

EX-10.105 2 nlnk-20141231xex10105.htm EXHIBIT 10.105

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



Exhibit 10.105

EXECUTION COPY

LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this “**Agreement**”) is effective as of November 21, 2014 (the “**Effective Date**”), and is entered into by and between **MERCK SHARP & DOHME CORP.**, a corporation organized and existing under the laws of New Jersey (“**Merck**”), and **BIOPROTECTION SYSTEMS CORPORATION**, a corporation organized and existing under the laws of Delaware (“**NewLink**”) and a wholly owned subsidiary of **NEWLINK GENETICS CORPORATION**, a corporation organized and existing under the laws of Delaware (“**NL**”), and for purposes of Section 10.19, NL.

RECITALS:

WHEREAS, NewLink is currently developing a rVSV-EBOV (Ebola) vaccine; and

WHEREAS, NewLink and Merck desire to enter into a collaboration in order to research, develop, manufacture and commercialize Compounds (as hereinafter defined) and Products (as hereinafter defined), upon the terms and conditions set forth herein; and

WHEREAS, NewLink desires to grant to Merck licenses under the NewLink Patent Rights (as hereinafter defined) and NewLink Know-How (as hereinafter defined) to research, develop, manufacture and commercialize Compounds and Products upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, Merck and NewLink hereby agree as follows:

Article 1 DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below.

1.1 “**AAA**” shall have the meaning given to such term in Section 10.6.1.

1.2 “**Act**” means, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., in each case, as such may be amended from time to time.

- 1.3 “**Affiliate**” means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of more than fifty percent (50%) of the voting securities of such Person, by contract or otherwise.
- 1.4 “**Agreement**” shall have the meaning given to such term in the preamble.
- 1.5 “**Agreement Payments**” shall have the meaning given to such term in Section 5.6.1.
- 1.6 “**Alliance Manager**” shall have the meaning given to such term in Section 2.8.
- 1.7 “**Alternative Product**” shall have the meaning given to such term in Section 8.2.2.
- 1.8 “**Applicable Laws**” means any and all applicable laws of any jurisdiction which are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions, including the Act and GLPs, GCPs and GMPs.
- 1.9 “[*]” shall have the meaning given to such term in Section 3.10.3.
- 1.10 “**Biosimilar Application**” shall have the meaning given to such term in Section 7.4.5(b).
- 1.11 “**BLA**” means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Act, Premarket Approval Application or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.
- 1.12 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (i) the first Calendar Quarter of this Agreement shall commence on the Effective Date and end at the end of the Calendar Quarter in which the Effective Date occurs and (ii) the last Calendar Quarter of this Agreement shall commence at the commencement of such Calendar Quarter and end on the date of expiration or termination of this Agreement.

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- 1.13 “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, however, that (i) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year and (ii) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of expiration or termination of this Agreement.
- 1.14 “**Change of Control**” means, with respect to Merck, NL or NewLink, as applicable, a transaction with a Third Party(ies) involving, (i) the acquisition, merger or consolidation, directly or indirectly, of Merck, NL or NewLink, as applicable, and, immediately following the consummation of such transaction, the shareholders of Merck, NL or NewLink, as applicable, immediately prior thereto hold, directly or indirectly, as applicable, shares of capital stock of the surviving company representing less than fifty percent (50%) of the outstanding shares of such surviving or continuing company, (ii) the sale of all or substantially all of the assets or business of Merck, NL or NewLink, as applicable, or (iii) a Person, or group of Persons acting in concert, acquire more than fifty percent (50%) of the voting equity securities or management control of Merck, NL or NewLink, as applicable.
- 1.15 “**Clinical Trial**” means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or post-regulatory approval clinical trial involving human subjects.
- 1.16 “**Code**” shall have the meaning given to such term in Section 8.3.3.
- 1.17 “**Combination Product**” means a Product which includes one or more Compound(s) in combination with one or more active ingredients other than such Compound(s), [*]; provided, however, nothing contained in this Agreement shall be interpreted as a grant of a license by NewLink to Merck to any other proprietary active compounds of NewLink (other than Compounds).
- 1.18 “**Commercialize**” means to promote, market, distribute, sell and provide product support for a Product, and “**Commercializing**” and “**Commercialization**” shall have correlative meanings.
- 1.19 “**Commercially Reasonable Efforts**” means with respect to the efforts to be expended by a Party with respect to any objective, the [*]. It is understood and agreed that with respect to the Development, Manufacture and Commercialization of Product by either Party, such efforts [*] and [*] taking into account [*] and other [*]. Commercially Reasonable Efforts shall be [*], and it is [*], and [*].
- 1.20 “**Competitor**” shall have the meaning given to such term in Section 10.2.3.

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- 1.21 “**Compound**” means (i) the Current Compound and (ii) [*], including [*], in each case, [*], and in each case of this clause (ii) [*].
- 1.22 “**Confidential Information**” means any and all proprietary Know-How, information and data, including scientific, pre-clinical, 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 or on behalf of one Party to the other Party and/or its Affiliate in connection with this Agreement.
- 1.23 “**Control**”, “**Controls**” or “**Controlled by**” means, with respect to any Patent Rights, Know-How or other intellectual property assets or rights, as applicable, the possession of (whether by ownership or license or other right, other than pursuant to this Agreement) or the ability of a Party 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 would be required hereunder to grant the other Party such access or license or sublicense.
- 1.24 “**Covered by**” or “**Cover**” or the like, means, with respect to a given Product in a given country, that [*] is claimed by a Valid Claim in such country and such Valid Claim would be infringed by the sale of such Product in such country but for the licenses granted to Merck hereunder; provided, that [*] for which [*] has been [*], and [*] is actually [*].
- 1.25 “**Critical Issue**” shall have the meaning given to such term in Section 2.7.2.
- 1.26 “**Current Compound**” means the [*] vaccine candidate known as rVSV-EBOV and more particularly described on Schedule 1.26.
- 1.27 “**Current Product**” means the [*] or [*] containing the Current Compound [*] or any [*], as the [*], for the treatment of Ebola [*] other than [*], but excluding, for clarity, [*].
- 1.28 “**Current Product Commercially Reasonable Efforts Obligation**” shall have the meaning given to such term in Section 3.5.1.
- 1.29 “[*]” shall have the meaning given to such term in [*].
- 1.30 “**Develop**” means to research, develop, analyze, test and conduct preclinical, clinical and all other regulatory trials for Compound or a Product, as well as any and all activities pertaining to manufacturing development, formulation development, manufacturing scale-up and lifecycle management, including new indications, new formulations and all other activities related to securing and maintaining Marketing Authorization for a Product,

including pre- and post-Marketing Authorization regulatory activities in connection with a Product. “**Developing**” and “**Development**” shall have correlative meanings.

- 1.31 “**Dollar**” or “**\$**” means United States dollars.
- 1.32 “**Effective Date**” shall have the meaning given to such term in the preamble.
- 1.33 “**EU**” or “**European Union**” means (a) the European Union and its member states as of the Execution Date, which are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom, and (b) each of their successors to the extent such successors occupy the same territory and are included as part of the European Union.
- 1.34 “**Excluded Claim**” shall have the meaning given to such term in Section 10.6.6.
- 1.35 “**Existing Confidentiality Agreement**” means that certain Confidential Disclosure Agreement, dated [*], between Merck and NewLink.
- 1.36 “**Existing IND**” shall have the meaning given to such term in Section 2.9.2.
- 1.37 “**FDA**” means the United States Food and Drug Administration or any successor governmental authority having substantially the same function.
- 1.38 “**Field**” means any and all uses or purposes, including the treatment, palliation, diagnosis or prevention of any human or animal disease, disorder or condition.
- 1.39 “**First Commercial Sale**” means, with respect to a Product in a given country in the Territory, the first shipment to a Third Party of commercial quantities of such Product sold in such country to such Third Party on arm’s length terms by Merck, its Affiliate or sublicensee for end use or consumption of such Product in the Field in such country (following, in all cases, the receipt of Marketing Authorization for such Product in such country). For clarity, First Commercial Sale shall be determined on a Product-by-Product basis.
- 1.40 “**GAVI Alliance**” means the Global Alliance for Vaccines and Immunization (GAVI), an independent non-profit organization established under the laws of Switzerland, with the purpose of providing support for improvements of vaccinations and immunization in the poorest countries of the world.
- 1.41 “**GAVI Eligible Countries**” means [*], as such [*]; provided that in no event [*]. For the avoidance of doubt, [*] shall, following [*].

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- 1.42 “**Good Clinical Practices**” or “**GCPs**” means then-current Good Clinical Practices as such term is defined from time to time by the FDA and governmental authorities in the European Union, pursuant to its regulations, guidelines or otherwise.
- 1.43 “**Good Laboratory Practice**” or “**GLPs**” means then-current standards for laboratory activities for pharmaceuticals or biologicals, as applicable, as defined from time to time by the FDA and governmental authorities in the European Union, pursuant to its regulations, guidelines or otherwise.
- 1.44 “**Good Manufacturing Practices**” or “**GMPs**” means then current Good Manufacturing Practices as such term is defined from time to time by the FDA and governmental authorities in the European Union, pursuant to its regulations, guidelines or otherwise.
- 1.45 “**Human Materials**” shall have the meaning given to such term in Section 2.3.2.
- 1.46 “**IND**” means 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.
- 1.47 “**Indemnified Party**” shall have the meaning given to such term in Section 9.1.3.
- 1.48 “**Indemnifying Party**” shall have the meaning given to such term in Section 9.1.3.
- 1.49 “**Initiation**” means, with respect to a Clinical Trial, the administration of the first dose of the Current Product (or an Alternative Product, as applicable) to a properly enrolled patient in such Clinical Trial.
- 1.50 “**Insolvency Event**” shall have the meaning given to such term in Section 8.3.1(b).
- 1.51 “**Inventory**” shall have the meaning given to such term in Section 2.9.3(a).
- 1.52 “**Joint Program Know-How**” shall have the meaning given to such term in Section 7.2.1(c).
- 1.53 “**Joint Program Patent Rights**” shall have the meaning given to such term in Section 7.2.1(c).
- 1.54 “**Joint Steering Committee**” or “**JSC**” means the joint steering committee established to oversee the activities hereunder as more fully described in Section 2.6.
- 1.55 “**Know-How**” means any and all proprietary information and materials, including discoveries, improvements, processes, methods, protocols, formulas, molecular constructs,

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cell lines, reagents, assays, data, seeds (including pre-seeds, master seeds and working seeds), cell banks (including master cell banks and working cell banks), clones, primers, vectors, antibodies, serum samples, biological samples, results, inventions, know-how, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise.

- 1.56 “**Liabilities**” shall have the meaning given to such term in Section 9.1.1.
- 1.57 “**Manufacture**” or “**Manufacturing**” means, with respect to a compound or product, including a Compound, Product and any other active pharmaceutical ingredient in a Product, the receipt, handling and storage of active pharmaceutical ingredients and other materials, the manufacturing, processing, packaging and labeling (excluding the development of packaging and labeling components for Marketing Authorization), holding (including storage), quality assurance and quality control testing (including release and stability) of such compound or product (other than quality assurance and quality control related to development of the manufacturing process, which activities shall be considered Development activities) and shipping of such compound or product.
- 1.58 “**Manufacturing Consultation**” shall have the meaning given to such term in Section 2.9.3(b).
- 1.59 “**Marketing Authorization**” means all approvals (including BLA approval, as applicable) from the relevant Regulatory Authority necessary to market and sell a Product in any country (including all applicable Price Approvals even if not legally required to sell Product in a country).
- 1.60 “**Merck**” shall have the meaning given to such term in the preamble.
- 1.61 “**Merck Background Know-How**” means all Know-How which (i) is in the Control of Merck or its Affiliates as of the Effective Date or during the Term, (ii) is not in the public domain, and (iii) [*]; provided, however, that Merck Background Know-How shall not include any Program Know-How.
- 1.62 “**Merck Background Patent Rights**” means Patent Rights that (i) are in the Control of Merck or its Affiliates as of the Effective Date or during the Term, and (ii) claim, cover or disclose Merck Background Know-How; provided, however that Merck Background Patent Rights shall not include any Program Patent Rights.
- 1.63 “**Merck Indemnitees**” shall have the meaning given to such term in Section 9.1.2.

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- 1.64 “**Merck Know-How**” means (i) all Merck Background Know-How and (ii) all Merck Program Know-How Controlled by Merck or any of its Affiliates.
- 1.65 “**Merck Patent Rights**” means (i) all Merck Background Patent Rights and (ii) all Merck Program Patent Rights Controlled by Merck or any of its Affiliates.
- 1.66 “**Merck Program Know-How**” shall have the meaning given to such term in Section 7.2.1(b).
- 1.67 “**Merck Program Patent Rights**” shall have the meaning given to such term in Section 7.2.1(b).
- 1.68 “**Milestone Event**” shall have the meaning given to such term in Section 5.2.
- 1.69 “**Milestone Payment**” shall have the meaning given to such term in Section 5.2.
- 1.70 “**NewLink**” shall have the meaning given to such term in the preamble.
- 1.71 “**NewLink Canada License**” means, collectively, (i) that certain Sole License Agreement for Recombinant Vesicular Stomatitis Virus Vaccines For Viral Hemorrhagic Fevers, between Her Majesty the Queen in Right of Canada (as represented by the Minister of Health, acting through the Public Health Agency of Canada (“**Public Health Canada**”)) and NewLink, dated as of [*], and (ii) [*] between Public Health Canada and NewLink dated as of [*], in each case, as the foregoing may be further amended in accordance with Section 3.1.3.
- 1.72 “**NewLink Existing Funding Agreements**” means the agreements set forth on Schedule 1.72.
- 1.73 “**NewLink Existing Manufacturing Agreements**” means the agreements set forth on Schedule 1.73.
- 1.74 “**NewLink Existing Third Party Agreements**” means (i) the NewLink Canada License, (ii) the NewLink Existing Manufacturing Agreements, and (iii) the NewLink Existing Funding Agreements.
- 1.75 “**NewLink Funding Agreements**” shall have the meaning given to such term in Section 3.10.1.
- 1.76 “**NewLink Future Funding Agreements**” shall have the meaning given to such term in Section 3.10.1.
- 1.77 “**NewLink Indemnitees**” shall have the meaning given to such term in Section 9.1.1.

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- 1.78 “**NewLink Know-How**” means all Know-How which (i) is in the Control of NewLink or its Affiliates as of the Effective Date or during the Term (subject to Section 10.2), (ii) is not in the public domain, and (iii) [*] is otherwise [*]. For the avoidance of doubt, NewLink Know-How shall include (x) any and all Know-How licensed under the NewLink Canada License, (y) all NewLink Program Know-How and (z) NewLink’s interest in any Joint Program Know-How.
- 1.79 “**NewLink Patent Rights**” means Patent Rights that (i) are in the Control of NewLink or its Affiliates as of the Effective Date or during the Term (subject to Section 10.2), and (ii) (a) claim, cover or disclose [*], and/or (b) claim, cover or disclose any NewLink Know-How. The NewLink Patent Rights shall include the Patent Rights identified in Schedule 1.79 as well as any Patent Rights licensed under the NewLink Canada License. Schedule 1.79 may be updated by the Parties from time to time as provided in Section 3.2. NewLink Patent Rights shall include (x) NewLink Program Patent Rights and (y) NewLink’s interest in any Joint Program Patent Rights.
- 1.80 “**NewLink Program Know-How**” shall have the meaning given to such term in Section 7.2.1(a).
- 1.81 “**NewLink Program Patent Rights**” shall have the meaning given to such term in Section 7.2.1(a).
- 1.82 “**NewLink Third Party Agreements**” means (i) the NewLink Existing Third Party Agreements, (ii) any other agreements [*] relating to the Development, Manufacture, Commercialization or other exploitation of Compounds or Products, including any agreements [*] or the [*], and (iii) any NewLink Funding Agreement [*] and any agreement included on Schedule 3.10.
- 1.83 “**NIH-Liberia Clinical Trial**” means the Clinical Trial which is [*], and which [*].
- 1.84 “**Officials**” shall have the meaning given to such term in Section 2.5.2.
- 1.85 “**Other Product Commercially Reasonable Efforts Obligation**” shall have the meaning given to such term in Section 3.5.1.
- 1.86 “[*]” shall have the meaning given to such term in [*].
- 1.87 “**Party**” means Merck or NewLink, individually, and “**Parties**” means Merck and NewLink, collectively.
- 1.88 “**Payment**” shall have the meaning given to such term in Section 2.5.2.

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- 1.89 **“Patent Rights”** means any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, and the like of any such patents and patent applications, and foreign equivalents of the foregoing.
- 1.90 **“Person”** means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.
- 1.91 **“Phase I Clinical Trial”** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- 1.92 **“Phase II Clinical Trial”** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).
- 1.93 **“Phase III Clinical Trial”** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- 1.94 **“Pivotal Clinical Trial”** means the first to occur of (i) [*] or (ii) [*] which is [*] of the [*] for clarity, any [*].
- 1.95 **“Price Approvals”** means in countries in the Territory where Regulatory Authorities may approve or determine pricing or pricing reimbursement for pharmaceutical products, such approval or determination.
- 1.96 **“Product”** means any pharmaceutical composition or preparation (in any and all dosage forms) in final form containing a Compound, [*]. For clarity, except with respect to [*], different [*] for the purposes of this Agreement.
- 1.97 **“Product Diligence Obligations”** shall have the meaning given to such term in Section 3.5.1.
- 1.98 **“Product Materials”** shall have the meaning given to such term in Section 6.2.21.
- 1.99 **“Product Net Sales”** means the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Product in the Royalty Bearing Territory for use in the Field 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) [*];

- (b) [(];
- (c) [*] that are [*];
- (d) [*]; or any other [*]; provided, that for clarity, nothing in this clause (d) shall be deemed to exclude [*] to the [*];
- (e) [*];
- (f) [*], including [*]; provided that any such [*];
- (g) [*] of the [*] and [*]; and
- (h) [*].

Product Net Sales shall not include [*].

With respect to sales of Combination Products, Product Net Sales shall be calculated on the basis of [*]. In the event that a Product is sold only as a Combination Product, Product Net Sales shall be calculated on the basis of [*] and the [*]. [*] shall be determined [*]. The deductions set forth above will be applied in calculating Product Net Sales for a Combination Product. In the event that a Product is sold only as a Combination Product and [*] to the [*], the Parties shall [*].

1.100 **“Program Know-How”** means any Know-How (including any Compounds) that is first conceived, discovered, made and/or reduced to practice (as would be necessary to establish inventorship under United States patent law (regardless of where the applicable activities occurred)) by or on behalf of either Party or its Affiliate (or their respective employees, agents or consultants) or jointly by both Parties or their respective Affiliates (or their respective employees, agents or consultants) in performing the Transition Program or other activities under this Agreement.

1.101 **“Program Patent Rights”** means any and all Patent Rights that claim, cover or disclose Program Know-How.

1.102 **“Project Leader”** shall have the meaning given to such term in Section 2.8.

1.103 **“Prosecute”** means, in relation to any Patent Rights, (i) to prepare and file patent applications, including re-examinations or re-issues thereof, and represent applicant(s) or assignee(s) before relevant patent offices or other relevant authorities during examination, re-examination and re-issue thereof, in appeal processes and interferences, oppositions or any equivalent proceedings, (ii) to secure the grant of any Patent Rights arising from such patent application, (iii) to maintain in force any issued Patent Right (including through

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payment of any relevant maintenance fees), and (iv) to make all decisions with regard to any of the foregoing activities. **“Prosecution”** has a corresponding meaning.

- 1.104 **“Providers”** shall have the meaning given to such term in Section 2.3.2.
- 1.105 **“Regulatory Authority”** means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a pharmaceutical product in the Territory, including, in the United States, the FDA.
- 1.106 **“Regulatory Documentation”** shall have the meaning given to such term in Section 2.9.2.
- 1.107 **“Related Party”** means each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.
- 1.108 **“Royalty Bearing Territory”** means the Territory excluding [*] and [*].
- 1.109 **“Royalty Term”** shall have the meaning given to such term in Section 5.4.2.
- 1.110 **“rVSV”** means the replication-competent recombinant vesicular stomatitis virus vector system.
- 1.111 **“Safety Termination”** shall have the meaning given to such term in Section 8.2.1.
- 1.112 **“Sensitive Information”** shall have the meaning given to such term in Section 10.2.3.
- 1.113 **“Term”** shall have the meaning given to such term in Section 8.1.
- 1.114 **“Terminated Products”** shall have the meaning given to such term in Section 8.3.2(a).
- 1.115 **“Territory”** means worldwide, including all of the countries in the world, and their territories and possessions.
- 1.116 **“Third Party”** means a Person other than Merck and its Affiliates, NL and its Affiliates and NewLink and its Affiliates.
- 1.117 **“Third Party Claim”** shall have the meaning given to such term in Section 9.1.1.
- 1.118 **“Third Party Funding Sources”** means Third Party funding sources, including [*] and [*] with respect to the Development, Manufacture and/or Commercialization of Compound and/or Product.
- 1.119 **“Transfer Taxes”** shall have the meaning given to such term in Section 5.6.1.
- 1.120 **“Transition Period”** shall mean the period commencing on the Effective Date and ending upon the later to occur of (i) completion of all activities under the Transition Plan, or (ii)

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[*]; provided that in no event shall the Transition Period end later than [*] unless [*], as applicable, [*], in which case the Transition Period shall continue [*], until such time as [*] in accordance with the terms of this Agreement.

- 1.121 “**Transition Plan**” means the plan for transitioning [*] activities with respect to [*] from NewLink to Merck, as such plan is established by the JSC in accordance with this Agreement, and as such plan may be updated from time to time in accordance with this Agreement.
- 1.122 “**Transition Plan Outline**” means the outline for the plan for transitioning [*] activities with respect to Compound and Product as set forth on Schedule 1.122.
- 1.123 “**Transition Program**” means the conduct of certain ongoing [*] activities by or on behalf of NewLink with respect to [*], and the transition of such activities to Merck, as set forth in Article 2 and in the Transition Plan.
- 1.124 “**Tri-Party Confidentiality Agreement**” means that certain Confidentiality and Non-Disclosure Agreement, dated [*], between Public Health Canada, Merck, NewLink and NL.
- 1.125 “**Valid Claim**” means a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension) within the NewLink Patent Rights, which claim has not been abandoned or revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period), and has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.
- 1.126 “**Violation**” means that a Party or any of its officers or directors or any other NewLink personnel (or other permitted agents of a Party performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<http://oig.hhs.gov/exclusions/authorities.asp>); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://exclusions.oig.hhs.gov/>) or listed as having an active exclusion in the System for Award Management (<http://www.sam.gov>); or (3) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (1), (2) and (3) collectively the “**Exclusions Lists**”).

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ARTICLE 2 TRANSITION PROGRAM

2.1 **General.** Each Party, at such Party's cost, shall engage in the Transition Program upon the terms and conditions set forth in this Agreement, including performing all activities to be performed by such Party as set forth in the Transition Plan.

2.2 **Transition Plan; Conduct of Transition Program.** Within [*] after the Effective Date, the Parties shall establish the initial Transition Plan which shall be based on the Transition Plan Outline. Each Party shall, [*] perform its activities under the Transition Program, including by using its good faith, diligent efforts to allocate sufficient time, effort, equipment and facilities to the Transition Program and to use personnel with sufficient skills and experience as are required to accomplish the Transition Program in accordance with the terms of this Agreement and the Transition Plan, as applicable. Merck shall be prepared to receive, and NewLink shall promptly deliver to Merck, [*] pursuant to and as set forth in the Transition Plan or [*]. In performing activities under the Transition Program, NewLink shall consult with Merck and shall [*] with respect to the activities conducted under the Transition Program, including [*], subject to Section 3.10.2 with respect to the activities under NewLink Funding Agreements and subject to Section 2.7.2 with respect to amendments of the Transition Plan.

2.3 **Compliance; Additional Requirements.**

2.3.1 **General.** Each Party shall conduct its activities hereunder, including activities under the Transition Program and activities under the NewLink Funding Agreements, in compliance with all Applicable Laws. Each Party shall notify the other in writing of any deviations from Applicable Laws. In addition, each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Transition Program or other activities under this Agreement (including activities under the NewLink Funding Agreements). Each Party shall notify the other in writing immediately if any such suspension, proposed debarment or debarment occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment or debarred, promptly remove such Person from performing any Transition Program activities, function or capacity related to the Transition Program or any other activities under this Agreement (including activities under the NewLink Funding Agreements).

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2.3.2 Use of Human Materials. Without limiting the provisions of Section 2.3.1, if any human cell lines, serum samples, biological samples, tissue, human clinical isolates or similar human-derived materials (“**Human Materials**”) have been or are to be collected and/or used in the Transition Program (or under the NewLink Funding Agreements), NewLink represents and warrants (i) that it has complied, and shall comply, with all Applicable Laws relating to the collection and/or use of the Human Materials and (ii) that it has obtained, and shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. NewLink shall provide documentation of such approvals and consents upon Merck’s request. NewLink further represents and warrants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities (“**Providers**”) who contributed the Human Materials, including any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purpose.

2.3.3 Use of Third Party Intellectual Property. In performing activities under the Transition Program (or activities under the NewLink Funding Agreements), [*] shall not (i) incorporate any Know-How or other intellectual property owned by any Third Party into any Compound, Product or other Program Know-How or (ii) otherwise use any Know-How or other intellectual property owned by any Third Party in the performance of the Transition Program (or activities under the NewLink Funding Agreements). Notwithstanding the foregoing, [*] shall be allowed to [*] under the [*] to perform the Transition Program.

2.3.4 Clinical Trial-related Adverse Events. With respect to Clinical Trials being carried out by or on behalf of a Party for the Current Product during the Transition Period, serious adverse experience reports as defined in 21 CFR 312.32 must be forwarded to the other Party within [*] after receipt of the information. In addition, each Party shall furnish to the other Party copies of the end of study summary of adverse experiences in English as promptly as possible following completion of such Clinical Trial (or earlier, as reasonably requested by such other Party). Within [*] after the Effective Date, NewLink and Merck (or its Affiliate) shall enter into a pharmacovigilance agreement in order to share safety information and satisfy related requirements of Regulatory Authorities and Applicable Law with respect to Compounds and Products.

2.4 Use of Third Parties. Each Party shall be entitled to utilize the services of Third Parties to perform its activities hereunder; provided that [*] that are identified in [*] or [*] expand

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the scope of activities being performed [*]. Notwithstanding the foregoing, each Party shall remain at all times responsible for the performance of its responsibilities under this Agreement, and shall ensure compliance with the applicable terms of this Agreement by any such Third Party, including (a) that such Third Party's employees involved in performing activities hereunder shall comply with the confidentiality provisions of this Agreement, (b) that such Third Party (including the employees of such Third Party) shall be obligated to assign any rights they may have in any Know-How and Patent Rights resulting from such activities in accordance with Section 7.2, and (c) that such Third Party shall comply with the terms of this Agreement applicable to the subcontracted activities, including Sections 2.3, 2.5 and 2.10. In addition, each Party hereby certifies that it has not retained or otherwise used in any capacity a Third Party, and will not retain or otherwise use in any capacity, the services of any Third Party suspended, proposed for debarment or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the activities under this Agreement (including activities under the NewLink Funding Agreements). Each Party shall notify the other in writing immediately if any such suspension, proposed debarment or debarment occurs or comes to its attention, and shall, with respect to any Third Party or entity so suspended, proposed for debarment or debarred promptly remove such Third Party or entity from performing any activities, function or capacity under this Agreement (including activities under the NewLink Funding Agreements). Each Party shall oversee the performance by any such Third Parties it utilizes, and shall remain responsible for the performance of such activities in accordance with this Agreement (including activities under the NewLink Funding Agreements). Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance hereunder, prior to proceeding directly against the Party engaging the subcontractor.

2.5 **Compliance with Ethical Business Practices.**

2.5.1 Compliance with Corporate Policy. NewLink acknowledges that Merck's corporate policies require that business must be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the activities contemplated herein (including activities contemplated under the NewLink Funding Agreements) in a manner which is consistent with both law and good business ethics.

2.5.2 Governments and International Public Organizations. Without limitation of the foregoing, each Party warrants that none of its employees, agents, officers or other members of its management are officials, officers, agents, representatives of any government or international public organization. Each Party agrees that it shall not make any payment, either directly or indirectly, of money or other assets, including

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to the compensation derived from this Agreement (hereinafter collectively referred as a “**Payment**”), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as “**Officials**”) where such Payment would constitute a violation of any law. In addition, regardless of legality, a Party shall make no Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the other Party’s businesses.

2.5.3 No Authority. Each Party acknowledges that no employee of the other Party or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of terms of this or any other provisions of this Agreement.

2.5.4 Exclusions Lists. Each Party certifies to the other that as of the Effective Date it has screened itself, and its officers and directors, against the Exclusions Lists and that it has informed such other Party whether it, or any of its officers or directors has been in Violation. After the execution of this Agreement, each Party shall notify the other in writing immediately if any Violation occurs or comes to its attention, and shall, with respect to any person or entity in Violation, promptly remove such person or entity from performing any Transition Program activities, function or capacity related to the Transition Program or otherwise related to activities under this Agreement (including activities under the NewLink Funding Agreements).

2.6 Joint Steering Committee. The Parties will establish a joint steering committee (the “**Joint Steering Committee**” or “**JSC**”) to generally oversee the Transition Program, and to oversee [*].

2.6.1 Composition of the JSC. As soon as practicable, but in no event more than [*] after the Effective Date, the Parties will establish the JSC, which will be comprised of an equal number of representatives of each Party, with three (3) representatives of NewLink (who shall be employees of NewLink) and three (3) representatives of Merck (who shall be employees of Merck or its Affiliate); provided, however, that the Parties may agree to increase or decrease the number of equal representatives from each Party. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Parties’ activities and interactions hereunder. Each Party may replace its representative(s) at any time upon prior notice to the other Party. The JSC will meet in person or by teleconference at

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least [*] per [*] at a mutually acceptable date and location; provided, however, that it is the intent of the Parties that the JSC shall have more frequent and regular interaction [*] in order to facilitate the Transition Program. Each Party may, if approved by the other Party (such approval not to be unreasonably withheld), from time to time invite a reasonable number of participants, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement. The JSC will be chaired by a Merck representative. The role of the chairperson shall be to preside in person or telephonically at meetings of the JSC, to prepare and circulate agendas and to ensure the preparation of minutes. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review and approval reasonably promptly after each JSC meeting. Such minutes will be deemed approved unless one or more of the members of the JSC objects to the accuracy of such minutes within [*] of receipt. Each Party shall bear its own expenses related to the attendance of such meetings by its representative(s).

2.6.2 **Responsibilities**. The JSC shall:

- (a) Review, oversee and direct the efforts, progress and status of the Transition Program (including technology transfer, if any), including reviewing and directing the conduct of the Transition Program;
- (b) Review, oversee and direct the efforts, progress and status of [*];
- (c) Review and approve amendments to the Transition Plan from time to time;
- (d) Review [*] issues that arise in connection with [*], during the [*];
- (e) Oversee and make decisions with respect to matters related to [*] in connection with Compound and Product; and
- (f) Address such other matters relating to the activities under this Agreement designated to be addressed by the JSC under this Agreement or as either Party may otherwise bring before the JSC.

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2.6.3Subcommittees. The JSC shall have the right to form subcommittees as determined by the JSC in order to address any particular matters within the authority of the JSC. For clarity, any such subcommittee shall have no broader rights and no broader authority than the JSC, and shall only exercise those rights and authorities as designated to such subcommittee by the JSC. Any such subcommittee shall have no decision making authority, but shall make recommendations to the JSC for the JSC's review and approval.

2.6.4Disbandment of JSC. The JSC shall be automatically disbanded (without any further actions by either Party) and shall have no further authority with respect to the activities hereunder, upon the end of the Transition Period. Thereafter, the JSC shall have no further obligations under this Agreement and the Project Leaders shall be the contact persons for the exchange of information under this Agreement.

2.6.5Development Forums. During the [*] period following the disbanding of the JSC in accordance with Section 2.6.4, the Parties shall meet in person or by teleconference no less than [*] to discuss Merck's Development of Products, including Products other than the Current Product (the "**Development Forum**"). At each such meeting, Merck will provide NewLink with an update on the status of the Development of the Products, and Merck's ongoing plan for the Development of Products (provided that, for clarity, such plan shall be non-binding and for informational purposes only). In addition, during such period, Merck will promptly notify NewLink if Merck suspends or otherwise terminates the Development or Commercialization of any Compound or Product.

2.7 Scope of Committee Oversight and Decision-Making Authority.

2.7.1Scope of Committee Oversight. The JSC shall not have the right to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement or (iv) following agreement with respect to the initial Transition Plan, amend the Transition Plan in a manner that would [*], unless such amendment is mutually agreed to by the Parties in writing; provided that, for the avoidance of doubt, if the work proposed in the amendment to the Transition Plan [*] or otherwise [*], then [*] such work and the [*].

2.7.2Decision-Making Authority. The goal of all decision-making of the JSC shall be to achieve consensus. All decisions of the JSC with respect to matters over which it has decision-making authority shall be made by unanimous vote of the applicable

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committee's representatives, with each Party collectively having one (1) vote. However, in the event that the JSC is unable to reach consensus within [*] of the matter first being referred to the JSC, then [*], subject to [*], unless such matter is one of the following matters (each, a "**Critical Issue**"): (i) [*]; or (ii) [*]. If the Parties cannot agree on any Critical Issue, then the status quo of such matter shall continue; provided, however, with respect to a Critical Issue in (i) above, [*]. Any decision made by [*] must be consistent with the terms of this Agreement and within the scope of authority delegated to the JSC under this Agreement.

2.8 **Project Leads and Alliance Managers.** Merck and NewLink each shall appoint an employee of such Party (or its Affiliate, as applicable) as its project leader (the "**Project Leader**") who shall be the primary contact between the Parties with respect to the Transition Program and who shall coordinate each Party's role in the Transition Program. Each Party shall notify the other within [*] of the Effective Date of the appointment of its Project Leader and shall notify the other Party as soon as practicable upon changing this appointment. In addition, each Party may also appoint, at its discretion, an alliance manager to facilitate communications between the Parties hereunder (the "**Alliance Manager**"). If a Party appoints an Alliance Manager, such Party shall notify the other of the appointment of its Alliance Manager and shall notify the other Party as soon as practicable upon changing this appointment.

2.9 **Exchange of Information and Materials.**

2.9.1 **General.** As soon as reasonably practicable following Effective Date (but in all cases within [*] after the Effective Date or such other period of time as agreed to by the Parties), NewLink shall disclose to Merck in English (in writing and in an electronic format) all NewLink Know-How. Thereafter on an ongoing basis during the Term upon the reasonable request of Merck, NewLink shall cooperate with Merck and promptly disclose to Merck in English (and deliver in writing and in an electronic format) (i) any other NewLink Know-How (including any Program Know-How) relating to Compound or Product (or the Development, Manufacture, use or Commercialization thereof) as may be developed or identified by or on behalf of NewLink (or its Affiliates), and (ii) from the Effective Date until [*], any other materials and documentation (including [*]) in NewLink's (or its Affiliate's or subcontractor's) possession or Control as may be reasonably requested by Merck from time to time that relate to Compounds or Products and are to be used by or on behalf of Merck in the performance of its activities under this Agreement, including [*]. Without limiting the generality of the foregoing, [*], NewLink shall [*] to provide [*] pursuant to, and in accordance with, [*].

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2.9.2 Technology Transfer; Transition of Activities. As soon as reasonably practicable following the Effective Date (but in all cases within [*] or such other period of time as agreed to by the Parties), NewLink shall (i) transfer to Merck (or its designee) all materials (other than Inventory) related to Compound or Product in NewLink's (or any of its Affiliate's or contractor's) possession or Control, including [*], and (ii) transfer and assign to Merck (or its designee), and NewLink hereby does transfer and assign to Merck, all Regulatory Documentation (other than the Existing IND) related to Compound or Product (including the transfer to Merck of a database that contains all relevant information regarding adverse events that have been observed during any clinical trials or studies with respect to Compound or Product prior to the Effective Date). In addition, upon Merck's request, NewLink shall transfer and assign to Merck (or its designee) [*] (the "**Existing IND**"). NewLink shall assist Merck, and each Party shall reasonably cooperate, to ensure [*], including providing [*] in connection therewith. As used herein, the term "**Regulatory Documentation**" means all applications, registrations, licenses, authorizations and approvals (including all Marketing Authorizations), all correspondence submitted to or received from Regulatory Authorities (including [*]) and all supporting documents in connection therewith, and all reports and documentation in connection with clinical studies and tests (including [*]), and [*] in any of the foregoing, including all INDs, BLAs, [*], in each case related to a Compound and/or Product.

2.9.3 Inventory Transfer and Manufacturing Technology Transfer.

- (a) **Inventory Transfer.** At the request of Merck from time to time as set forth in the Transition Plan, NewLink shall promptly transfer title to Merck and deliver to Merck (or its designee) (at a location to be [*]), [*] any or all (as and to the extent [*]) inventory of Compound and Product (including [*]) held by or on behalf of NewLink or any of its Affiliates (including any such inventory [*]) (the "**Inventory**").
- (b) **Manufacturing Technology Transfer.** Without limiting the provisions of Sections 2.9.1 and 2.9.2, as soon as reasonably practicable following the Effective Date (but in all cases within [*] after the Effective Date or such other period of time as agreed to by the Parties), NewLink shall transfer or cause to be transferred (including from its Third Party contract manufacturers) to Merck or its Affiliate (or a Third Party manufacturer designated by Merck), copies in English (in writing and in an electronic format) of all [*] that is related to the manufacture of the Compounds and/or Products, in order to enable Merck (or its designee) to manufacture the Compounds and Products, including [*] to manufacture Compounds and Products, including [*]. In addition, at the request of Merck from time to time, NewLink shall make its (and its Affiliates') employees and consultants (including personnel of its

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Third Party contract manufacturers) available to Merck to provide reasonable consultation and technical assistance in order to ensure an orderly transition of the manufacturing technology and operations to Merck (or its designee) and to assist Merck (or its designee) in the start-up of its manufacture of Compound and Product (such consultation, the “**Manufacturing Consultation**”). For clarity, the Manufacturing Consultation shall be [*].

2.9.4 Assignment of Certain Existing Agreements. At the written request of Merck, NewLink shall, to the extent legally permissible (and, to the extent consent is required from the relevant counterparty, [*]), (i) assign to Merck (or its Affiliate) any or all (as designated by Merck) of [*] and/or (ii) assist Merck (or its Affiliate) in [*] to cover the subject matter of such [*], as applicable, in each case of (i) and/or (ii), [*]; provided that NewLink shall not be obligated to assign any such [*] if such [*] is [*]. In the event that any [*] is assigned to Merck, NewLink shall [*], or related to, any such [*] as a result of, or in connection with, [*] of such [*], but which [*]. In the event that a given [*] is assigned to Merck in accordance with this Section 2.9.4, then such [*] shall [*].

2.9.5 Transition and Transition Plan; Ongoing Assistance. Without limiting the foregoing provisions of this Section 2.9, NewLink shall perform the activities to be performed by NewLink as set forth in the Transition Plan (including technology transfer). NewLink shall, during the period from the Effective Date [*], perform such other reasonable activities and provide such other reasonable assistance as Merck may reasonably request from time to time, in order to transition the Development, Manufacturing and Commercialization of Compound and Product to Merck and [*] Develop, Manufacture and Commercialize Compound and Product, including [*]; provided, that if Merck requests any such assistance after the end of the Transition Period, the Parties will agree on the scope and plan for such activities (including a plan for addressing the costs and expenses of such activities) prior to NewLink’s performance thereof, [*].

2.9.6 Data From Third Party Studies. To the extent that any Development activities (including clinical trials) are being conducted by, or sponsored by, a Third Party (including [*]) with respect to Compound or Product, [*] to obtain [*], and to [*], including the [*].

2.9.7[*]. The Parties agree and acknowledge that, except as expressly set forth in Section 2.9.5, the activities set forth in this Section 2.9, and any other activities [*], shall be [*].

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2.10 Records and Reports.

2.10.1 **Records.** Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Transition Program or other activities under this Agreement (including activities under the NewLink Funding Agreements).

2.10.2 **Copies and Inspection of Records; Reports.** Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such records of NewLink referred to in Section 2.10.1. Merck shall maintain such records and the information disclosed therein in confidence in accordance with Section 4.1. Merck shall have the right to arrange for its employee(s) and/or consultant(s) involved in the activities contemplated hereunder to visit the offices and laboratories of NewLink and any of its Third Party contractors as permitted under Section 2.4 during normal business hours and upon reasonable notice, and to discuss work performed for the Transition Program [*] with the technical personnel and consultant(s) of NewLink. Upon the reasonable request of Merck, NewLink shall provide copies of such NewLink records described in Section 2.10.1.

2.10.3 [*] **Reports.** Within [*] following the end of each [*], NewLink shall provide to Merck a written progress report in English which shall summarize the work performed to date on the Transition Program [*] in relation to the [*] of the [*] and provide [*] by the [*] relating to the progress of the goals or performance of the Transition Program [*] under the [*]. NewLink shall use Commercially Reasonable Efforts to [*]. For clarity, all such reports shall be considered the Confidential Information [*].

2.10.4 **Data Integrity.** Each Party acknowledges the importance of ensuring that the Transition Program (and the activities under the NewLink Funding Agreements) is undertaken in accordance with the following good data management practices: (i) data is being generated using sound scientific techniques and processes; (ii) data is being accurately and reasonably contemporaneously recorded in accordance with good scientific practices by Persons conducting research hereunder; (iii) data is being analyzed appropriately without bias in accordance with good scientific practices; and (iv) all data and results are being stored securely and can be easily retrieved. Each Party agrees that it shall carry out the Transition Program (and activities under the NewLink Funding Agreements) so as to collect and record any data generated therefrom in a manner consistent with the foregoing requirements.

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2.11 **Transition Program Costs.** [*] costs in connection with performing Transition Program activities.

ARTICLE 3 LICENSE, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

3.1 License Grants by NewLink.

3.1.1 **NewLink Patent Rights and NewLink Know-How.** Subject to the terms and conditions of Section 3.1.3, NewLink hereby grants to Merck an exclusive (even as to NewLink and its Affiliates), royalty-bearing license in the Territory under the NewLink Patent Rights and NewLink Know-How, with a right to grant and authorize sublicenses (subject to the restriction set forth below) through multiple tiers, to research, develop, make, have made, use, offer to sell, sell, import, export and/or otherwise exploit Compounds and Products in the Field. Merck may grant sublicenses of the rights granted to it under this Section 3.1.1 [*]; provided, however, that (a) promptly following the execution of any such sublicense for Commercialization rights with a Third Party, Merck shall [*], and (b) Merck shall be responsible for ensuring that the performance by any of its sublicensees hereunder that are exercising rights under a sublicense hereunder is in accordance with the applicable terms of this Agreement, and the grant of any such sublicense shall not relieve Merck of its obligations under this Agreement (except to the extent they are performed by any such sublicensee(s) in accordance with this Agreement).

3.1.2 **NewLink Retained Rights.** Notwithstanding the scope of the exclusive license granted to Merck under Section 3.1.1, subject to the terms and conditions of this Agreement, NewLink shall retain rights under the NewLink Patent Rights and the NewLink Know-How for the sole purpose of performing NewLink's obligations under the Transition Program in accordance with this Agreement and the Transition Plan and to perform activities expressly set forth in the NewLink Funding Agreements in accordance with this Agreement (including Section 3.10). NewLink shall [*].

3.1.3 **NewLink Canada License.** Notwithstanding anything to the contrary herein, all licenses or other grants granted by NewLink to Merck hereunder with respect to any NewLink Know-How or NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License shall at all times be subject to the terms and conditions of the NewLink Canada License. It is the intent of the Parties that [*], and as such, each Party hereby covenants that it shall [*] and shall [*] to include in [*] (provided that, [*] may also [*] that are not

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[*], which [*] and the Parties [*]), and [*]. NewLink shall [*], it being understood that [*] this sentence to the extent [*] is [*] or the [*]; provided that [*].

- 3.2 **Non-Exclusive License Grant to Merck.** In the event that the research, development, making, having made, use, offer for sale, sale, import and/or other exploitation by Merck, or Merck's Related Parties, of Compound(s) or Product(s) would infringe a claim of an issued letters patent which NewLink (or its Affiliate) Controls and which patents are not covered by the grant in Section 3.1 (an "**Additional NewLink Patent**"), Merck or NewLink, as applicable, shall so notify the other Party thereof. Thereafter, (i) the Parties will [*] and (ii) such Additional NewLink Patent [*]. Notwithstanding the foregoing, if Merck notifies NewLink in writing that [*] shall [*] included in the [*] and shall [*]. Notwithstanding the foregoing, if the exercise by Merck of the license under Section 3.1 with respect to any Additional NewLink Patent would [*], such patent shall [*] for such [*] were notified by [*] at the time the Additional NewLink Patent [*]; provided, however, that [*] to [*] the [*].
- 3.3 **Non-Exclusive License Grants to NewLink.** If NewLink's performance of activities under the Transition Program requires a license under any Merck Patent Rights or under any Merck Know-How, as applicable, Merck shall grant and hereby grants to NewLink, a non-exclusive, non-transferable, non-sublicensable, royalty-free license under such Merck Patent Rights and/or Merck Know-How, as applicable, solely to perform such activities under the Transition Program in accordance with this Agreement. For clarity, the foregoing licenses set forth in this Section 3.3 shall not limit in any way the exclusive licenses granted to Merck under Section 3.1.
- 3.4 **No Grant of Inconsistent Rights by NewLink.** NewLink (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise) (i) any rights to any NewLink Know-How or NewLink Patent Rights (or any rights to any intellectual property that would otherwise be included in the NewLink Know-How or NewLink Patent Rights), in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck hereunder, or (ii) any rights to any Compounds or Products (provided that NewLink shall grant to Merck the rights to the Compounds and Products as set forth herein). Without limiting the foregoing, [*] any Compounds or Products [*], except for [*] to be [*] as set forth in the [*] shall not [*] to any Third Parties [*].
- 3.5 **Development, Manufacturing and Commercialization.**
- 3.5.1 **General.** Merck (and its Affiliates), either itself or with or through Third Party(ies), shall have the sole right to (and shall control all aspects of) Develop and Commercialize Compounds and Products in accordance with the terms of this

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Agreement, and for clarity, [*] NewLink [*] to be [*] under the Transition Program in accordance with this Agreement and [*] expressly set forth in the [*]. With respect to the Current Product, Merck (and its Affiliates), either itself or with or through Third Party(ies), shall use Commercially Reasonable Efforts to Develop and, following receipt of all applicable Marketing Authorizations (if achieved), to Commercialize the Current Product (the “**Current Product Commercially Reasonable Efforts Obligation**”), and [*] Merck (and its Affiliates), either itself or with or through Third Party(ies), shall [*] use Commercially Reasonable Efforts [*], and, together with the Current Product Commercially Reasonable Efforts Obligation, the “**Product Diligence Obligations**”). [*] efforts and decisions with respect to the Compounds and Products [*]. Merck (and its Affiliates), either itself or with or through Third Party(ies), shall have the sole right to (and shall control all aspects of) Manufacture Compound and Product, and [*] NewLink [*] to be [*] under the Transition Program in accordance with this Agreement and [*] expressly set forth in the [*].

3.5.2 Booking of Sales; other Commercialization. Without limiting the generality of the provisions of Section 3.5.1, Merck (and its Affiliates), either itself or with or through Third Party(ies), shall have the sole right to, and shall control all aspects of, (i) handling all returns, recalls, order processing, invoicing and collection, distribution, inventory and receivables arising from sales to Third Parties, in each case, with respect to Product, (ii) booking of sales of Product, and (iii) establishing and modifying the terms and conditions with respect to the sale of the Product, including any terms and conditions relating to the price (including discounts) at which the Product will be sold.

3.6 Progress Updates. At the written request of NewLink (but no more than [*]), Merck will provide to NewLink an update on the progress of its Development activities related to Product.

3.7 Regulatory Matters. In the event that Merck determines that any regulatory filings for any Compounds or Products are required for any activities hereunder (including any activities under the Transition Program), including INDs, BLAs and other Marketing Authorizations (as applicable), then as between the Parties, Merck (or its Affiliate or Related Party or other designee) shall have the sole right, in its discretion, to obtain such regulatory filings (in its (or its Affiliate’s or its Related Party’s or other designee’s) name) and as between the Parties, Merck (or its Affiliate or its Related Party or other designee) shall be the owner of all such regulatory filings. As between the Parties, Merck (or its Affiliate or Related Party or other designee) shall have the sole right to communicate and otherwise interact with Regulatory

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Authorities with respect to the Compounds and/or Products, including with respect to any INDs, BLAs and other Marketing Authorizations in connection therewith. NewLink (and its Affiliates) shall have no right to, and shall not, make any regulatory filings related to any Compounds or Products or otherwise interact with any Regulatory Authorities with respect to the Compounds or Products; provided that [*] expressly set forth in the NewLink Funding Agreements in accordance with this Agreement [*] and [*], NewLink shall [*]; provided that, in connection with [*], as applicable, NewLink shall [*] with respect thereto (including [*]) and, to the extent not inconsistent with Applicable Law or [*], NewLink shall [*] in connection therewith (and in connection therewith, NewLink [*]). At the request of Merck, NewLink shall use Commercially Reasonable Efforts to assist Merck in communicating with, filing with, or responding to questions of Regulatory Authorities.

3.8 **Excused Performance.** The obligation of Merck with respect to any Product under Section 3.5 is [*] of the [*], and the obligation of Merck to develop or commercialize any such Product [*].

3.9 **No Implied Licenses.** Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Confidential Information disclosed to it under this Agreement or under any patents or patent applications owned or Controlled by the other Party or its Affiliates.

3.10 **Third Party Funding.**

3.10.1 **Government Funding Opportunities.** Each Party shall [*] for the Development, Manufacturing or Commercialization of Product of which it becomes aware during the Transition Period. The Parties will [in good faith discuss each such opportunity] and determine [which Party has the capabilities and resources to obtain such funding]. Unless otherwise agreed by the Parties, Merck [shall be given the opportunity (but Merck shall not be obligated) to pursue such funding opportunity (and NewLink shall not pursue any such funding opportunity unless approved by Merck in writing)] and NewLink [shall not be obligated to pursue any funding opportunity (except as expressly set forth in the following proviso) unless it agrees otherwise]; provided that, notwithstanding the foregoing, but subject to Section 3.11, NewLink [*] (the [*], the “**NewLink Future Funding Agreements**” and together with the NewLink Existing Funding Agreements, the “**NewLink Funding Agreements**”). Subject to Section 3.10.2, [*] under this Section 3.10.1 shall [*] with which it [*].

3.10.2 **NewLink Agreements.** NewLink shall be responsible for, and shall control all aspects of, the administration of the NewLink Funding Agreements; provided that [*] with respect to the [*] and [*] with respect to the [*], including to allow [*] under

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such [*] that such [*]; provided further, that in no event shall NewLink be required to [*] (provided that, for clarity, if [*] then NewLink shall [*]), or [*] obligations under the NewLink Funding Agreements. In addition, the Parties agree that [*] under a NewLink Funding Agreement (and in such case, [*] to comply with [*]); provided, however, that in the event that either (x) [*] to provide [*], (y) [*], or (z) [*] under the applicable [*] then, in each case, the Parties [*] with respect to, and shall [*] with any [*]. In connection with any [*], NewLink shall [*]; provided that NewLink shall [*] to the extent any [*]. To the extent that [*] that would be [*], NewLink shall [*] to Merck [*], unless the Parties otherwise agree that [*] pursuant to [*], in which case NewLink shall [*].

3.10.3 Activities and Materials under NewLink Funding Agreements. NewLink shall be responsible for compliance with the terms of the NewLink Funding Agreements; provided that Merck shall have the rights as set forth in Section 3.10.2. Promptly (and no later than [*] with respect to any material Know-How or other materials and [*] with respect to all other Know-How and materials) after the creation or generation of any Know-How or other materials under any NewLink Funding Agreement, NewLink [*]. NewLink shall ensure ([*]) that Merck has the rights to use, and hereby grants to Merck and its Related Parties the rights to use, such Know-How and materials in accordance with the exercise of the license set forth in Section 3.1 (and for clarity, such Know-How and materials shall be included in the licenses granted under Section 3.1); provided that, to the extent that NewLink [*] in and to any [*], NewLink shall, [*] (the “[*]”) (and in such case, such [*] shall not be included in the licenses granted under Section 3.1); provided further that, Merck (and its Related Parties) shall only [*] in connection with the Compounds and Products.

3.10.4 Merck Agreements. Merck will use Commercially Reasonable Efforts to establish [*] by the end of the Transition Period. Following the expiration of the Transition Period (or prior to the expiration of the Transition Period, if agreed to by the Parties), at the written request of Merck, NewLink shall [*], and in connection therewith, NewLink shall [*] Merck (or its Affiliate), including [*]; provided that (i) NewLink shall not [*] to the extent any [*] to provide [*] and (ii) NewLink shall not [*] provide any [*] unless such [*].

3.11 Additional NewLink Third Party Agreements. NewLink shall [*] after the Effective Date [*] not to be [*]. In connection therewith, (i) NewLink shall [*] and (iii) [*] of any such [*].

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ARTICLE 4 CONFIDENTIALITY AND PUBLICATION

- 4.1 **Non-Disclosure and Non-Use Obligation.** All Confidential Information disclosed by one Party to the other Party or its Affiliate hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any 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 Confidential Information:
- (a) is known by the 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;
 - (b) is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;
 - (c) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or
 - (d) is independently developed by the receiving Party without access to or reference to Confidential Information received from the disclosing Party, as documented by the receiving Party's business records contemporaneous with such development.

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.

- 4.2 **Permitted Disclosures.** Notwithstanding Section 4.1, a receiving Party shall be permitted to disclose Confidential Information of the disclosing Party, if such Confidential Information:
- (a) is disclosed to governmental or other regulatory agencies in order to obtain patents or to gain or maintain approval to conduct clinical trials or to market Product under this Agreement, in each case, in accordance with this Agreement, but such disclosure may be only to the extent reasonably necessary to obtain patents or authorizations, and provided that reasonable steps are taken to ensure confidential treatment of such Confidential Information (if available);
 - (b) is disclosed by the receiving Party (or its Affiliates) to Related Parties, agent(s), consultant(s), and/or other Third Parties for any and all purposes the receiving Party or its Affiliates deem necessary or advisable in the course of conducting activities in accordance with this

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Agreement (including the exercise of licenses granted to the receiving Party hereunder, and/or, in the case of Merck (or its Affiliates), engaging in transactions with potential Third Party collaborators, service providers and/or other transferees of rights and/or obligations hereunder) on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, that, with respect to Confidential Information received by NewLink from Public Health Canada, the foregoing shall at all times be subject to terms of confidentiality and non-use provisions of the NewLink Canada License;

- (c) is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement;
- (d) is deemed necessary by the receiving Party to be disclosed in connection with a potential or actual financing, merger or acquisition of the receiving Party (or its Affiliate), in which case such Party shall have the further right to disclose Confidential Information to Third Parties involved in such financing, merger or acquisition, provided that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; or
- (e) is required by the terms of the NewLink Canada License to be disclosed to Public Health Canada to satisfy NewLink's or Merck's, as applicable, obligations to report any required information, on the condition that, Public Health Canada be bound by terms of confidentiality and non-use provisions with respect to such information, as specified in the NewLink Canada License.

In addition, if a Party is required by judicial or administrative process or Applicable Law to disclose Confidential Information of the other Party that is subject to the non-disclosure provisions of Section 4.1, such 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. Confidential Information that is disclosed by judicial or administrative process or as required by Applicable Law shall remain otherwise subject to the confidentiality and non-use provisions of Section 4.1, and the Party disclosing Confidential Information pursuant to law or court order or as required by Applicable Law shall take all steps reasonably necessary, including without limitation obtaining an order of

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confidentiality, to ensure the continued confidential treatment of such Confidential Information.

- 4.3 **Know-How; Joint Know-How.** Without limiting the provisions of Section 4.1, with respect to any [*], subject to Section 4.1.
- 4.4 **Ownership of Confidential Information.** For the purposes of this Article 4, where pursuant to the terms of this Agreement one Party owns Confidential Information that has been generated by the other Party, then such Confidential Information shall be treated as if it had been generated by such owning Party and disclosed by such owning Party to such other Party.
- 4.5 **Terms of Agreement.** Neither Party nor its Affiliates shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as follows: A Party and its Affiliates may disclose the terms or conditions of this Agreement (but not any other Confidential Information, which may be disclosed only as described elsewhere in this Article 4), (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary; provided that such advisors are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or are bound by written agreements providing for confidentiality and non-use obligations, in each case, that are no less stringent than those confidentiality and non-use provisions contained in this Agreement; (b) to a Third Party in connection with a potential or actual (i) merger, consolidation or similar transaction by such Party or its Affiliates, (ii) sale of all or substantially all of the assets of such Party or its Affiliates (or, with respect to Merck, sale of all or substantially all of the assets of Merck to which this Agreement relates) or (iii) financing; provided that, in each case, the disclosing Party shall ensure that such Third Party is bound by confidentiality and non-use obligations with respect to Confidential Information of the other Party no less restrictive than those contained in this Agreement and such disclosing Party shall be fully liable to the other Party for breach of the confidentiality and non-use obligations under this Agreement by such Third Parties; (c) to the United States Securities and Exchange Commission or any other securities exchange or governmental authority, including as required to make an initial or subsequent public offering; or (d) as otherwise required by Applicable Law; provided that in the case of (c) and (d) the disclosing Party shall (x) submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [*] prior to the anticipated date of disclosure, unless such shorter period is reasonably necessary to comply with Applicable Law) so as to provide a reasonable opportunity to comment on any such required disclosure, (y) if requested by such other Party, seek, or cooperate with such Party's efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent

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available at such other Party's expense, and (z) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or protective order, and if disclosure of the terms of this Agreement is required by Applicable Law or the rules of any securities exchange or market on which a Party's securities are listed or traded, the Parties shall agree on a redacted version of this Agreement to be so disclosed; provided, however, that in the event the Parties cannot agree on such a redacted version of the Agreement, the disclosing Party shall have the right to disclose such terms of this Agreement as such Party's counsel determines is necessary to comply with Applicable Law or the rules of any securities exchange or market on which such Party's securities are listed or traded.

4.6 **Publicity/ Use of Names; Press Releases.**

4.6.1 **General.** The Parties have mutually agreed on the press release with respect to this Agreement, a copy of which is set forth in Schedule 4.6. Either Party may make subsequent public disclosures that are limited to the specific contents of such press release. Except as otherwise expressly set forth herein, no disclosure of the terms of this Agreement may be made by either Party (or its respective Affiliates), and no Party (or its respective Affiliates) shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, 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 Applicable Law, including the rules of any securities exchange or market on which a Party's securities are listed or traded; provided that in the event disclosure is required by Applicable Law, the disclosing Party shall use good-faith efforts to give the non-disclosing Party an opportunity, with reasonable advance notice, as practicable under the circumstances, to review and comment on any proposed disclosure.

4.6.2 **NewLink Publicity.** NewLink shall not issue any other press release or public announcement related to the Transition Program and/or any Compound or Product without the prior written approval of Merck; provided that if (i) such press release or public announcement is required by Applicable Law or (ii) the failure to issue such press release or public announcement would cause NewLink to breach a NewLink Funding Agreement, then NewLink may issue such press release or public announcement; provided that NewLink shall provide a copy thereof to Merck at least [*] prior to the proposed publication thereof (or with as much advance notice as possible under the circumstances if it is not possible to provide at least [(notice). Merck shall be allowed to review and comment on such proposed publication and

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NewLink shall reasonably consider any comments provided by Merck with respect thereto in a timely fashion.

4.6.3 Merck Publicity. During the Transition Period, Merck may not issue any other press release or public announcement relating to the Transition Program and/or any Compound or Product, without providing NewLink a copy of such proposed press release or public announcement at least [*] prior to the proposed publication thereof (or with as much advance notice as possible under the circumstances if it is not possible to provide at least [*] notice), and in connection therewith, NewLink shall be allowed to review and comment on such proposed publication and Merck shall reasonably consider any comments provided by NewLink with respect thereto in a timely fashion. Following the Transition Period, Merck may issue any press release or public announcement relating to the Transition Program and/or any Compound or Product; provided that, to the extent practicable, Merck shall notify NewLink thereof at least [*] prior to the proposed publication thereof (or with as much advance notice as possible under the circumstances if it is not possible to provide at least [*] notice).

4.7 Publications. NewLink shall publish scientific information related to the Compounds or Products (including the results of the Transition Program), only with the prior written consent of Merck]; provided that if [*], then NewLink may make such publication; provided that NewLink shall [*] on any [*] and [*]. Merck shall have the right to publish information related to the Compounds and Products (including the results of the Transition Program) [*].

4.8 Clinical Trial Registration. Notwithstanding the foregoing, in all cases, Merck shall have the right to register clinical trials and publish the results or summaries of results of any clinical trials conducted hereunder with respect to Compound or Product on clinicaltrials.gov or other similar registry.

4.9 Remedies. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 4.

4.10 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 4 shall supersede (i) the Existing Confidentiality Agreement and (ii) the Tri-Party Confidentiality Agreement (but solely to the extent that the Tri-Party Confidentiality Agreement applies as between Merck on the one hand, and NewLink and NL, on the other hand), and, this Article 4 shall apply to any confidential information disclosed by a Party

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(or its Affiliate) under either the Existing Confidentiality Agreement or the Tri-Party Confidentiality Agreement, as applicable.

ARTICLE 5 PAYMENTS AND REPORTS

5.1 **Upfront Payment.** In consideration of the license and other rights granted to Merck herein, Merck shall pay to NewLink, within [*] following the Effective Date, a one-time, non-refundable upfront payment in the amount of Thirty Million Dollars (\$30,000,000).

5.2 **Milestone Payment.** Subject to the terms and conditions of this Agreement, Merck shall pay to NewLink a one-time, non-refundable payment in the amount of Twenty Million Dollars (\$20,000,000) (the “**Milestone Payment**”) within [*] following [*] as [*] (the “**Milestone Event**”).

5.3 [*].

5.3.1[*]. If, at any time during the Term, [*] Merck or a Related Party [*] or to [*] (the “[*]”), [*] shall promptly notify the other Party thereof. If Merck or a Related Party [*], then, upon [*], to the extent legally permissible, Merck (or such Related Party, as applicable) shall [*], and in connection therewith, the Parties [*] of such [*]. In all cases (whether [*] was received by [*] or [*] of its intent to [*], then [*] in the [*] plus [*] in connection with [*] in connection with [*], and [*] a Third Party, then [*], and [*] not to [*], and [*] of any and all [*] in connection with [*] by Merck (or its Related Party) solely in connection with [*]. For clarity, the provisions of this Section 5.3 shall only apply with respect to [*], and [*]. As used in this Section 5.3.1, the term “[*]” shall mean [*], which shall be mutually agreed to by the Parties [*]; provided that if [*], then [*] to each of the Parties.

5.3.2[*]. If, at any time during the Term, [*] Merck or a Related Party [*] or to [*] (the “[*]”), [*] shall promptly notify the other Party thereof. If Merck or a Related Party [*], then, upon [*], to the extent legally permissible, Merck (or such Related Party, as applicable) shall [*], and in connection therewith, the Parties [*]. In all cases (whether [*] was received by [*] or [*] of its intent to [*], then [*] in the [*] plus [*] in connection with [*] in connection with [*], and [*] to a Third Party, then [*], and [*] not to [*], and [*] of any and all [*] in connection with [*] by Merck (or its Related Party) solely in connection with [*]. For clarity, the provisions of this Section 5.3 shall only apply with respect to [*], and [*]. As used in this Section 5.3.1, the term “[*]” shall mean [*], which shall be mutually agreed to by the Parties [*]; provided that if [*], then [*] to each of the Parties.

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5.3.3 **Obligation to [*]**. Merck shall, upon NewLink's reasonable request [*], undertake [*] to [*] or [*] that may be available to [*].

5.3.4 **Tax Matters**. Upon the issuance of [*] or [*], the Parties shall discuss in good faith [*] under this Section 5.3.4 [*].

5.4 **Royalty Payments.**

5.4.1 **Royalty Rates**. Subject to the other terms of this Section 5.4, on a Product-by-Product basis, during the Royalty Term for a given Product in a given country in the Royalty Bearing Territory, Merck shall make, on a Calendar Year basis, royalty payments to NewLink on the Product Net Sales of such Product in a given Calendar Year in such countries at the applicable royalty rate set forth below (which royalty rates shall be different for the Current Product and for any other Product as set forth below). For clarity, the royalties (and royalty tiers) shall be calculated separately on a Product-by-Product basis.

Current Product	
Annual Product Net Sales of a given Product in the Royalty-Bearing Territory in a given Calendar Year	Royalty Rate for Product Net Sales
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory up to and including \$[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than \$[*] and less than or equal to \$[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than \$[*] and less than or equal to \$[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than \$[*] in a given Calendar Year	[*]%
Products other than Current Product	

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Annual Product Net Sales of a given Product in the Royalty-Bearing Territory in a given Calendar Year	Royalty Rate for Product Net Sales
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory up to and including \$[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than \$[*] and less than or equal to \$[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than \$[*] and less than or equal to \$[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than \$[*] in a given Calendar Year	[*]%

For clarity, (i) if no royalty is payable on a given unit of Product (e.g., following the Royalty Term for such Product in a given country or sales of a given Product outside of the Royalty Bearing Territory), then the Product Net Sales of such unit of Product shall not be included for purposes of determining the foregoing royalty tiers and (ii) Product Net Sales of a given Product will not be combined with Product Net Sales of any other Product for purposes of determining the foregoing royalty tiers.

5.4.2 Royalty Term. Merck’s royalty payment obligations under this Agreement with respect to a given Product shall commence upon [*] in the Field anywhere in the Royalty Bearing Territory by Merck or Related Parties, and shall continue, (i) with respect to the [*] Product, on a Product-by-Product basis, until [*] expiration of the last to expire Valid Claim included in NewLink Patent Rights [*] that Covers such Product, and (ii) with respect to [*], on a Product-by-Product and country-by-country basis, until the later of (x) the expiration of the last to expire Valid Claim included in NewLink Patent Rights in the country of sale that Covers such Product in such country or (y) [*] after the [*] of such Product in such country (the “**Royalty Term**”).

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5.4.3 Royalty Reduction.

- (c) **Know-How Royalty.** Subject to Section 5.4.3(c) below, if a Product is generating Product Net Sales in a country in the Royalty Bearing Territory during the Royalty Term at a time when there is no Valid Claim (i) with respect to the [*] Product, included in the NewLink Patent Rights [*] that Covers such Product, [* (ii) with respect to [*] than the [*] Product, included within the NewLink Patent Rights in such country that Covers such Product in such country, then the royalty rate applicable to Product Net Sales of such Product in such country in the Royalty Bearing Territory pursuant to Section 5.4.1 thereafter shall be reduced by [*].
- (d) **Reduction for Third Party Payments.** Subject to Section 5.4.3(c) and 5.4.3(d) below, Merck or any Related Party obtains a right or license under any intellectual property of a Third Party (whether prior to, or after, the Effective Date), where the research, development, making, using, selling, offering for sale, or importing of Product (or Compound contained in such Product) by Merck or any Related Party would result in a payment to such Third Party, then Merck may deduct from the royalty payment that would otherwise have been due under this Section 5.4 with respect to Product Net Sales of such Product in a particular Calendar Quarter, an amount equal to [*] pursuant to such right or license in connection with the research, development, making, using, selling, offering for sale, or importing of Product (or Compound contained therein) during such Calendar Quarter; provided, however, that in no event shall the royalties payable on Product Net Sales of Product be reduced by more than [*] in any Calendar Quarter by operation of this Section 5.4.3(b) (provided, however, that [*] as a result of [*] shall be [*] with respect to such [*]).
- (e) **Payments to Public Health Canada by Merck.** Notwithstanding anything to the contrary contained herein, in the event that Merck (or its Related Party, as applicable) pays any royalties or other amounts directly to Public Health Canada in connection with any Compound or Product (or the research, development, making, using, selling, offering for sale, or importing thereof), then (i) [*], and [*] and (ii) to the extent that Merck [*] from the [*] to NewLink in a [*], then NewLink [*] for the [*].
- (f) **Minimum Royalty Rate.** Notwithstanding the foregoing provisions of this Section 5.4.3 (but subject to Section 5.4.3(c) and 5.4.6), for so long as NewLink [*] as a result of sales of Product by Merck or its Related Parties in the Royalty Bearing Territory hereunder, in no event shall the royalty rate payable by Merck under this Section 5.4 due on Product Net Sales hereunder be reduced pursuant to the foregoing provisions of this Section 5.4.3 to less than [*], including [*]; provided that, for clarity, the provisions of this Section 5.4.3(d) are not intended to, and shall not be interpreted to, expand Merck's royalty obligations hereunder

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(other than with respect to the royalty rate payable by Merck as expressly set forth in this Section 5.4.3(d)), including [*].

5.4.4 Change in Sales Practices. The Parties acknowledge that during the term of this Agreement, Merck's sales practices for [*] to the extent [*] may become [*]. In such event, at the request of Merck, the Parties [*] to the extent currently contemplated under this Section 5.4.

5.4.5 Royalties for Bulk Compound. In those cases in which Merck (or its Related Party) sells bulk Compound rather than Product in packaged form to an independent Third Party, the royalty obligations of this Section 5.4 shall be applicable to the bulk Compound only (but solely to the extent that a royalty would otherwise be payable on the Product incorporating such Compound).

5.4.6[*]. If [*] with respect to Product in any country in the Royalty Bearing Territory [*], then the [*] in such country [*] shall be [*] and in such case, [*]; provided that if as a result of this Section 5.4.6, the royalty rate on Product Net Sales of such Product in such country [*] (or [*], including taking into account [*]), then for so long as [*] pursuant to the [*] hereunder in such country in the Royalty Bearing Territory (and provided that [*] is still in effect with respect to [*]), then the Parties [*] between the [*] on such [*] and the [*] with respect to [*] in such country.

5.4.7 Additional Conditions. All royalties are subject to the following conditions:

- (a) that only one royalty shall be due with respect to the same unit of Product; and
- (b) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck's or its Related Party's Product Net Sales to the first independent Third Party; and
- (c) the determination of whether a royalty will be calculated and payable hereunder shall be determined on a Product-by-Product basis.

5.4.8 Royalty Reports and Payments. Within [*] after each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of the first Product is made anywhere in the Royalty Bearing Territory, Merck shall provide NewLink with a report that contains the following information for the applicable Calendar Quarter, on a Product-by-Product and country-by-country basis for the Royalty Bearing Territory: (i) the amount of gross sales of the Products, (ii) a reconciliation between gross sales and Product Net Sales, as specified in the definition thereof, and (iii) a calculation of the royalty payment due on such sales,

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including any royalty reduction made in accordance with this Section 5.4. Concurrent with the delivery of the applicable quarterly report, Merck shall pay in Dollars all royalties due to NewLink with respect to Product Net Sales by Merck and its Related Parties for such Calendar Quarter.

5.4.9 Currency Exchange. All payments to be made by a Party under this Agreement shall be made in Dollars, by wire transfer, pursuant to the instructions of the Party receiving payment, as designated from time to time. The wire instructions for NewLink are set forth on Schedule 5.4.9 (which instructions may be updated in writing by NewLink to Merck). For purposes of calculating the net royalty obligation, to the extent Product is sold in a currency other than Dollars, the amount received shall be converted into Dollars on a monthly basis using as a rate of exchange [*].

5.5 Records and Audits.

5.5.1 Merck shall (and shall cause its Affiliates to) maintain complete and accurate records in sufficient detail to permit NewLink to confirm the accuracy of the royalty payments under this Agreement. Upon reasonable prior notice, such records shall be open during regular business hours for a period of [*] from the creation of individual records for examination by an independent international certified public accountant selected by NewLink and reasonably acceptable to Merck for the sole purpose of verifying for NewLink the accuracy of the royalty reports furnished by Merck pursuant to this Agreement or of any royalty payments made, or required to be made by Merck pursuant to this Agreement. Such audits shall not occur more often than [*] each Calendar Year. Such auditor shall not disclose Merck's Confidential Information to NewLink, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Merck or the amount of payments by Merck under this Agreement. If the accountant correctly identifies a discrepancy, any amounts shown to be owed but unpaid (or overpaid, as applicable) shall be paid by the applicable Party within [*] after the accountant's report. NewLink shall bear the full cost of such audit unless such audit reveals an underpayment by Merck that resulted from a discrepancy in the financial report provided by Merck for the audited period, which underpayment was more than [*], in which case Merck shall reimburse NewLink for the fees of the accountant for such audit.

5.5.2 Upon the expiration of [*] following the end of any Calendar Year, the calculation royalties payable with respect to such Calendar Year shall be binding and conclusive

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upon NewLink, and Merck (and its Affiliates) shall be released from any liability or accountability with respect to such royalties for such Calendar Year.

5.5.3 NewLink shall treat all financial information subject to review under this Section 5.5 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 Affiliates obligating it to retain all such Confidential Information in confidence pursuant to such confidentiality agreement.

5.6 Taxes.

5.6.1 **Generally.** Each Party will pay any and all taxes levied on account of all payments it receives under this Agreement except as otherwise provided in this Section 5.7.

5.6.2 **Transfer Taxes.** [*] shall be liable for all transfer taxes (including value added tax (VAT), Canadian Goods and Services taxes (GST), sales and use tax, and other similar taxes), including interest (“**Transfer Taxes**”) imposed upon any [*] under this Agreement, including this Article 5. The Parties shall reasonably cooperate in accordance with Applicable Laws to (i) minimize Transfer Taxes payable in connection with this Agreement and (ii) ensure all tax returns relating to Transfer Taxes are properly filed.

5.6.3 **Income Tax Withholding.** If Applicable Laws require that taxes be withheld with respect to any payments by under this Agreement, the payor will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to the payee on a timely basis following that tax payment. Each Party agrees to reasonably cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with Applicable Laws.

5.7 **NewLink Third Party Agreements.** Notwithstanding anything to the contrary herein, [*], NewLink shall be solely responsible for (and [*] to the extent [*]) all costs and payments of any kind (including all upfront fees, annual payments, milestone payments and royalty payments) arising under any NewLink Third Party Agreements in connection with the Development, Manufacture, Commercialization or other exploitation of Compounds and/or Products hereunder.

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ARTICLE 6 REPRESENTATIONS AND WARRANTIES

6.1 **Representations And Warranties Of Each Party.** Each Party represents and warrants to the other Party that as of the Effective Date:

6.1.1 such Party is duly organized and validly existing under the laws of the state or jurisdiction of its organization and has full corporate power and authority to enter into this Agreement and to perform its obligations hereunder;

6.1.2 the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Party. This Agreement has been duly executed by such Party. This Agreement and any other documents contemplated hereby constitute valid and legally binding obligations of such Party enforceable against it in accordance with their respective terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; and

6.1.3 the execution, delivery and performance by such Party of this Agreement and any other agreements and instruments contemplated hereunder will not (i) in any respect violate any statute, regulation, judgment, order, decree or other restriction of any governmental authority to which such Party is subject, (ii) violate any provision of the corporate charter, by-laws or other organizational documents of such Party, or (iii) constitute a violation or breach by such Party of any provision of any material contract, agreement or instrument to which such Party is a party or to which such Party may be subject although not a party.

6.2 **Additional NewLink Representations and Warranties.** NewLink represents and warrants to Merck that as of the Effective Date:

6.2.1 NewLink and NL each has the full right, power and authority to enter into this Agreement, to perform the activities hereunder (including the Transition Program) and to grant the license set forth in Section 3.1.1 and Section 3.2;

6.2.2 there are no claims, judgments or settlements against or owed by NewLink (or any of its Affiliates) and no pending or, to NewLink's knowledge, threatened claims or litigation, in each case, relating to the NewLink Patent Rights and/or NewLink Know-How and/or Compounds and/or Products;

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- 6.2.3 Schedule 1.79 sets forth a true, correct and complete list of NewLink Patent Rights existing as of the Effective Date and such schedule contains all application numbers and filing dates, registration numbers and dates, jurisdictions and owners. The NewLink Patent Rights and NewLink Know-How constitute [*], the Compounds and/or Products or the Development, Manufacture, Commercialization and/or use thereof, or the performance of the Transition Program;
- 6.2.4 all issued patents within the NewLink Patent Rights are in full force and effect, and, [*], in whole or in part;
- 6.2.5 it (and its Affiliates) has not prior to the Effective Date (i) assigned, transferred, conveyed or otherwise encumbered its right, title and/or interest in NewLink Patent Rights or NewLink Know-How, or (ii) otherwise granted any rights to any Third Parties that would, in the case of clauses (i) and/or (ii), conflict with the rights granted to Merck hereunder;
- 6.2.6 to NewLink's knowledge, [*];
- 6.2.7 it [*] the NewLink Patent Rights and NewLink Know-How, all of which are, as at the Effective Date, [*];
- 6.2.8 neither it nor any of its Affiliates has received any written notification from a Third Party that the research, development, manufacture, use, sale or import of Compounds or Products infringes or misappropriates the Patent Rights or Know-How owned or controlled by such Third Party, and NewLink has no knowledge that a Third Party has any basis for any such claim;
- 6.2.9 NewLink has [*] regarding [*], including [*], and [*];
- 6.2.10 NewLink has [*] related to NewLink Patent Rights or NewLink Know-How licensed under this Agreement;
- 6.2.11 NewLink has [*] Compound and/or Product [*] from any [*] or any [*] in any [*], or any other [*] to NewLink or any of the Affiliates [*], or [*] subject of any [*], in each case, with respect to [*] related to the [*];
- 6.2.12 other than [*] or any other [*] for any Compounds or Products, and, to the best of NewLink's knowledge, [*] for any Compounds or Products. The [*] and neither NewLink nor any of its Affiliates [*];
- 6.2.13 NewLink has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by it as of the

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Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement;

6.2.14 NewLink (and its Affiliates) has not employed or otherwise used in any capacity, and will not (during the Transition Program) employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment or debarred under United States law, including under 21 USC 335a or any foreign equivalent thereof, with respect to the Compounds or Products or otherwise in performing any portion of the Transition Program (or any portion of the NewLink Funding Agreements);

6.2.15 all [*] related to the Compounds and/or Products [*] and, to NewLink's knowledge, all [*] related to the Compounds and/or Products [*] in accordance with all Applicable Laws;

6.2.16 all information and data provided by or on behalf of NewLink to Merck on or before the Effective Date in contemplation of this Agreement was and is true and accurate and complete in all material respects, and NewLink has not disclosed, failed to disclose, or cause to be disclosed, any material information or data that would reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect;

6.2.17 it [*];

6.2.18 other than [*], there are no [*] or other [*] the NewLink Know-How or NewLink Patent Rights;

6.2.19 with respect to each NewLink Existing Third Party Agreement and each NewLink Future Funding Agreement [*] it is in full force and effect; [*] to such [*] or [*] from the [*] any of the [*], and [*] which could [*] the scope of [*] any of the [*]; and [*] relating to any [*] or any other [*];

6.2.20 the [*] provided to Merck [*] in accordance with [*]. Such [*] is not [*] and is not [*], under the [*]. All such [*];

6.2.21 Schedule 6.2.21 sets forth [*] by NewLink to be [*] (the "**Product Materials**");

6.2.22 Other than the [*], neither NewLink nor any of its Affiliates has [*], and with respect to the [*], NewLink has [*] under the [*];

6.2.23 Except with respect to [*], neither NewLink nor its Affiliates [*] for the [*], in each case, other than with respect to the Current Compound and Current Product;

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- 6.2.24 No Know-How or other intellectual property within the NewLink Know-How or NewLink Patent Rights [*];
- 6.2.25 Except with respect to the rights expressly retained by Public Health Canada under the NewLink Canada License, [*] Know-How, Patent Rights or other intellectual property [*], and, except with respect to the rights expressly retained by Public Health Canada under the NewLink Canada License [*] to any such [*]; and
- 6.2.26 NewLink is a wholly-owned subsidiary of NL, and, except as set forth on Schedule 6.2.26, there are no other Affiliates of either NewLink or NL.

6.3 **Additional Merck Representations and Warranties.**

- 6.3.1 Merck represents and warrants to NewLink that as of the Effective Date, Merck has determined pursuant to 16 C.F.R. Sec. 801.10 that no filing is required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended and the rules promulgated thereunder, with respect to the subject matter of this Agreement.
- 6.4 **Warranty Disclaimer.** EACH PARTY HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREIN NOT EXPRESSLY MADE IN THIS AGREEMENT TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAWS, INCLUDING WITH RESPECT TO THE COMPOUNDS, PRODUCTS, OR ANY TECHNOLOGY OR OTHER INTELLECTUAL PROPERTY LICENSED OR GRANTED UNDER THIS AGREEMENT, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS SECTION 6.4 SHALL OPERATE TO LIMIT OR INVALIDATE ANY EXPRESS REPRESENTATION OR WARRANTY CONTAINED HEREIN.
- 6.5 **NewLink Third Party Agreements.** NewLink represents and warrants to Merck that [*] and [*], and [*] as of the Effective Date. NewLink [*] (a) [*] in full force and effect, [*]; (b) [*] has been [*] any of the [*]; (c) [*] of any [*] any of the [*] or [*], made by [*] and (d) to the extent [*], it shall promptly [*] of all other [*] to such [*] related to such [*].
- 6.6 [*]. During the period from the Effective Date until [*], each Party agrees and covenants to [*] or the Parties [*]; provided, however, that [*] such Party [*]. A violation of [*] may be [*].

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ARTICLE 7 INTELLECTUAL PROPERTY

7.1 **Ownership of Background Technology.** As between the Parties, any NewLink Know-How existing prior to the Effective Date and owned by NewLink shall, during the Term and upon expiration or termination of this Agreement, continue to be owned exclusively by NewLink. As between the Parties, any Merck Know-How shall, during the Term and upon expiration or termination of this Agreement, continue to be owned exclusively by Merck.

7.2 Program Know-How.

7.2.1 **Ownership.** For purposes of determining ownership under this Section 7.2.1, inventorship of Program Know-How and Program Patent Rights shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Notwithstanding the foregoing, all right, title and interest in any Program Know-How and Program Patent Rights, in each case, shall be determined in accordance with the following terms and conditions:

- (a) As between the Parties, NewLink shall own all right, title and interest in any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice solely by one or more employees, agents or consultants of NewLink, its Affiliates, or its subcontractors (but excluding Merck (or its Affiliates) as a subcontractor of NewLink under any NewLink Funding Agreement) (such Program Know-How, the “**NewLink Program Know-How**” and such Program Patent Rights, the “**NewLink Program Patent Rights**”);
- (b) As between the Parties, Merck shall own all right, title and interest in any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice solely by one or more employees, agents or consultants of Merck, its Affiliates, or its subcontractors (such Program Know-How, the “**Merck Program Know-How**” and such Program Patent Rights, the “**Merck Program Patent Rights**”); and
- (c) NewLink and Merck shall jointly own all right, title and interest in any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice by one or more employees, agents or consultants of NewLink, its Affiliates, or its subcontractors, together with one or more employees, agents or consultants of Merck, its Affiliates, or its subcontractors (such Program Know-How, the “**Joint Program Know-How**” and such Program Patent Rights, the “**Joint Program Patent Rights**”). Subject to the licenses granted to the other Party under this Agreement and the other terms of this Agreement, each Party has a right to exploit its interest in such Joint

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Program Know-How and Joint Program Patent Rights without the consent of, and without accounting to, the other Party; provided, however, that for clarity, the foregoing joint ownership rights with respect to Joint Program Know-How and Joint Program Patent Rights shall not be construed as granting, conveying or creating any license or other rights to the other Party's intellectual property, unless otherwise expressly set forth in this Agreement.

7.2.2 **Assignment of Interests to Effectuate Ownership of Joint Program Know-How and Joint Program Patent Rights.** With respect to any Joint Program Know-How and Joint Program Patent Rights, each of NewLink and Merck shall on behalf of itself and each of their respective Affiliates, employees and contractors hereunder, assign to one another (without payment of additional consideration), in perpetuity throughout the world, ownership of an undivided interest in and to such Program Know-How and Program Patent Rights if necessary to effect the ownership of such Program Know-How and Program Patent Rights as set forth in Section 7.2.1(c), subject to any licenses expressly granted under this Agreement. In furtherance of the foregoing, each Party shall, upon request by the other, promptly undertake and perform (and/or cause its Affiliates and its and their respect employees and/or agents to promptly undertake and perform) such further actions as are reasonably necessary for NewLink and Merck to, as between the Parties, perfect its title in any such Program Know-How and Program Patent Rights as set forth in Section 7.2.1(c), as, and to the extent, applicable, including by causing the execution of any assignments or other legal documentation, and/or providing the other Party or its patent counsel with reasonable access to any employees or agents who may be inventors of such Program Know-How and Program Patent Rights.

7.3 **Filing, Prosecution and Maintenance of Patent Rights.**

7.3.1 **Joint Program Patent Rights and NewLink Patent Rights.**

(a) **Joint Program Patent Rights and NewLink Patent Rights.** With respect to any Joint Program Patent Rights and any NewLink Patent Rights, [*] shall have the first right (in its discretion), at its cost, to Prosecute such Patent Rights in the name of both Parties (with respect to Joint Program Patent Rights) or NewLink (with respect to NewLink Patent Rights); provided, however, that [*] shall only have the right to Prosecute [*] and [*] to the extent such Prosecution [*]. In connection therewith, [*] as may be [*] the Joint Program Patent Rights and NewLink Patent Rights. [*] may elect to use outside counsel for such Prosecution. With respect to a given Joint Program Patent Right or NewLink Patent Right, [*] (i) may elect not to Prosecute, (ii) may elect not to Prosecute in a particular country (including electing not to validate in a particular country) and/or (iii) may elect to discontinue Prosecution in a particular country; and in case of clause (ii) or clause (iii), [*] shall provide

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[*] with notice thereof (provided that with respect to the foregoing clause (iii), such notice shall be provided in a timely manner) and [*] shall have the right (but not the obligation), at its sole expense and upon written notice to [*], to assume such responsibility for the Prosecution of such Joint Program Patent Right (in the name of both Parties) or NewLink Patent Rights (in the name of NewLink) to the extent [*] has elected not to do so; provided, however, that if [*] elects to [*] in the [*] in such [*], then, in the event that [*] thereafter [*], and the [*] in such country under such [*], then [*] shall [*] incurred by [*] in such country [*]. [*] shall comply with all applicable obligations (but [*]) under [*] applicable to the Prosecution of [*] by [*] and [*].

- (b) **Review and Consultation.** With respect to the Joint Program Patent Rights and NewLink Patent Rights, upon the written request of the non-Prosecuting Party, the Prosecuting Party shall give the non-Prosecuting Party an opportunity to review the text of any application before filing, shall consult with the non-Prosecuting Party with respect thereto (and shall consider the non-Prosecuting Party's comments thereto in good faith), and shall supply the non-Prosecuting Party with a copy of the application as filed, together with notice of its filing date and serial number. Upon request of the non-Prosecuting Party, the Prosecuting Party shall keep the other Party advised of the status of such actual and prospective patent filings and, upon such other Party's request, shall provide advance copies of any material papers to be filed related to the filing, prosecution and maintenance of such patent filings. Each Party shall promptly give notice to the other Party of the grant, lapse, revocation, surrender, invalidation or abandonment of such Joint Program Patent Rights or NewLink Patent Rights for which it is responsible for the filing, prosecution and maintenance.

7.3.2 Merck Patent Rights. Merck shall have the sole right, in its discretion and at its own expense, to Prosecute the Merck Patent Rights, and NewLink shall have no rights in connection therewith.

7.3.3 Cooperation. As requested by the Prosecuting Party, the non-Prosecuting Party shall provide the Prosecuting Party with reasonable assistance in connection with the Prosecution of Patent Rights under this Section 7.3, including (i) giving the Prosecuting Party reasonable access to its employees, agents, consultants and subcontractors and those of the non-Prosecuting Party's Affiliates for the purposes of identifying inventors of subject matter in any such Patent Rights, and (ii) obtaining any necessary declarations and assignments from its named inventors or those under obligation to assign inventions hereunder, and providing relevant technical reports (including, if necessary, laboratory notebooks), to the Prosecuting Party concerning the subject invention. Without limiting the foregoing, if a power of attorney from the non-Prosecuting Party is needed to facilitate the Prosecuting Party's Prosecution

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of Patent Rights in accordance with this Section 7.3, the non-Prosecuting Party shall obtain and provide to the Prosecuting Party such power of attorney.

7.3.4 Prosecution Matters. For the avoidance of doubt, all interferences, oppositions, appeals or petitions to any board of appeals in any patent office, appeals to any court for any patent office decisions, reissue proceedings, invalidation proceedings, re-examination proceedings, *inter partes* reviews, post grant reviews, derivation proceedings or other similar administrative proceedings or administrative appeals thereof, with respect to any Patent Rights under this Agreement shall be considered patent Prosecution matters, and shall be handled in accordance with this Section 7.3. With respect thereto, the non-Prosecuting Party shall (i) join (if required to bring such action) such action voluntarily, and (ii) execute and cause its Affiliates to execute all documents necessary for the Prosecuting Party to initiate such action in the event that the Prosecuting Party is unable to initiate or prosecute such action solely in its own name. In all cases, with respect to the Prosecution of the NewLink Patent Rights or Joint Program Patent Rights, as applicable, the Prosecuting Party shall not enter into any settlement that would oblige the non-Prosecuting Party (or any of its Related Parties) to make any payment or would have a detrimental effect on the Compounds or Products, or the rights or licenses of the non-Prosecuting Party hereunder, without the non-Prosecuting Party's prior written consent (not to be unreasonably withheld).

7.4 Enforcement of Patent Rights.

7.4.1 NewLink Patent Rights and Joint Program Patent Rights. NewLink shall give Merck prompt written notice of either (i) any infringement of NewLink Patent Rights or Joint Program Patent Rights and/or (ii) any misappropriation or misuse of NewLink Know-How or Joint Program Know-How that may come to NewLink's attention. Merck and NewLink shall thereafter consult and cooperate fully to determine a course of action, including the commencement of legal action by either or both Merck and NewLink, to terminate any infringement of NewLink Patent Rights or Joint Program Patent Rights or any misappropriation or misuse of NewLink Know-How or Joint Program Know-How, as applicable. However, subject at all times to any applicable terms and conditions of the NewLink Canada License with respect to NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License, Merck, upon notice to NewLink, shall have the first right to initiate and prosecute such legal action at its own expense (including, in the name of NewLink, if necessary) or to control the defense of any declaratory judgment action relating to NewLink Patent Rights, Joint Program Patent Rights, NewLink Know-How or Joint Program Know-How, as

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applicable. If NewLink is required to join in such action in order for Merck to bring such action, then, at the reasonable request of Merck, NewLink shall join such action. Merck shall promptly inform NewLink if it elects not to exercise such first right and NewLink shall thereafter have the right (in its discretion) to initiate and prosecute such action (or to control the defense of such declaratory judgment action, as applicable), at its own expense; provided, however, that in all cases, NewLink shall not enter into any settlement that would oblige Merck to make any payment or would have a detrimental effect on the Compounds or Products, or the rights or licenses of Merck hereunder, without Merck's prior written consent. Each Party shall have the right to be represented by counsel of its own choice. For clarity, NewLink shall not bring any action to enforce any NewLink Patent Rights or NewLink Know-How or Joint Program Patent Rights or Joint Program Know-How, as applicable, unless (i) Merck has elected not to exercise its first right as set forth in this Section 7.4.1 or (ii) Merck otherwise consents thereto in writing (in Merck's sole discretion), and in all cases, NewLink shall not agree to any settlement in connection therewith without the prior written consent of Merck (in Merck's sole discretion). Merck shall comply with all obligations (other than [*]) under the NewLink Canada License applicable to the enforcement of the NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License.

7.4.2Cooperation. For any action to terminate any infringement of NewLink Patent Rights or Joint Program Patent Rights, or any misappropriation or misuse of NewLink Know-How or Joint Program Know-How, in the event that Merck is unable to initiate or prosecute such action solely in its own name, NewLink shall join such action voluntarily and execute and cause its Affiliates to execute all documents necessary for Merck to initiate litigation to prosecute and maintain such action. In connection with any action by Merck, NewLink shall cooperate fully with Merck and NewLink shall provide Merck with any information or assistance that Merck may reasonably request.

7.4.3Information. In connection with the foregoing, each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

7.4.4Recoveries. Subject at all times to any applicable recovery terms of the NewLink Canada License with respect to enforcement actions of the NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License, any recovery obtained by either or both Merck and NewLink in

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connection with or as a result of any action contemplated by the foregoing provisions of Section 7.4.1, whether by settlement or otherwise, shall be shared in order as follows:

- (a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;
- (b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and
- (c) the amount of any recovery remaining shall [*].

7.4.5 Biosimilar Applications.

- (a) Notwithstanding the foregoing provisions of this Section 7.4, if either Party receives a copy of a Biosimilar Application referencing a Product or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for marketing authorization (such as in an instance described in 42 U.S.C. §262(l)(9)(C), the remainder of this Section 7.4.5 shall apply. Such Party shall within [*] notify the other Party. The owner of the relevant patents shall then seek permission to view the application and related confidential information from the filer of the Biosimilar Application if necessary under 42 U.S.C. §262(l)(1)(B)(iii). If either Party receives any equivalent or similar communication or notice in the United States or any other jurisdiction, either Party shall within [*] notify and provide the other Party copies of such communication to the extent permitted by Applicable Laws. Regardless of the Party that is the “reference product sponsor,” as defined in 42 U.S.C. §262(l)(1)(A), for purposes of such Biosimilar Application:
 - (i) Merck shall designate, to the extent permitted by law, or otherwise NewLink shall designate in accordance with Merck’s instructions, the outside counsel and in-house counsel who shall receive confidential access to the Biosimilar Application pursuant to 42 U.S.C. §262(l)(1)(B)(ii).
 - (ii) Merck shall have the right, after consulting with NewLink, to list any patents, including those within the NewLink Patent Rights, as required pursuant to 42 U.S.C. §262(l)(3)(A) or 42 U.S.C. §262(l)(7), to respond to any communications with respect to such lists from the filer of the Biosimilar Application, to negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange other than that specified in 42 U.S.C. §262(l)(1) and as to the patents that will be subject to the initial litigation procedure as described in 42 U.S.C. §262(l)(4), to decide which patent or patents shall be selected for initial litigation under 42 U.S.C. §262(l)(5)(B)(i)(II), and to commence

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such litigation under 42 U.S.C. §262(l)(6). If required pursuant to Applicable Law, upon Merck's request, NewLink shall execute these tasks after consulting with Merck.

- (iii) Merck shall have the right, after consulting with NewLink, to identify patents, including those within the NewLink Patent Rights, or respond to relevant communications under any equivalent or similar listing to those described in the preceding clause (ii) in any other jurisdiction outside of the United States. If required pursuant to Applicable Law, upon Merck's request, NewLink shall assist in the preparation of such list and make such response after consulting with Merck.
- (iv) NewLink shall cooperate with Merck's reasonable requests in connection with the foregoing activities to the extent required or permitted by Applicable Laws. Merck shall consult with NewLink prior to identifying any NewLink Patent Rights to a Third Party as contemplated by this Section 7.4.5. Merck shall consider in good faith advice and suggestions with respect thereto received from NewLink, and notify NewLink of any such lists or communications promptly after they are made.
- (v) Each Party shall within [*] after receiving any notice of commercial marketing provided by the filer of a Biosimilar Application pursuant to 42 U.S.C. §262(l)(8)(A), notify the other Party. To the extent permitted by law, Merck shall have the first right, but not the obligation, to seek an injunction against such commercial marketing as permitted pursuant to 42 U.S.C. §262(l)(8)(B) and to file an action for infringement. If required pursuant to Applicable Law, upon Merck's request, NewLink shall assist in seeking such injunction or filing such infringement action after consulting with Merck. Except as otherwise provided in this Section 7.4.5, any such action shall be subject to the terms and conditions of Section 7.4.1 through 7.4.4 in relation to actions for infringement brought by Merck.
- (vi) The Parties recognize that procedures other than those set forth above in Section 7.4.5 may apply with respect to Biosimilar Applications. In the event that the Parties determine that certain provisions of Applicable Laws in the United States or in any other country in the Territory apply to actions taken by the Parties with respect to Biosimilar Applications under Section 7.4.5 in such country, the Parties shall comply with any such Applicable Laws in such country (and any relevant and reasonable procedures established by Parties) in exercising their rights and obligations with respect to Biosimilar Applications under this Section 7.4.5
- (b) As used herein, the term "**Biosimilar Application**" means an application or submission filed with a Regulatory Authority for Marketing Authorization of a pharmaceutical or biological product claimed to be biosimilar or interchangeable to any Product or otherwise

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relying on the approval of such Product, including, for example, an application filed under 42 U.S.C. §262(k).

7.4.6 Merck Patent Rights and Merck Know-How. Notwithstanding the foregoing provisions of this Section 7.4, Merck shall have the sole right, in its discretion, to handle any action with respect to any infringement of Merck Patent Rights, or misappropriation of Merck Know-How, including that Merck shall have the sole right, in its discretion, to handle any certification matter regarding any Merck Patent Rights with respect to any Biosimilar Application as set forth in Section 7.4.5, and NewLink shall have no rights in connection with any of the foregoing. For any action with respect to any infringement of Merck Patent Rights or misappropriation of Merck Know-How (including in connection with any Biosimilar Application), in the event that Merck is unable to initiate or prosecute such action solely in its own name, NewLink shall, at Merck's request and expense, join such action voluntarily and execute and cause its Affiliates to execute all documents necessary for Merck to initiate litigation to prosecute and maintain such action. In connection with any action, at the request of Merck, NewLink shall, at Merck's expense, provide Merck with reasonable assistance that Merck may reasonably request. As between the Parties, any recovery obtained by Merck in connection with or as a result of any action contemplated by the provisions of this Section 7.4.6, whether by settlement or otherwise, shall be retained solely by Merck. In all cases, NewLink shall give Merck prompt written notice of any infringement of any Merck Patent Rights that may come to its attention and/or any certification regarding any Merck Patent Rights it has received or otherwise becomes aware in connection with any Biosimilar Application (and NewLink shall provide Merck with a copy of such certification within [*] of receipt).

7.5 Patent Term Extension. NewLink shall reasonably cooperate with Merck, including providing reasonable assistance to Merck (including executing any documents as may reasonably be required), in efforts to seek and obtain patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Joint Program Patent Rights, NewLink Patent Rights or Merck Patent Rights, including as may be available to the Parties under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States of America, in each case, in connection with the Products. In the event that elections with respect to obtaining such patent term restoration or supplemental protection certificates or their equivalents are to be made in relation to Joint Program Patent Rights or NewLink Patent Rights or Merck Patent Rights, Merck shall have the right to make the election and NewLink agrees to abide by such election.

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- 7.6 **Other Patent Cooperation.** At the request of [*] shall reasonably cooperate with [*] with respect to patent protection with respect to the Program Know-How, including to take reasonable actions [*] for United States patents and patent applications, in each case, as determined by [*].
- 7.7 **Infringement or Misappropriation Claims with Respect to Compound or Product.** NewLink shall give Merck prompt written notice if any Third Party asserts, or if NewLink otherwise becomes aware, that a Third Party's Patent Rights or Know-How may be infringed or misappropriated by the research, development, making, using, selling, offering for sale, importing, exporting or otherwise exploiting any Compounds or Products. Subject to the provisions of Section 9.1.1 (Indemnity-Merck) and 9.1.2 (Indemnity-NewLink), Merck shall have the sole right (regardless of whether notified by NewLink pursuant to the foregoing provisions of this Section 7.7), but not the obligation, using counsel of its choice, to control the defense of any infringement or misappropriation action (including any declaratory judgment action) brought by a Third Party relating to the infringement or misappropriation of a Third Party's Patent Rights or Know-How or other intellectual property by the research, development, making, using, selling, offering for sale, importing, exporting or otherwise exploiting any Compounds or Products, and NewLink shall have no rights, and shall not take any actions, in connection therewith. In connection with any such action, NewLink shall cooperate fully with Merck and NewLink will provide Merck with any information or assistance that Merck may request, and in the event that Merck is unable to bring such action solely in its own name, NewLink shall join such action voluntarily and execute and cause its Affiliates to execute all documents necessary for Merck to bring such action.

ARTICLE 8 TERM AND TERMINATION

- 8.1 **Term and Expiration.** This Agreement shall become effective upon the Effective Date and, if not otherwise terminated earlier pursuant to this Article 8, shall expire on a Product-by-Product basis upon the expiration of the royalty payment obligations hereunder with respect to the applicable Product (the "Term"). This Agreement shall expire in its entirety (if not otherwise terminated earlier pursuant to this Article 8) on the date that this Agreement has expired with respect to all Products. Upon expiration of this Agreement with respect to a given Product under this Section 8.1, [*], and, upon expiration of this Agreement in its entirety under this Section 8.1, [*].
- 8.2 **Other Termination.**
- 8.2.1 Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving [*] advance written notice to NewLink; provided, however, that such termination shall be effective immediately if Merck elects to terminate this

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Agreement for [*] (a “**Safety Termination**”). The Parties hereby acknowledge and agree that in the event that Merck delivers notice of termination to NewLink pursuant to this Section 8.2.1, but prior to such termination becoming effective, [*], then, notwithstanding [*] or anything to the contrary contained herein, [*].

8.2.2 If, at any time during the Term, a BLA has not been submitted for at least one (1) Product and Merck [*] for an Alternative Product, NewLink shall have the right to terminate this Agreement on [*] advance written notice to Merck with respect to all Products other than [*]; provided that such notification of NewLink’s exercise of its termination right under this Section 8.2.2 shall be provided within [*] for [*] Alternative Product. As used herein, “**Alternate Product**” shall mean [*].

8.3 Termination for Cause.

8.3.1 **Cause for Termination.** This Agreement may be terminated at any time during the Term:

- (a) upon written notice by NewLink if Merck is in material breach of (i) its Product Diligence Obligations pursuant to Section 3.5.1 by causes and reasons within its control or (ii) any obligation to make payments to NewLink hereunder, and has not cured such breach within [*] after written notice requesting cure of the breach (provided, however that such initial [*] cure period shall be extended for an additional [*] for so long as [*]; 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 10.6; provided further, however, that it is agreed that termination pursuant to this Section 8.3.1(a) shall be on a Product-by-Product basis to which the breach relates and that NewLink cannot terminate this Agreement under this Section 8.3.1(a) with respect to the non-affected Products (and the effects of termination in Section 8.3.2 shall only apply with respect to such terminated Product); or
- (b) by a 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, that 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 (an “**Insolvency Event**”).

8.3.2 **Effect of Termination.** Upon termination (but not expiration) of this Agreement for any reason (other than termination by Merck pursuant to Section 8.3.1(b)), all licenses and other rights granted hereunder shall terminate (except those that

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expressly survive as set forth in Section 8.4). In addition in such case, [*] the following consequences shall apply; provided that if this Agreement is terminated only with respect to a particular Product or Product(s) the following shall apply solely with respect to such Product or Product(s):

- (a) **Terminated Products.** Following termination NewLink may elect to receive (which election shall be made in writing to Merck within [*] following termination), and Merck hereby grants to NewLink, effective upon such election, [*]) to research, develop, import, use, make, have made, offer for sale and sell the Current Product (if this Agreement is terminated with respect to the Current Product) and any other Product [*], but excluding [*] (such Products, [*] “**Terminated Products**”), in each case, in the Field in the Territory. In consideration for such license, the Parties shall agree to, [*] shall be [*]. If the Parties are unable to agree [*], either Party [*] and all of [*]. Each Party shall [*], and the [*]. The Parties shall [*] and the [*]. Notwithstanding the provisions of this Section 8.3.2(a), the licenses in this Section 8.3.2(a) shall not be effective until such time as the Parties agree [*].
- (b) **Regulatory Documentation.** Promptly following the effective date of such termination, Merck shall transfer and assign to NewLink all of its (and its Affiliates) material Regulatory Documentation and data relating solely and exclusively to any Terminated Products (provided, however, that if there is additional Regulatory Documentation or data in Merck’s (or its Affiliates) Control related to the Terminated Products that is necessary for NewLink to continue to Develop and Commercialize such Terminated Product, then at the written request of NewLink (which request shall be made within [*] following the effective date of termination), Merck shall use Commercially Reasonable Efforts to provide NewLink with access to such Regulatory Documentation and data (provided that Merck may redact any and all portions thereof not related to the Terminated Product)), in each case, to the extent [*].
- (c) **Transition Assistance.** Merck shall, [*], provide the following transitional assistance upon request by NewLink:
- (i) Merck shall promptly destroy or return to NewLink all Know-How, data, materials and other Confidential Information made available to Merck by NewLink under this Agreement.
- (ii) Merck shall, at NewLink’s request, provide to NewLink (including when available, in electronic format) a copy of the physical embodiment of all Merck Know-How that is directly related to any Terminated Product and licensed to NewLink pursuant to Section 8.3.2(a); provided that NewLink shall comply with the confidentiality and non-use provisions set

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forth in Article 4 with respect to such Merck Know-How, and NewLink shall only use such Merck Know-How in accordance with the licenses pursuant to Section 8.3.2(a).

- (iii) Merck shall [*] all inventory of Terminated Product in Merck's (or its Affiliate's) possession, and in connection therewith, [*].
- (iv) Merck shall assign back to NewLink any [*] that relate solely and exclusively to the Terminated Product.
- (v) Merck shall assign or transfer to NewLink any manufacturing agreement between Merck and a Third Party contract manufacturer with respect to such Terminated Product, to the extent assignable (and solely to the extent that such manufacturing agreement does not relate to any other products).
- (d) **[*]; Other Provisions.** Notwithstanding the foregoing provisions of this Section 8.3.2, any [*] to provide [*] shall not [*]. All Regulatory Documentation, Know-How, data, information, correspondence and other items provided to NewLink pursuant to this Section 8.3.2 shall be provided [*], and shall [*]. NewLink shall provide reasonable assistance to Merck in connection with the transfer and delivery of the foregoing items.
- (e) **Wind-Down.** Notwithstanding the foregoing provisions of this Section 8.3.2, the licenses granted to Merck pursuant to Section 3.1 and Section 3.2 shall survive for [*] following the effective date of termination in order for Merck (and its Affiliates, sublicensees and distributors), [*], during the [*] period immediately following the effective date of termination, to (i) finish or otherwise wind-down any ongoing Clinical Trials with respect to any Compounds or Products hereunder or transfer such Clinical Trials (where Merck is permitted to do so under Applicable Laws) to NewLink and (ii) finish any work-in-progress and sell any Products or Compounds remaining in inventory, in accordance with the terms of this Agreement; provided that, for clarity, [*] and; provided further, that such licenses shall be non-exclusive.

8.3.3 Effect of Termination by Merck for Insolvency Event. In the event that this Agreement is terminated by Merck under Section 8.3.1(b) then the provisions of this Section 8.3.3 shall apply (and the provisions of Section 8.3.2 shall not apply). In the event that this Agreement is terminated due to the rejection of this Agreement by or on behalf of NewLink due to an Insolvency Event (including under Section 365 of the United States Bankruptcy Code (the "Code"), as applicable), all licenses and rights to licenses granted under or pursuant to this Agreement by NewLink to Merck are and shall otherwise be deemed to be (including for purposes of Section 365(n) of the Code, as applicable) licenses of rights to "intellectual

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property” (including as defined under Section 101(35A) of the Code, as applicable). The Parties agree that Merck, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under any applicable insolvency statute (including the Code), and that upon commencement of an Insolvency Event by or against NewLink, Merck shall be entitled to a complete duplicate of or complete access to (as Merck deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Merck (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by Merck, unless NewLink elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of NewLink, then upon written request therefore. The provisions of this Section 8.3.3 shall be (1) without prejudice to any rights Merck may have arising under any applicable insolvency statute or other Applicable Law (including the Code, as applicable) and (2) effective only to the extent permitted by Applicable Law (including the Code, as applicable).

8.4 **Effect of Expiration or Termination; Survival.** Subject to a Party’s continuing right to use and disclose Confidential Information of the other Party under the surviving license pursuant to this Article 8, if any, following expiration or any early termination of this Agreement, each Party shall destroy, and confirm in writing that it has destroyed, all Confidential Information in tangible form and substances or compositions delivered or provided by the other Party, as well as any other material provided by the other Party in any medium (provided, however, that the receiving Party may keep one copy of Confidential Information received from the other Party in its confidential legal archives to confirm compliance with the non-use and non-disclosure provisions of this Agreement). Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Each Party shall pay all amounts then due and owing as of the expiration or termination date. 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. The provisions of Sections 4.1, 4.2, 4.4, 4.5, 4.6.1, 4.9 and 4.10 shall survive the expiration or termination of this Agreement and shall continue in effect for [*]. In addition, the provisions of Articles 1 (as necessary for the interpretation of the other surviving provisions), 9 and 10, and Sections 2.9.4 (but solely with respect to the penultimate sentence thereof), 2.10.1, 2.10.2, 5.3 (but solely with respect to any [*] or [*], as applicable, received during the Term, and excluding Section 5.3.3), 5.4 (solely with respect to Product Net Sales hereunder prior to the effective date of termination or Product Net Sales by Merck under Section 8.3.2(e), but in each case, solely

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to the extent royalties would otherwise be payable on such Product Net Sales in accordance with Section 5.4), 5.5, 5.6, 5.7, 6.4, 7.1, 7.2, 8.1, 8.3.2, 8.3.3 and this Section 8.4 shall survive any expiration or termination of this Agreement.

ARTICLE 9 INDEMNITY; LIMITATIONS ON LIABILITY

9.1 Indemnity; Insurance.

9.1.1 **Merck**. Merck shall indemnify, defend and hold NewLink and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the “**NewLink Indemnitees**”) harmless from and against any losses, costs, claims, damages, liabilities or expense (including reasonable attorneys’ and professional fees and other expenses of litigation) (collectively, “**Liabilities**”) arising, directly or indirectly out of or in connection with Third Party claims, suits, actions, demands or judgments (a “**Third Party Claim**”) relating to (a) any breach by Merck of its representations, warranties or covenants made in this Agreement, (b) the gross negligence or willful misconduct of Merck, its Affiliates or their respective officers, directors, agents or employees, in performing any obligations under this Agreement or (c) the Development, Manufacture or Commercialization of any Compound or Product by or on behalf of Merck or Related Parties; except, in each case, to the extent such Liabilities result from a breach of this Agreement by NewLink or the negligence or willful misconduct of NewLink or other NewLink Indemnitees, or to the extent NewLink has an obligation to indemnify Merck Indemnitees under Section 9.1.2(a), (b), (c), (d) or (e).

9.1.2 **NewLink**. NewLink shall indemnify, defend and hold Merck and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the “**Merck Indemnitees**”) harmless from and against any Liabilities arising, directly or indirectly out of or in connection with Third Party Claims relating to (a) any breach by NewLink of its representations, warranties or covenants made in this Agreement, (b) the gross negligence or willful misconduct of NewLink, its Affiliates or their respective officers, directors, agents or employees, in performing any obligations under this Agreement, (c) the Development or Manufacture of any Compound or Product prior to the Effective Date, (d) any breach by NewLink of the NewLink Third Party Agreements; or (e) the Development, Manufacture or Commercialization of any Terminated Product; except, in each case, to the extent such Liabilities result from a breach of this Agreement by Merck, or the negligence or willful misconduct of Merck or other Merck Indemnitees, or to

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the extent Merck has an obligation to indemnify NewLink Indemnitees under Section 9.1.1(a) or (b).

9.1.3 Procedure. If a Party is seeking indemnification under this Article 9 (the “**Indemnified Party**”), it shall inform the other Party (the “**Indemnifying Party**”) of the claim giving rise to the obligation to indemnify pursuant to this Article 9 as soon as reasonably practicable after receiving notice of the claim (provided, however, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party’s rights to indemnification under this Article 9, except to the extent that such delay or failure materially prejudices the Indemnifying Party’s ability to defend against the relevant claims). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld. The Indemnified Party shall not settle or compromise any such claim without the prior written consent of the Indemnifying Party, which it may provide in its sole discretion. If the Parties cannot agree as to the application of Section 9.1.1 or 9.1.2 to any claim, pending resolution of the dispute pursuant to Section 10.6, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 9.1.1 or 9.1.2 upon resolution of the underlying claim.

9.1.4 Insurance. Each Party shall procure and maintain insurance, including product liability insurance (or self-insure), adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this Section 9.1 or otherwise. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [*] prior to the cancellation, non renewal or material change in such insurance or self insurance which materially adversely affects the rights of the other Party hereunder. Notwithstanding the foregoing, the foregoing provisions shall not apply to Merck if Merck self-insures.

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9.2 **Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT (INCLUDING BREACH OF THIS AGREEMENT) OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.2 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (1) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1.1, 9.1.2 OR 2.9.4 IN CONNECTION WITH ANY THIRD PARTY CLAIMS, OR (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 4.

ARTICLE 10 MISCELLANEOUS

10.1 **Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, 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 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.

10.2 **Assignment; Change of Control.**

10.2.1 **Assignment.** Except as provided in this Section 10.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; provided, that a Party may, without such consent, assign this Agreement and its rights and obligations hereunder (i) to an Affiliate (provided, however, that a Party assigning to an Affiliate shall remain fully and unconditionally liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate), and the assigning Party shall promptly notify the other Party in writing of any such assignment, or (ii) subject to Section 10.2.3, in connection with the transfer or sale of all or substantially all of its assets to which this Agreement relates, or (iii) subject to Section 10.2.3, in connection with

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a Party's Change of Control (including, with respect to NewLink, any Change of Control of NL); provided that, in connection with any such assignment by NewLink to a Third Party pursuant to the foregoing clauses (ii) or (iii), as applicable, [*]. Any attempted assignment not in accordance with this Section 10.2 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

10.2.2 Exceptions to Assignment by NewLink [*]. Notwithstanding the provisions of Section 10.2.1, neither NewLink nor its Affiliate shall be permitted to assign this Agreement (or its rights and obligations hereunder) [*]. However, [*] pursuant to [*] provided that [*] (a "[*]"). For clarity, such [*] shall thereafter also be [*].

10.2.3 Change of Control of NewLink. In the event of a Change of Control of NL or NewLink (or in the event of any assignment of this Agreement by NewLink pursuant to clause (ii) of Section 10.2.1), NewLink must notify Merck in writing at least [*] prior to completion of any such Change of Control (to the extent such notification is legally permissible prior to completion of such Change of Control, and if such notification is not legally permissible prior to such Change of Control, then such notification shall be provided to Merck in writing [*] with respect to such Change of Control) or assignment, as applicable, and, where the Third Party counterparty to such Change of Control (or assignment, as applicable) is [*] (a "**Competitor**"), Merck shall have the right, at any time within [*] of receipt of such notice, to elect [*] upon written notice to NewLink: (i) [*]; provided that (a) [*] effective upon such termination and (b) to the extent [*] as part of the [*]; (ii) require NewLink, including its acquiring party, to adopt reasonable procedures to be agreed upon in writing with Merck, such agreement not to be unreasonably withheld, to prevent the disclosure of all Confidential Information of Merck and its Affiliates and other information with respect to the Development, Manufacturing and Commercialization of Compounds or Products (the "**Sensitive Information**") beyond [*] or, where [*] in order for [*] hereunder and that [*], and to control the dissemination of Sensitive Information disclosed after the NewLink Change of Control, which procedures shall include reasonable restrictions on the scope of any Sensitive Information to be provided by Merck; (iii) [*]; (iv) [*] hereunder to [*] as is necessary for NewLink to [*]; and/or (v) request NewLink (or its Affiliate, as applicable) to [*], and in such case, [*], to the extent legally permitted, [*]. No Patent Rights, Know-How or other intellectual property rights owned or otherwise controlled by the Third Party acquiror (or any Affiliates of such Third Party prior to such Change of Control, but excluding, for clarity, NewLink and Affiliates of NewLink prior to such Change of Control) acquiring NewLink or NL pursuant to a Change of Control shall be included in the

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rights licensed hereunder or otherwise subject to this Agreement; provided that, for clarity, all Patent Rights, Know-How and other intellectual property licensed to Merck hereunder prior to such Change of Control (or otherwise coming under the Control of NewLink (or any of its Affiliates that were Affiliates prior to such Change of Control) following such Change of Control) shall, in all cases, continue to be licensed to Merck hereunder.

- 10.3 **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.
- 10.4 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

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if to NewLink, to: BioProtection Systems Corporation
C/O NewLink Genetics Corporation
2503 South Loop Drive
Suite 5100
Ames, IA 50010
Attention: Chief Financial Officer
Facsimile No. [*]

and NewLink Genetics Corporation
2503 South Loop Drive
Suite 5100
Ames, IA 50010
Attn: Chief Financial Officer
Facsimile No. [*]

with a copy to: Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5656
Attn: Kenneth J. Krisko
Fax: [*]

if to Merck, to: Merck Sharp & Dohme Corp.
One Merck Drive
P.O. Box 100, WS3A-65
Whitehouse Station, NJ 08889-0100
Attention: Office of Secretary
Facsimile No.: [*]

and Merck Sharp & Dohme Corp.
One Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100
Attention: Vice-President, Business Development and
Licensing, Merck Research Laboratories
Facsimile No.: [*]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given (a) when delivered if personally delivered or sent by facsimile on a business

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day (or if delivered or sent on a non-business day, then on the next business day), (b) on the business day after dispatch if sent by nationally-recognized overnight courier, or (c) on the [*] day following the date of mailing, if sent by mail. To the extent practicable, the Party delivering a notice shall also send a copy of such notice to the Project Leader of other the Party.

10.5 **Applicable Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws or renvoi.

10.6 **Dispute Resolution.**

10.6.1 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. If the Parties do not fully settle, 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.

10.6.2 The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within [*] after initiation of arbitration, each Party shall select one person to act as arbitrator and the two 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 by the AAA. The place of arbitration shall be New York, New York. All proceedings and communications shall be in English.

10.6.3 Either Party may apply to the arbitrators for 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’ fees and any administrative fees of arbitration.

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10.6.4 Except to the extent necessary to confirm an award or as may be required by law, 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 New York law statute of limitations.

10.6.5 The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this 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.

10.6.6 As used in this Section, the term “**Excluded Claim**” means a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

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

10.8 **Independent Contractors.** It is expressly agreed that NewLink and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither NewLink 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.

10.9 **Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

10.10 **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.

10.11 **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

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rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

- 10.12 **Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Attachment or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Attachment 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”, “hereunder” and derivative or similar words refer to this Agreement, including the Attachments, as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”, (e) the word “or” shall not be construed as exclusive, (f) the word “law” or “laws” means any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a governmental authority (including a court, tribunal, agency, legislative body or other instrumentality of any (i) government or country or territory, (ii) any state, province, county, city or other political subdivision thereof, or (iii) any supranational body) and (g) references to any Articles or Sections include Sections and subsections that are part of the reference Article or section (e.g., a section numbered “Section 2.2.1” would be part of “Section 2.2.”, and references to “Article 2” or “Section 2.2.” would refer to material contained in the subsection described as “Section 2.2.2”). In addition, any payment which is deemed to be non-creditable or non-refundable shall not in any way limit Merck’s right to indemnification under this Agreement or to otherwise recover damages for breach of this Agreement.
- 10.13 **Counterparts.** This 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. In addition, this Agreement may be executed by facsimile or “PDF” and such facsimile or “PDF” signature shall be deemed to be an original.
- 10.14 **Entire Agreement; Amendments.** **This Agreement, together with the Schedules and** other attachments hereto, contains the entire understanding of the Parties with respect to the Transition Program and the licenses and rights granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter of this Agreement, including the Transition Program and the licenses and rights granted hereunder, are superseded by the terms of this Agreement. The Schedules and other attachments to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended,

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or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

- 10.15 **Further Actions.** Each Party will execute, acknowledge and deliver such further instruments, and to do all such other ministerial, administrative or similar acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 10.16 **No Third Party Rights.** The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.
- 10.17 **Expenses.** Except as otherwise specifically provided in this Agreement, each Party (and its Affiliates) shall bear its own costs and expenses in connection with entering into this Agreement and the consummation of the transactions and performance of its obligations contemplated hereby.
- 10.18 **Extension to Affiliates.** Merck shall have the right to extend the rights, licenses, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Merck. Merck shall remain fully liable for any acts or omissions of such Affiliates.
- 10.19 **Parent Guarantee.** This Agreement provides for the performance by NewLink, an Affiliate of NL. NL hereby unconditionally and irrevocably guarantees, and shall be fully liable for, the prompt and complete performance (including any amounts payable hereunder) of this Agreement, as may be amended from time to time, by NewLink. The performance guaranty described in this Section 10.19 shall be effective [*] as to which [*]. NL's obligations are [*] of any [*] and it shall not be necessary for [*] as a condition to the [*]. NL, hereby [*] to [*] that any other [*] and expressly [*] that it may have [*].

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MERCK SHARP & DOHME CORP.

NEWLINK GENETICS CORPORATION

By: /s/ Rita A. Karachun

By: /s/ Charles J. Link Jr., MD

Name: Rita A. Karachun

Name: Charles J. Link Jr., MD

Title: President

Title: CEO

BIOPROTECTION SYSTEMS CORPORATION

By: /s/ Charles J. Link Jr., MD

Name: Charles J. Link Jr., MD

Title:

SIGNATURE PAGE TO LICENSE AND COLLABORATION AGREEMENT

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Schedule 1.26

Current Compound

The Current Compound means the following [*]

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Schedule 1.72

NewLink Existing Funding Agreements

[*]

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Schedule 1.73

NewLink Existing Manufacturing Agreements

ATTACHMENT 1 [*]

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Schedule 1.79

NewLink Patent Rights

[*]

[*]

[*]

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Schedule 1.122

Transition Plan Outline

(See Attached)

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Schedule 1.122 – Transition Plan Outline

[*]

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Schedule 3.1.3

Certain Terms of NewLink Canada License Amendment

[*]

ATTACHMENT 2

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Schedule 3.10

NewLink Future Funding Agreements

- [*]
- [*]

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Schedule 4.6

Form of Press Release

(See Attached)

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News

Release

FOR IMMEDIATE RELEASE**Merck Media Contacts:**

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Merck and NewLink Genetics Enter into Licensing and Collaboration Agreement for Investigational Ebola Vaccine

Clinical Development, Manufacturing Expertise, and Scale Critical to Success

WHITEHOUSE STATION, N.J. and AMES, I.A., Nov. XX, 2014 – Merck (NYSE:MRK), known as MSD outside the United States and Canada, and NewLink Genetics Corporation (NASDAQ: NLNK), announced today that they have entered into an exclusive worldwide license agreement to research, develop, manufacture, and distribute NewLink's investigational rVSV-EBOV (Ebola) vaccine candidate.

The vaccine candidate, originally developed by the Public Health Agency of Canada (PHAC), is currently being evaluated in Phase I clinical trials. Pending the results of ongoing Phase I trials in the U.S. National Institutes of Health (NIH) has announced plans to initiate, in early 2015, a large randomized, controlled Phase III study to evaluate the safety and efficacy of the rVSV-EBOV vaccine and another investigational Ebola vaccine co-developed by the National Institute of Allergy and Infectious Diseases (NIAID) and GlaxoSmithKline.

"Effective Ebola vaccines will be a critical component of comprehensive prevention and control measures for people at risk of Ebola virus infection and to stem future outbreaks globally," said Dr. Julie Gerberding, president of Merck Vaccines. "Merck is committed to applying our vaccine expertise to address important global health needs and, through our

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collaboration with NewLink, we hope to advance the public health response to this urgent international health priority."

According to Dr. Charles Link, chairman and chief executive officer of NewLink Genetics, "Merck's vaccine development expertise, commercial leadership and history of successful strategic alliances make it an ideal partner to expedite the development of rVSV-ZEBOV and, if demonstrated to be efficacious and well-tolerated, to make it available to individuals and communities at risk of Ebola virus infection around the world."

Under the terms of the agreement, Merck will be granted the exclusive rights to the rVSV-EBOV vaccine candidate as well as any follow-on products. The vaccine candidate is under an exclusive licensing arrangement with a wholly-owned subsidiary of NewLink Genetics. Under these license arrangements, the PHAC retains non-commercial rights pertaining to the vaccine candidate.

Phase I clinical trials of the rVSV-EBOV vaccine are now underway at the Walter Reed Army Institute of Research and the NIAID at the NIH. Additional Phase I studies are underway or planned to begin in the near future at clinical research centers in Switzerland, Germany, Kenya and Gabon in a World Health Organization-coordinated effort, and in Canada by the Canadian Immunization Research Network.

"This vaccine is the result of years of hard work and innovation by Canadian scientists. We are pleased that this new alliance coupled with the clinical trials currently underway will further strengthen the possibility that the vaccine will make a difference in global response to the Ebola outbreak," said Canada's Minister of Health, Rona Ambrose.

About rVSV Vaccine Platform

This vaccine platform is based on an attenuated strain of vesicular stomatitis virus that has been modified to express an Ebola virus protein that plays an essential role in establishing virus infection. The rVSV-EBOV vaccine was created by scientists at the Public Health Agency of Canada's National Microbiology Laboratory. A significant portion of the funding for the further development of the vaccine came from the CBRN Research and Technology Initiative, a federal program led by Defence Research and Development Canada. In 2010, PHAC signed a licensing arrangement with BioProtection Systems (BPS), a wholly-owned subsidiary of NewLink Genetics, as the sole licensee for these vaccines and the underlying technology. BPS has worked with the PHAC to produce clinical trial materials and to move this vaccine candidate into Phase I studies.

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About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#).

About NewLink Genetics Corporation

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for patients with cancer. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. BioProtection Systems, a wholly-owned subsidiary of NewLink Genetics Corporation, is focused on the research, development and commercialization of vaccines. BPS is focused on control of emerging infectious diseases, including improvement of existing vaccines and providing rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism. For more information please visit <http://www.linkp.com>.

Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

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Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the SEC available at the SEC's Internet site (www.sec.gov).

NewLink Genetics Corporation Forward-Looking Statement

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements regarding plans to develop and commercialize our product candidates and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2013, and subsequent filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change.

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However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this press release.

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Schedule 5.4.9

NewLink Wire Instructions

[*]

Account Name: [*]

Account Number: [*]

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Schedule 6.2.12

Third Party Clinical Studies

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Schedule 6.2.21

Product Materials

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Schedule 6.2.26

NewLink Affiliates

NewLink International

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