that MERCK provide more detailed information and data regarding such reports by MERCK, and MERCK shall promptly provide EXELIXIS with information and data as is reasonably related to such request, at EXELIXIS’ expense. All such reports shall be considered Information of MERCK subject to Article 3.

2.6 Development, Commercialization and Regulatory Costs

(a) After the Effective Date of the Agreement, MERCK will be responsible for all costs and activities relating to research, development and regulatory affairs of Compounds and Products, except that EXELIXIS would bear its own costs to transfer to MERCK the licensed EXELIXIS Technology.

(b) After the Effective Date of the Agreement, MERCK will be responsible for all costs and activities relating to commercialization and manufacturing of Compounds and Products.

2.7 Excused Performance

The obligation of MERCK with respect to any Product under Section 2.5 are [*], and the obligation of MERCK to develop or market any such Product shall be delayed or suspended so long as [*].

2.8 No Implied Licenses; MERCK Covenants

Except as expressly provided in Sections 2.1, 2.2, and Article 7, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). For clarity, the licenses granted in Sections 2.1 and 2.2 by EXELIXIS to MERCK do not give MERCK any right or license to incorporate into any Product (e.g., as a combination product) any compound that is Controlled by EXELIXIS and that is not a PI3Kdelta Specific Compound. MERCK hereby covenants that MERCK shall not (and shall ensure that any of its Related Parties shall not) use any EXELIXIS Know-How or EXELIXIS Patent Rights for a purpose other than that expressly permitted in Sections 2.1, 2.2, and Article 7.

[*] = 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.

3. CONFIDENTIALITY; PUBLICITY AND PUBLICATION

3.1 Nondisclosure Obligation

All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to a Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:

(a) is known by receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party’s business records;

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Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

If a Party receiving Information that is subject to the non-disclosure provisions of this Section 3.1 is required by judicial or administrative process to disclose such Information, such receiving Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 3.1, and the Party disclosing Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.

3.2 Publicity and/or Use of Names

Upon full execution of this Agreement, EXELIXIS may issue a press release as set out in Schedule F. In addition, after full execution of this Agreement each Party may, in its public and confidential disclosures to Third Parties refer to the name of the other Party and the information set out in Schedule F. Any other publication, news release or other public announcement relating to the execution of this Agreement shall first be reviewed and approved by both Parties. Furthermore, no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law, rule or regulation. The foregoing provisions of this Section 3.2 notwithstanding, each Party shall have the right to disclose information related to the existence and/or terms and conditions of this Agreement as follows: (i) to the extent necessary (as reasonably determined by its legal counsel) to be disclosed in order to comply with the rules and regulations of the United States Securities and Exchange Commission (or another similar securities exchange authority in Territory); (ii) to existing or potential acquirers or merger candidates, potential sublicensees or collaborators (to the extent contemplated hereunder), or to Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 3; (iii) to investment bankers, existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing, if such recipients are bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 3; (iv) to governmental or other regulatory agencies in order to obtain patents on the Patent Rights subject to this Agreement (EXELIXIS Patent Rights, MERCK Patent Rights and/or Joint Patent Rights) or to gain or maintain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain such patents or approvals; or (f) is deemed necessary by a MERCK to be disclosed to Related Parties, agents, consultants, and/or other Third Parties for any and all purposes MERCK and/or its Affiliates deem necessary or advisable in the ordinary course of business in accordance with this Agreement on the condition that such Third Parties agree to be bound by the confidentiality and non-use obligations contained this Agreement; provided the term of confidentiality for such Third Parties shall be no less than [*].

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

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If a Party requests modifications to the publication, the Party seeking to publish shall edit such publication to prevent disclosure of trade secret or proprietary business information prior to submission of the publication.

4. PAYMENTS; ROYALTIES AND REPORTS

4.1 Consideration for License

In consideration for the licenses granted herein under the EXELIXIS Technology, upon the terms and conditions contained herein, MERCK shall pay to EXELIXIS twelve million dollars ($12,000,000) within [*] of the Effective Date of this Agreement. Such payment shall be non-creditable and non-refundable.

[*] = 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.

4.2 Development and Regulatory Milestone Payments

Subject to the terms and conditions in this Agreement, MERCK shall pay to EXELIXIS the following development and regulatory milestone payments with respect to Royalty Compounds or Royalty Products:

Event
Milestone Payment

[*] [*]

Each of the foregoing milestones would be payable [*], and [*] unless [*] as indicated above.

MERCK shall notify EXELIXIS in writing [*] upon the achievement of each milestone, and shall make the appropriate milestone payment within [*] of the achievement of such milestone. Each such payment shall be non-creditable and non-refundable.

4.3 Sales Threshold Milestone Payments

The following Sale Threshold Milestones shall be payable [*] after the end of the Calendar Year in which such Sales Threshold Milestone was first achieved by Merck or its Related Parties. Sales Threshold Milestones shall be payable only once regardless of the number of additional Indications developed.

Aggregate Annual Net Sales (Worldwide)
Payment

[*] [*]

4.4 Royalties

4.4.1 Patent Royalties Payable By MERCK Subject to the terms and conditions of this Agreement and except as set forth in Section 4.4.3, MERCK shall pay EXELIXIS, during the Royalty Period, royalties on worldwide annual Net Sales of Royalty Product in the Territory (for all Indications and without regard to formulation) as follows:

Royalty Net Sales

[*] of: Net Sales in the applicable countries in the Territory in each Calendar Year up to and including [*] in worldwide Net Sales

[*] of: Net Sales in the applicable countries in the Territory in each Calendar Year for the portion of worldwide Net Sales exceeding [*] up to and including [*]

[*] of: Net Sales in the applicable countries in the Territory in each Calendar Year for the portion of worldwide Net Sales exceeding [*]

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All royalties shall be calculated based on Net Sales in US Dollars and payment shall be made to EXELIXIS in US Dollars. All royalties shall be non-creditable and non-refundable (except to the extent provided under Section 4.6).

4.4.2 Royalty Period Royalties will be payable on a product-by-product and country-by-country basis from First Commercial Sale of such Royalty Product in such country until the later of: [ * ] (the "Royalty Period"); provided that, [ * ] a particular Royalty Product in a particular country, the Royalty Period for such Royalty Product in such country shall [ * ].

4.4.3 Know-How Royalties Payable By MERCK On Net Sales of Royalty Product which would not infringe a Valid Patent Claim, royalties would be payable on a product-by-product, country-by-country basis at [ * ] of the applicable royalty rate set forth in Section 4.4.1 [ * ].

4.4.4 Compulsory Licenses If a compulsory license is granted to a Third Party with respect to Royalty Product in any country in the Territory [ * ], then the royalty rate to be paid by MERCK on Net Sales in that country under this Section 4.4 shall be [ * ].

4.4.5 Third Party Licenses In the event that one or more licenses under patents that claim or cover the Royalty Compound as a composition of matter are required from Third Parties in order for MERCK and/or its Related Parties to develop, make, have made, use, offer to sell, sell or import Royalty Compound or Royalty Product(s) (hereinafter "Third Party Patent Licenses"), [ * ] of the consideration actually paid under such Third Party Patent Licenses by MERCK or its Related Parties for sale of such Royalty Compound or Royalty Product in a country for a Calendar Quarter shall be creditable against the royalty payments due EXELIXIS by MERCK with respect to the sale of such Royalty Compound or Royalty Products in such country. Notwithstanding the foregoing, in no event shall the royalty credit set forth above apply to reduce the royalty paid to EXELIXIS for the sale of such Royalty Product by more than [ * ] of the amount otherwise owed under the terms of Section 4.4.1 for such sale.

4.5 Reports; Payment of Royalty

During the term of the Agreement following the First Commercial Sale of a Product, MERCK shall furnish to EXELIXIS a quarterly written report for the Calendar Quarter showing the Net Sales of all Royalty Products subject to royalty payments sold by MERCK and its Related Parties in the Territory during the reporting period and the royalties payable under this Agreement. Reports shall be due on the [ * ] following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. MERCK shall keep (and shall ensure that its Related Parties shall keep) complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined, and MERCK shall keep (and shall ensure that its Related Parties shall keep) such records for the period that is the greater of [ * ] or the expiration of the statute of limitations under applicable tax law.

4.6 Audits

(a) Upon the written request of EXELIXIS [ * ], MERCK shall permit an independent certified public accounting firm of nationally recognized standing selected by EXELIXIS and reasonably acceptable to MERCK, at the EXELIXIS’ expense, to have access during normal business hours to such of the records of MERCK as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any year ending not more than [ * ] prior to the date of such request. The accounting firm shall disclose to EXELIXIS only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to EXELIXIS.

(b) If such accounting firm correctly identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within [ * ] of the date EXELIXIS delivers to MERCK such accounting firm’s written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by EXELIXIS; provided, however, that if such audit uncovers an underpayment of royalties by MERCK that exceeds [ * ], then the fees of such accounting firm shall be paid by MERCK.

(c) MERCK shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to MERCK, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by EXELIXIS’ independent accountant to the same extent required of MERCK under this Agreement.

(d) Upon the expiration of [ * ] following the end of any year, the calculation of royalties payable with respect to such year shall be binding and conclusive upon EXELIXIS, and MERCK and its Related Parties shall be released from any liability or accountability with respect to royalties for such year.

(e) EXELIXIS shall treat all financial information subject to review under this Section 4.6 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with MERCK and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

4.7 Payment Exchange Rate

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All payments to be made by MERCK to EXELIXIS under this Agreement shall be made in United States dollars and may be paid by check made to the order of EXELIXIS or bank wire transfer in immediately available funds to such bank account in the United States designated in writing by EXELIXIS from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due EXELIXIS shall be made at the monthly rate of exchange utilized by MERCK in its worldwide accounting system, prevailing on the third to the last business day of the month preceding the month in which such sales are recorded by MERCK.

4.8 Income Tax Withholding

EXELIXIS shall be liable for all income and other taxes (including interest) imposed upon any payments made by MERCK to EXELIXIS under this Article 4. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article 4, MERCK shall [ * ] and [ * ]. MERCK shall submit appropriate proof of payment of the withholding taxes to EXELIXIS within [ * ] of filing with the relevant tax authority.

5. REPRESENTATIONS AND WARRANTIES

5.1 EXELIXIS Representation and Warranty

EXELIXIS represents and warrants to MERCK that as of the date of this Agreement:

(a) to the best of EXELIXIS’ knowledge, the EXELIXIS Patent Rights and EXELIXIS Know-How set forth in Schedule D exist;

(b) it has the full right, power and authority to grant the licenses granted under Article 2 hereof;

(c) it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the EXELIXIS Patent Rights or EXELIXIS Know-How;

(d) to EXELIXIS’ knowledge (without duty of inquiry), it is the sole and exclusive owner of the EXELIXIS Patent Rights and EXELIXIS Know-How, all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the EXELIXIS Patent Rights and EXELIXIS Know-How;

(e) to EXELIXIS’ knowledge (without duty of inquiry) there are no claims, judgments or settlements against or owed by EXELIXIS or pending or threatened claims or litigation relating to the EXELIXIS Patent Rights and EXELIXIS Know-How; and

(f) EXELIXIS has disclosed to MERCK all reasonably relevant information regarding the EXELIXIS Patent Rights and EXELIXIS Know-How licensed under this Agreement.

5.2 Mutual Representation and Warranty

Each of MERCK and EXELIXIS represents and warrants to the other Party that as of the date of this Agreement:

(a) it has the authority and right to enter into and perform this Agreement;

(b) this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, subject to applicable limitations on such enforcement based on bankruptcy laws and other debtors’ rights; and

(c) its execution, delivery and performance of this Agreement shall not conflict in any material fashion with the terms of any other agreement or instrument to which it is or becomes a party or by which it is or becomes bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.

6. INTELLECTUAL PROPERTY PROVISIONS

6.1 Ownership

6.1.1 All rights title and interest in or to any and all intellectual property shall be determined in accordance with the following terms and conditions:

(a) EXELIXIS shall solely own all EXELIXIS Patent Rights and EXELIXIS Know-How;

(b) MERCK shall solely own all MERCK Patent Rights and MERCK Know-How; and
6.1.2 In the event of a dispute regarding ownership, the Parties shall establish a procedure to resolve such dispute, which may include engaging independent Third Party patent attorneys jointly selected by the Parties to resolve such dispute. The Parties acknowledge that the ownership rights set out in this Section 6.1 are subject to the terms and conditions of this Agreement (including the license granted by EXELIXIS to MERCK), and subject thereto, including without limitation Sections 2.1 and 2.3, each

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Party shall be free to use and exploit (which shall include the right to grant licenses under) any Joint Patent Rights and Joint Know-How, without any duty of accounting to the other Party during the term and after expiry or termination of this Agreement.

6.2 Prosecution of Patents

6.2.1 Prosecution of Patent Rights [*] (using external patent counsel reasonably acceptable to [*]) agrees to Prosecute in the Territory, upon appropriate consultation with [*], the [*] Patent Rights [*], [*] agrees to Prosecute in the Territory, upon appropriate consultation with [*], the [*] Patent Rights in the Territory. [*] shall implement all reasonable requests made by [*] with regard to the Prosecution of [*] Patent Rights. With respect to [*] Patent Rights, [*] may elect not to file and/or Prosecute and if so, [*] shall notify [*] and [*] shall have the right to Prosecute such [*] Patent Rights. In such event, [*] shall execute such documents and perform such acts at [*] expense as may be reasonably necessary to provide [*] with a power of attorney for such Patent Rights to [*] in a timely manner to allow [*] to continue such prosecution or maintenance. Thereafter, such assigned [*] Patent Rights shall be considered [*] Patent Rights under this Agreement. With respect to [*] Patent Rights, [*] may elect not to file and/or Prosecute and if so, [*] shall notify [*] and [*] shall have the right to Prosecute such [*] Patent Rights. In such event, [*] shall execute such documents and perform such acts at [*] expense as may be reasonably necessary to provide [*] with a power of attorney for such [*] Patent Rights to [*] in a timely manner to allow [*] to continue such prosecution or maintenance. With respect to both [*] Patent Rights and [*] Patent Rights, the non-filing Party shall have full rights of consultation with filing Party and the patent counsel selected by the filing Party in all matters related to such [*] Patent Rights or [*] Patent Rights, as the case may be. In addition, the filing Party shall give the non-filing Party an opportunity to review the text of the application before filing, shall consult with the non-filing Party with respect thereto, and shall supply the non-filing Party with a copy of the application as filed, together with notice of its filing date and serial number. The filing Party shall keep the non-filing Party advised of the status of the actual and prospective patent filings and upon the request of the non-filing Party, provide advance copies of any papers related to the Prosecution of such patent filings. The filing Party shall promptly give notice to the non-filing Party of the grant, lapse, revocation, surrender, invalidation or abandonment of any [*] Patent Rights or [*] Patent Rights, as the case may be.

6.2.2 Prosecution Costs for [*] Patent Rights [*] shall bear all reasonable and documented out-of-pocket costs and expenses incurred [*] in connection with the Prosecution of [*] Patent Rights [*] in [*]. [*] shall also reimburse the reasonable and documented out-of-pocket costs and expenses for the Prosecution of [*] Patent Rights in [*] and for [*] Patent Rights [*]; provided, that [*] provides [*] with advance written notice of such Prosecutions and [*] that such Prosecution in such country is commercially reasonable. If [*] provides notice to [*] within [*] of receiving notice of Prosecution of [*] Patent Rights [*], [*] that [*] does not agree with Prosecution, or at any time thereafter notifies [*] that its does not agree that continuing the Prosecution of such [*] Patent Rights in such country is commercially reasonable, [*] shall thereafter [*] Prosecute the [*] Patent Rights in such country. [*] shall reimburse [*] for the reasonable and documented out-of-pocket costs and expenses as set forth above within [*] after receiving an invoice from [*] for such costs. Notwithstanding anything to the contrary above, in the event that [*] or [*] or [*] any of the [*] Patent Rights [*], [*] shall [*] the costs of Prosecution for such [*] Patent Rights. By way of example, if [*] the [*] Patent Rights [*], [*] shall [*] the costs of Prosecution of such [*] Patent Rights.

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6.2.3 Prosecution Costs for [*] Patent Rights With respect to [*] Patent Rights, [*] shall be responsible for payment of the costs and expenses related to Prosecution of such Patent Rights [*]. If [*], then [*] shall bear the expenses for [*].

6.3 Interference, Derivation, Opposition, Reissue Reexamination and Post Grant Review Proceedings

(a) The filing Party shall, within [*] of learning of any request for, or filing or declaration of, any interference, derivation, opposition, reexamination, or post grant review (or similar proceedings as set forth under the America Invents Act) relating to [*] Patent Rights or [*] Patent Rights, as the case may be, inform the non-filing Party of such event. MERCK and EXELIXIS shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The non-filing Party shall have the right to review and approve any submission to be made in connection with such proceeding.

(b) [*] shall not initiate any interference, derivation, reissue, or reexamination proceeding (or similar proceedings as set forth under the America Invents Act) relating to [*] Patent Rights without the prior written consent to [*], which consent shall not be unreasonably withheld, delayed or
conditioned.

(c) In connection with any interference, derivation, opposition, reissue, reexamination, or post grant review proceeding (or similar proceedings as set forth under the America Invents Act) relating to [*] Patent Rights or [*] Patent Rights, MERCK and EXELIXIS will cooperate fully and will provide each other with any information or assistance that either may reasonably request. The filing Party shall keep the non-filing Party informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

(d) To the extent MERCK and EXELIXIS mutually agree with the course of action with respect to any interference, derivation, opposition, reexamination, reissue, or post grant review proceeding (or similar proceedings as set forth under the America Invents Act) relating to [*] Patent Rights or [*] Patent Rights, [*] shall bear the expense of such proceeding, subject to [*].

6.4 Enforcement and Defense

(a) Each of EXELIXIS and MERCK shall give the other Party notice of either (i) any infringement of [*] Patent Rights and/or [*] Patent Rights, or (ii) any misappropriation or misuse of [*] Know-How, that may come to either EXELIXIS' or MERCK's attention. MERCK and EXELIXIS shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both MERCK and EXELIXIS, to terminate any infringement of [*] Patent Rights and/or [*] Patent Rights or any misappropriation or misuse of [*] Know-How. [*], upon written notice to [*], shall have the first right to initiate and prosecute such legal action at its own expense and in the name of [*], or to control the defense of any declaratory judgment action relating to [*] Patent Rights, [*] Know-How, or [*] Patent Rights. [*] shall promptly notify [*] in writing if it elects not to exercise such first right and [*] shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of [*]. Each Party shall have the right to be represented by counsel of its own choice.

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(b) In the event that [*] elects not to initiate and prosecute an action as provided in paragraph (a), and [*] elects to do so, the costs of any agreed-upon course of action to terminate infringement of [*] Patent Rights or [*] Patent Rights or misappropriation or misuse of [*] Know-How, including without limitation the costs of any legal action commenced or the defense of any declaratory judgment, shall be [*].

(c) For any action to terminate any infringement of [*] Patent Rights or [*] Patent Rights or any misappropriation or misuse of [*] Know-How, in the event that [*] is unable to initiate or prosecute such action solely in its own name, [*] will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for [*] to initiate litigation to prosecute and maintain such action. In connection with any action, MERCK and EXELIXIS will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, the consultation and approval of any settlement negotiations and the terms of any offer related thereto. The foregoing notwithstanding, neither Party shall have the right to settle any patent infringement litigation under this Section 6.4 without the prior written consent of the other Party if such settlement would: (i) impose an injunction or other similar restriction of the other Party; (ii) impose any financial obligations on the other Party; (iii) materially diminish or adversely affect the scope, exclusivity or duration of any Patent Rights licensed under this Agreement; and/or (iv) would constitute an admission of guilt or liability by or on behalf of the other Party, such consent not to be unreasonably withheld, delayed or conditioned.

(d) Any recovery obtained by either or both MERCK and EXELIXIS in connection with or as a result of any action contemplated by this Section 6.4, whether by settlement or otherwise, shall be shared in order as follows:

(i) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;

(ii) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and

(iii) the amount of any recovery remaining shall then be allocated between the Parties as follows: (A) [*]; and (B) [*].

(e) [*] shall inform [*] of any certification regarding any [*] Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vi)(IV) or it successor provisions or any similar provisions in a country in the Territory other than the United States and shall provide [*] with a copy of such certification within [*] of receipt. [*] shall inform [*] of any certification regarding any [*] Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vi)(IV) or it successor provisions or any similar provisions in a country in the Territory other than the United States and shall provide EXELIXIS with a copy of such certification within [*] of receipt. EXELIXIS' and MERCK's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Sections 6.4(a)-(d) hereof; provided, however, [*] shall exercise its first right to initiate and prosecute any action and shall inform [*] of such decision within [*] of receipt of the certification, after which time [*] shall have the right to initiate and prosecute such action.

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6.5 Patent Term Restoration

The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to [ * ] Patent Rights. In the event that elections with respect to obtaining such patent term restoration are to be made, [ * ] shall have the right to make the election and [ * ] agrees to abide by such election, and assist as needed with the filing and Prosecuting of any such application for patent term restoration or supplemental protection certificates.

7. TERM AND TERMINATION

7.1 Term and Expiration

This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 7.2 or 7.3 below, this Agreement shall continue in effect until expiration of payment obligations hereunder. Upon expiration of this Agreement, MERCK shall retain a perpetual, fully-paid, non-exclusive, non-royalty-bearing license, with the right to sublicense, under the EXELIXIS Technology to research, develop, make, have made, import, use, offer for sale and sell Compounds and or Products in the Territory for use in the Field.

7.2 Termination at Will

Notwithstanding anything contained herein to the contrary, MERCK shall have the right to terminate this Agreement at will at any time in its sole discretion by giving [ * ] advance written notice to EXELIXIS. Not later than [ * ] after the date of such termination, each Party shall return or cause to be returned to the other Party all Information in tangible form received from the other Party and all copies thereof, except that each Party may retain one copy in its confidential files for records purposes. In the event of termination under this Section 7.2: (a) each Party shall pay all amounts then due and owing as of the termination date (within the time period set forth in this Agreement for the applicable payment type); (b) the licenses granted to MERCK under Article 2 shall terminate; (c) each Party shall [ * ]; (d) MERCK shall [ * ] and [ * ]; (e) [ * ] and [ * ] shall survive until [ * ]; (f) MERCK and its Affiliates, sublicensees and distributors shall be entitled, during the [ * ] period immediately following the effective date of termination, to finish any work-in-progress and to sell any Compounds and or Products remaining in inventory, in accordance with the terms of this Agreement; (g) in the event that a clinical trial is being terminated (which termination would occur at MERCK’s sole discretion), MERCK would be responsible for its own costs of winding down of any clinical trials of Compounds and/or Products that were ongoing as of the effective date of the termination; and (h) except for the surviving provisions set forth in this Section 7.2 and in Section 7.4 hereof, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination.

7.3 Termination for Cause

7.3.1 Cause for Termination This Agreement may be terminated at any time during the term of this Agreement:

(a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within [ * ] after notice requesting cure of the breach. If such breach is not cured within such period, this Agreement shall terminate immediately at the end of such period on written notice of the termination from the non-breaching Party, or where the breach is not capable of being cured in [ * ] if the breaching Party fails to (i) initiate actions during such [ * ] period that are reasonably anticipated to cure the

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default within a reasonable period (not to exceed [ * ] and (ii) thereafter use continuing diligent efforts to cure the default, then the non-breaching Party may immediately terminate this Agreement at any time by providing written notice of the termination; provided, however, in the event of a good faith dispute with respect to the existence of a material breach, the [ * ] cure period shall be tolled until such time as the dispute is resolved pursuant to Section 9.6 hereof; or

(b) in the event that MERCK or its Affiliate challenges the validity of any patent application or patent within the EXELIXIS Patent Rights, EXELIXIS may, in its sole discretion, terminate MERCK’s licenses under this Agreement to such patent application or patent; and in the event that EXELIXIS or its Affiliate challenges the validity of any patent application or patent within the MERCK Patent Rights, [ * ] shall [ * ] under this Agreement with respect to such patent application (if and when a patent issues thereon) or patent.

(c) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [ * ] after the filing thereof.

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7.3.2 Effect of Termination for Cause on License

(a) If MERCK terminates this Agreement under Section 7.3.1(a) or (b) or (c), MERCK’s license pursuant to Article 2 shall become [*] subject to [*] reduction in MERCK’s payment obligations to EXELIXIS under Article 4), and EXELIXIS shall, within thirty (30) days after such termination, return or cause to be returned to MERCK all Information provided by MERCK in tangible form.

(b) If EXELIXIS terminates this Agreement under Section 7.3.1(a) or (b) or (c), MERCK’s licenses pursuant to Article 2 shall terminate as of such termination date, and MERCK shall, within [*] after such termination, return or cause to be returned to EXELIXIS Information in tangible form and substances or compositions delivered or provided by EXELIXIS. Furthermore, with respect to each Joint Product that: (i) [*]; (ii) [*] and (iii) [*] (each such Joint Product, a “Reverted Product”), MERCK shall, and hereby does, grant to EXELIXIS a worldwide, perpetual, irrevocable, fully-paid, exclusive license, with the right to grant sublicenses, under the Joint Technology to clinically develop, make, use, sell, offer for sale and import each such Reverted Product; provided, however, that (iv) that [*]; and (v) EXELIXIS shall Prosecute the Joint Patent Rights with respect to such Joint Technology and shall be responsible for payment of the costs and expenses related to such Prosecution. At EXELIXIS’ sole discretion, MERCK shall provide (or shall have provided) to EXELIXIS: (v) all Information reasonably necessary for the development and commercialization of the Reverted Products; (vi) all regulatory filings (including any Regulatory Approvals, drug dossiers, and drug master files) that relate to each such Reverted Product, including transferring ownership of such regulatory filings; (vii) trademark rights Controlled by MERCK or its Related Party, that relate to each such Reverted Product to the extent that such trademarks have been approved by a Regulatory Agency to be used in connection with the Reverted Product, but excluding any rights to the names, trademarks, logos and the like of MERCK and/or its Related Parties; and (viii) supplies of each such Reverted Product, that are existing and in the Control of MERCK or its Related Party and are reasonably available to MERCK; provide that [*] for [*] and [*]. MERCK shall take such other actions and execute such other documents as may be necessary to effect the assignment of rights hereunder to EXELIXIS, and any such actions or assignments shall be at the reasonable expense of MERCK, except as otherwise provided above. If EXELIXIS does not request that any items described in subsections 7.3.2(b)(v) – (viii) be assigned to EXELIXIS within [*] of the effective date of termination, then MERCK shall have no further obligation to EXELIXIS to provide any such items.

7.4 Effect of Expiration or Termination; Survival

Expiration or termination of the Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties on sales prior to such expiration or termination. The provisions of Article 3 shall survive the expiration or termination of the Agreement and shall continue in effect for [*]. In addition, the provisions of Articles [*], and Sections [*], Sections [*] shall survive any expiration or termination of this Agreement.

8. INDEMNITY

8.1 Indemnification by MERCK

MERCK shall indemnify, defend and hold EXELIXIS, its Affiliates and their respective agents, employees, officers and directors (each a “EXELIXIS Indemnitee”) harmless from and against any and all judgments, liabilities, expenses, costs and/or losses, including reasonable legal expense and attorneys’ fees (collectively, “Losses”) to which any EXELIXIS Indemnitee may become subject as a result of any claim, suit, demand, action or other proceeding by any Third Party against an EXELIXIS Indemnitee to the extent such Losses arise directly or indirectly out of (a) any breach by MERCK of any of its material obligations and/or its representations and warranties pursuant to this Agreement; (b) the research, development, manufacture, use, promotion, marketing, sale or other disposition of Compounds and Products by MERCK or its Related
Section 8.2) except, in each case, to the extent such Losses result from the material breach by EXELIXIS or its Affiliates of any covenant, representation, warranty or other agreement made by EXELIXIS in this Agreement or the negligence, gross negligence or willful misconduct of any EXELIXIS Indemnitee.

8.2 Indemnification by EXELIXIS

EXELIXIS shall indemnify, defend and hold MERCK, its Related Parties and their respective agents, employees, officers and directors (each a “MERCK Indemnitee”) harmless from and against any and all Losses, to which any MERCK Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party against a MERCK Indemnitee to the extent such Losses arise directly or indirectly out of (a) any breach by EXELIXIS of any of its material obligations and/or its representations and warranties pursuant to this Agreement; (b) any of EXELIXIS’ representations and warranties set forth in the Agreement being untrue in any material respect when made; (c) the negligence, gross negligence or willful misconduct of any of the EXELIXIS Indemnitees; or (d) the development, manufacture, use, promotion, marketing, sale or other disposition of Reverted Products by EXELIXIS or its Affiliates, licensees or sublicensee; except, in each case, to the extent such Losses result from the material breach by MERCK, its Related Parties or subcontractors of any agreement made by MERCK in this Agreement or the negligence, gross negligence or willful misconduct of any MERCK Indemnitee.

8.3 Notice of Indemnification Obligation and Defense

Any Party entitled to indemnification under Section 8.1 or 8.2 shall give notice to the indemnifying Party of any Losses that may be subject to indemnification, promptly after learning of such Losses, but the omission to so notify the indemnifying Party promptly will not relieve the indemnifying Party from any liability under Section 8.1 or 8.2 except to the extent that the indemnifying Party shall have been prejudiced as a result of the failure or delay in providing such notice. The indemnifying Party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified Party. If such defense is assumed by the indemnifying Party, the indemnifying Party will not be subject to any liability for any compromise or settlement of such Losses made by the indemnified Party without its consent (but such consent will not be unreasonably withheld, delayed or conditioned), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified Party with respect to such Losses. The indemnified Party shall provide the indemnifying Party with all information in its possession and all assistance reasonably necessary to enable the indemnifying Party to carry on the defense of any such Losses. The foregoing notwithstanding, the indemnifying Party may not enter into any compromise or settlement of such Losses without the prior written consent of the indemnified Party if such compromise or settlement would: (i) impose an injunction or other similar restriction of the indemnified Party; (ii) impose any financial obligations on the indemnified Party; (iii) materially diminish or adversely affect the scope, exclusivity or duration of any Patent Rights licensed under this Agreement; and/or (iv) would constitute an admission of guilt or liability by or on behalf of the indemnified Party.

9. MISCELLANEOUS

9.1 Force Majeure

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in performing any obligation under the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The foregoing sentence shall not apply to a Party’s obligation to pay the other Party under this Agreement when such payment obligation arose prior to the occurrence of such force majeure event and where such force majeure event does not prevent the method of making such payment. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

9.2 Assignment; Change of Control

Except as provided in this Section 9.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder (other than Exelixis’ right to receive payments under Article 4) be assigned or transferred, by either Party without the consent of the other Party; provided, however, that MERCK may, without such consent, assign the Agreement and its rights and obligations hereunder to an Affiliate or in connection with a Change of Control. EXELIXIS may, without MERCK’s consent, assign this Agreement and its rights and obligations hereunder
to a member of the Change of Control Group in connection with an EXELIXIS Change of Control subject to the following:

(a) EXELIXIS shall provide written notice to MERCK at least [*] prior to the completion of a Change of Control, subject to any confidentiality obligations of EXELIXIS then in effect (but, if such confidentiality obligations prevent EXELIXIS from providing such written notice, EXELIXIS shall so notify MERCK within [*] after completion of such Change of Control;

(b) the Change of Control Group in connection with the EXELIXIS Change of Control shall agree in writing with MERCK, within [*] from the Change of Control event, that [*] and that [*];

(c) in the event [*], [*] shall [*] and [*] with respect to the [*] and [*] of [*] and [*] and [*]; and

(d) [*] may, in its discretion, [*] with respect the [*] under this Agreement, including [*] and [*] to [*] that [*] or [*], and [*] shall [*] and [*].

Any attempted assignment not in accordance with this Section 9.2 shall be null and void. Any permitted assignee shall assume all assigned obligations of its assignor under the Agreement. The terms and conditions of this Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assigns.

9.3 Severability

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

9.4 Notices

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or a pdf document sent by electronic mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to EXELIXIS, to: Exelixis, Inc.
210 East Grand Ave.
So. San Francisco, CA 94080
Attention: EVP and General Counsel
Facsimile No.: (650) 837-7179

and Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304
Attention: Marya A. Postner, Esq.
Facsimile No.: (650) 849-7400

if to MERCK, to: Merck Sharp & Dohme Corp.
One Merck Drive
P.O. Box 100, WS3A-65
Whitehouse Station, NJ 08889-0100

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9.5 Applicable Law


9.6 Dispute Resolution

9.6.1

Except for any “Excluded Claim” (defined in Section 9.6.6 below), the Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement, or the breach thereof, as follows. A Party shall notify the other Party in writing of such dispute, controversy or claim, and the Parties shall meet within [*] of receipt of such notice. If the Parties do not resolve the dispute, controversy or claim, then the dispute, controversy or claim that is not an Excluded Claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (“AAA”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

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the Parties do not fully settle within [*] of such meeting, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (“AAA”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

9.6.2 The arbitration shall be conducted by a panel of three (3) persons experienced in the pharmaceutical business (provided that such arbitrators are not required to be selected from AAA’s list of arbitrators) as follows: (a) within [*] after initiation of arbitration, each Party shall select one (1) person to act as arbitrator, and (b) the two (2) Party-selected arbitrators shall select a third arbitrator within [*] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed promptly by the AAA. The place of arbitration shall be [*]. and all proceedings and communications shall be in English.

9.6.3 Either Party may apply to the arbitrators for any applicable interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ and any administrative fees of arbitration.

9.6.4 Except to the extent necessary to confirm an award, or as may be required by applicable law, rule or regulation, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable [*] statute of limitations.

9.6.5 The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate the Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.
9.6.6 As used in this Section 9.6, the term “Excluded Claim” shall mean a dispute, controversy or claim that concerns: (a) the validity or infringement of a patent, trademark or copyright; (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory; or (c) the need to seek preliminary or injunctive measures or other equitable relief (e.g., in the event of a potential or actual breach of the confidentiality and non-use provisions in Article 3). An Excluded Claim need not be resolved through the procedure described in Sections 9.6.1 – 9.6.5 and may be immediately brought in a court of competent jurisdiction.

9.7 Entire Agreement; Amendments

The Agreement contains the entire understanding of the Parties with respect to the licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the licenses granted hereunder are superseded by the terms of this Agreement. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

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9.8 Headings

The captions to the several Articles and Sections hereof are not a part of the Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

9.9 Independent Contractors

It is expressly agreed that EXELIXIS and MERCK shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither EXELIXIS nor MERCK shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

9.10 Waiver

The waiver by either Party hereto of any right hereunder, or the failure of the other Party to perform, or 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 any right under this Agreement must be in writing, must specify the right that is waived and the time period of such waiver, and must be signed by the waiving Party.

9.11 Cumulative Remedies

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

9.12 Waiver of Rule of Construction

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

9.13 Certain Conventions

Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, and (c) words using the singular shall include the plural, and vice versa.

9.14 Business Day Requirements

In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.

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9.15 Counterparts

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The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

MERCK SHARP & DOHME CORP. EXELIXIS, INC.

BY:

/s/ Barbara Yanni

BY:

/s/ Michael M. Morrissey

Barbara Yanni  Michael M. Morrissey, Ph.D

TITLE: Vice President and Chief Licensing Officer TITLE: President and CEO


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SCHEDULES

SCHEDULE A EXELIXIS PATENT RIGHTS

[*]

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SCHEDULE B EXELIXIS PI3Kdelta SPECIFIC COMPOUNDS

[*]

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SCHEDULE C EXELIXIS COMPOUNDS

[*]

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SCHEDULE D EXELIXIS KNOW-HOW

[*]

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SCHEDULE E EXELIXIS RELATED INACTIVE COMPOUNDS

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SCHEDULE F PRESS RELEASE

LOGO

Contact:

Charles Butler
Vice President,
Investor Relations and
Corporate Communications
Exelixis, Inc.
(650) 837-7277
cbutler@exelixis.com

Exelixis Licenses PI3K-Delta Program to Merck

Exelixis to receive $12M upfront payment and be eligible for potential development, regulatory and commercial milestones, plus royalties

South San Francisco, Calif. – December XX, 2011 – Exelixis, Inc. (NASDAQ:EXEL) today announced that it has granted to Merck, known as MSD outside of the United States and Canada, an exclusive worldwide license to its PI3K-delta research and development program, including XL499, the company’s most advanced preclinical PI3K-delta inhibitor and other related compounds. Under the agreement, Merck will have a worldwide exclusive license and have sole responsibility to research, develop, and commercialize compounds originating from the program.

Merck will make an upfront payment of $12 million to Exelixis and Exelixis will be eligible for potential development and regulatory milestone payments for multiple indications of up to $239 million. Exelixis will also be eligible for potential combined sales performance milestones and royalties on net-sales of products emerging from the agreement. Milestones and royalties are payable on compounds emerging from Exelixis’ PI3K-delta program or from certain compounds that arise from Merck’s internal discovery efforts targeting PI3K-delta during a certain period.

"PI3K-delta is an interesting target with potential utility in a number of therapeutic areas, including inflammation and oncology, said Michael M. Morrissey, president and chief executive officer of Exelixis. "Our PI3K-delta program builds on our prior interest in the PI3K family, which led to the advancement of pan-PI3K inhibitors into clinical development for cancer. Merck’s global presence and significant resources make it the ideal organization to carry the PI3K-delta program forward. At the same time, this agreement provides Exelixis with resources for the continued development and potential commercialization of our lead compound, cabozantinib, which is in late-stage development for medullary thyroid and prostate cancers."

"Exelixis has established a strong reputation for innovation in the development of targeted kinase inhibitors," said Don Nicholson, Ph.D., Vice President and Head of Worldwide Discovery, Respiratory and Immunology Franchise, Merck Research Laboratories. "Collaborations like this are an important part of our strategy as we seek new ways to address unmet needs in inflammatory disease and oncology."

PI3K-delta is a member of the Class 1 family of phosphoinositide-3 kinases and is predominantly expressed in cells of the immune system. Activation of PI3K-delta occurs in response to a variety of immune cell stimuli, and inappropriate PI3K delta activation is thought to contribute to multiple inflammatory and allergic disorders, including rheumatoid arthritis and allergic asthma. Selectively targeting PI3K-delta has also shown potential in the treatment of certain lymphomas.

About Exelixis

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Exelixis, Inc. is a biotechnology company committed to developing small molecule therapeutics for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on cabozantinib, its most advanced solely-owned product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis believes cabozantinib has the potential to be a high-quality, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs. For more information, please visit the company’s web site at www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the payment to Exelixis of an upfront payment; Exelixis’ potential receipt of development, regulatory and sales milestones, as well as royalties on sales of products; the clinical, therapeutic and commercial potential of the PI3K-delta program; the belief that Merck is the ideal organization to carry the PI3K-delta program forward; the belief that the agreement will provide resources for the continued development and potential commercialization of cabozantinib; and the clinical, therapeutic and commercial potential of cabozantinib. Words such as “will,” “eligible,” “potential,” “emerging,” “arise,” “provides,” “continued,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis’ current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis’ actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to Exelixis’ dependence on the activities of Merck under the described agreement, the potential failure of the PI3K-delta program or cabozantinib to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of the PI3K-delta program and cabozantinib; Exelixis’ ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the sufficiency of Exelixis’ capital and other resources; uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; market competition; and changes in economic and business conditions. These and other risk factors are discussed under “Risk Factors” and elsewhere in Exelixis’ quarterly report on Form 10-Q for the quarter ended September 30, 2011 and Exelixis’ other filings with the Securities and Exchange Commission. 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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