SAMPLE LICENSE AGREEMENT

This LICENSE AGREEMENT (the "**Agreement**") is made as of _____ (the "**Effective Date**") by and among the **Merck Sharp and Dohme LLC**, a company registered under the laws of The United States of America, and having a principal place of business at 120 E Lincoln Avenue, Rahway, NJ 07065, The United States of America("**COMPANY**"), and _____("**Licensee**"). Each of COMPANY and Licensee is referred to in this Agreement as a **Party** and collectively referred to in this Agreement as the **Parties**.

RECITALS

WHEREAS, COMPANY or its Affiliates holds rights to certain Patents (as hereinafter defined), regarding the Substance (as hereinafter defined) used in Products (as hereinafter defined), the LICENSEE acknowledging that the Patents in question are valid and enforceable; and

WHEREAS, COMPANY has the right to grant a license under the Patents and wishes to voluntarily grant such a license in furtherance of its policy of improving access to medicines used for HIV-1 pre-exposure prophylaxis (PrEP) in the countries set forth on Appendix 1 hereto; and

WHEREAS, Licensee is desirous of obtaining, and COMPANY is willing to grant a license under the Patents under the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. DEFINITIONS

1.1. **Affiliate** shall mean in relation to a Party, any corporation, firm, partnership, or other entity which is directly or indirectly controlled by, in control of, or under common control of such Party. For the purposes of this definition "control" shall mean the ability of any corporation, firm, partnership, or other entity, whether through ownership of shares or otherwise, to ensure that the affairs of a Party hereto are conducted in accordance with the wishes of such corporation, firm, partnership, or other entity.

1.2. **Agency** shall mean any government regulatory authorities responsible for granting any health or pricing approvals or registrations necessary for the Product to be imported, promoted, and/or sold in the Territory (as hereinafter defined).

1.3. **Agreement Quarter** shall mean any period of three months ending on the last day of March or June or September, or December.

1.4. **Authorized Supplier** shall mean a Third Party that has entered into a written agreement with COMPANY regarding the right to supply Substance and/or Product to other (receiving) third parties or to Licensee who have also entered into a written license agreement with COMPANY regarding the right to supply Substance and/or Product.

1.5. **Business Day** shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in New York, USA**.**

1.6. **Commercialization** or **Commercialize** shall mean sale, import, or export of the Product by the Licensee to an unrelated entity for the purposes of making the Product available in the Territory for use in the Field.

1.7. **Customer** shall mean the Third Party who is buying the Product from Licensee, but shall not include COMPANY, its Affiliates, another COMPANY Licensee, or the Authorized Suppliers.

1.8. **Control** shall mean direct or indirect ownership of more than fifty percent (50%) of all issued shares or other ownership interests of a legal entity with power to vote for the election of or to otherwise select the governing body or management authority of such entity, or the power in law or in fact to control the management decisions of such entity by any other means.

1.9. **Field** shall mean the HIV-1 pre-exposure prophylaxis (PrEP)

1.10. **Improvements** shall mean any (patentable or unpatentable) new or improved formulation, process, improvement, invention, development, or finding related to the Substance and/or the Product, or any (patentable or unpatentable) other pharmaceutical product using Substance, or any further invention (patentable or unpatentable) that relates to the manufacture or formulation of the Products and/or Substance or incorporate or are based on the Patents, developed by Licensee after the Effective Date.

1.11. **Key Approvals** shall mean, as applicable, (a) any approval, license, authorization, or other regulatory clearance required by the competent health authority in the country of manufacture for the manufacture and export of the Product, (b) any approval, license, authorization, or other regulatory clearance required by the competent health authority in any country within the Territory into which Licensee intends to export, import, distribute, or Commercialize the Product, in each case prior to such export, import, distribution, or Commercialization, and (c) WHO Prequalification and/or U.S. FDA Tentative Approval, to the extent applicable to the Product.

1.12. **Know-How** shall mean any and all confidential or proprietary information and

materials, including discoveries, improvements, processes, methods, protocols, formulas, molecular constructs, reagents, assays, data, results, inventions, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise, and including any copyrights therein.

1.13. COMPANY Know-How shall mean all Know-How, that: (i) directly relate to use in the Field of the Substance and/or the Product, (ii) are controlled by COMPANY or its Affiliates as of the execution date of this Agreement and, (iii) are not in the public domain or otherwise generally known. For avoidance of doubt, COMPANY Know-How shall not include any Know-How to the extent solely and directly related to any other COMPANY compound. Also, COMPANY Know-How includes only that Know-How, designated by COMPANY in its sole discretion, necessary for the manufacture, registration, and commercialization of the Substance and/or the Product for use in the Field.

1.14. COMPANY Trademarks shall mean trademarks, service marks, Internet domain names, trade dress, trade names, and corporate names, now existing or hereafter adopted or acquired, whether registered or unregistered, including without limitation any applications or registrations therefor, and all goodwill connected with the use thereof and symbolized thereby, that are owned, controlled or used by COMPANY or its Affiliates.

1.15. Own Use shall mean the act of Commercialization and/or the act of registration of the Product in the Territory for use in the Field.

1.16. Patents shall mean any unexpired letters patent or any pending patent applications as set forth in Appendix 3 hereto, that are granted or pending, relating to the Substance and/or Product and made a part of this Agreement, including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity, and the like of any such patents and patent applications, and international (i.e., WIPO), regional (e.g., ARIPO, OAPI), and foreign national equivalents of the foregoing.

1.17. Priority Countries shall mean list of high HIV burden countries given in Appendix 2 where Licensees are encouraged to prioritize for the registration and commercialization of the Product.

1.18. Product(s) shall mean the pharmaceutical form containing the Substance (as defined below) alone indicated for PrEP to reduce the risk of sexually acquired HIV-1 infection in persons at risk for HIV-1 acquisition in the Territory.

1.19. The term "**Private Market**" shall mean all persons, businesses, institutions, organizations or entities, including multilateral organization, or donor-funded procurement mechanism other than a Public Market.

1.20. The term "**Public Market**" shall mean (a) the following organizations to the extent that they are not for profit organizations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontiers, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and agencies based outside of an applicable country to the extent that they are supporting implementation locally in an applicable country, and (b) nominally for profit procurement organizations but only to the extent that such procurements are supporting not-for-profit treatment programs as described in (a) of this Clause.

1.21. Retail shall mean sale, import, or export of the Product by the Licensee to another COMPANY Licensee or an Authorized Supplier for the purpose of making the Product available in the Territory for the COMPANY Licensee or an Authorized Supplier's Own Use

1.22. Substance shall mean the chemical substance known as (2*R*,3*S*,5*R*) -5-(4-Amino-2-chloro-7*H*-pyrrolo[2,3-d]pyrimidin-7-yl)-2-ethynyl-2-(hydroxymethyl) tetrahydrofuran-3-ol

1.23. Territory shall mean those countries set forth in Appendix 1.

1.24. Territory Patents shall mean any Patents, granted or pending, in any country within the Territory. For the avoidance of doubt, to the extent international and regional patent applications are included in Patents, such international and regional patent applications are Territory Patents only with respect to countries within the Territory.

1.25. Third Party(ies) shall mean any person or entity other than a COMPANY; LICENSEE and their respective Affiliates.

1.26. Valid Claim means a claim of any issued and unexpired patent or pending patent application whose validity, enforceability, or patentability has not been affected by any

of the following: (a) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (b) a holding or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding or decision being final and unappealable or not appealed within the time allowed for appeal.

1.27. **Vend** shall mean sale, import, or export of the Substance by the Licensee to another Licensee or an Authorized Supplier for the purpose of manufacturing the Product for its Own Use.

2. SCOPE OF THE GRANT

2.1 **Within the Territory.** Subject to the terms and conditions of this Agreement, COMPANY hereby grants to Licensee a non-exclusive, non-transferable, non-sublicensable license under the Territory Patents and COMPANY Know-How to manufacture the Product at a facility located at _____ , that is in the Territory (excluding any Sanctions Targets as defined in Section 6.2) . Licensee shall promptly notify COMPANY in writing of any proposed change to the manufacturing facility and shall not implement any such change without COMPANY's prior written approval.

(a) To Commercialize the Product by itself or through its Affiliates in the Territory for use in the Field;

(b) To Retail the Product to other COMPANY Licensees or Authorized Suppliers for their Own Use within the Territory;

(c) to register the Product in the Territory by itself or through its Affiliates for use in the Field for (a) and (d); and

(d) to sell the Product to Customers for the sole purpose of enabling the Customers to supply the Product in the Territory for use in the Field.

2.2 **Within the Territory.** Subject to the terms and conditions of this Agreement, COMPANY hereby grants to Licensee a non-exclusive, non-transferrable, non-sublicensable license under the Territory Patents and COMPANY Know-How to manufacture the Substance at a facility located at _____,that is in the Territory (excluding any Sanctions Targets as defined in Section 6.2). Licensee shall promptly notify COMPANY in writing of any proposed change to the

manufacturing facility and shall not implement any such change without COMPANY's prior written approval.

(a) to manufacture the Product in accordance with Section 2.1; and

(b) to Vend the Substance.

2.3 No license or right is granted by implication or otherwise with respect to the Substance and/or Product, except as expressly granted herein. Subject to the above and except as permitted by statute, the Licensee shall not be entitled to manufacture, use, Commercialize, Retail, Vend, register with regulatory agencies, and/or sell the Substance and/or the Product for any other purpose or in combination with any other substance, product, intermediate, and/or active pharmaceutical ingredient (whether co-packaged, co-formulated or otherwise) ("**Combination**") unless prior written approval had been provided by COMPANY in its sole discretion.

For the avoidance of doubt, Parties agree that any approval of the Combination by COMPANY shall be subject to separate terms and conditions which shall be negotiated independently of this Agreement.

2.4 For the avoidance of doubt, nothing in this Agreement shall be construed to prevent the Licensee from engaging in activities within or outside the Territory provided that such activities do not (1) infringe the Patents and/or any other intellectual property rights; and/or (2) misappropriate any COMPANY Know-How. Licensee acknowledges that COMPANY has expressly reserved all its rights under the Patents, except as expressly set forth in this Agreement, and under any additional patents and/or patent applications owned or controlled by COMPANY. Licensee also acknowledges that COMPANY does not waive any applicable statutory and/or regulatory exclusivities owned or controlled by COMPANY, except as expressly set forth in this Agreement.

2.5 Except as otherwise provided and solely in the manner permissible under this Agreement, the license granted is solely for the stated Territory. Licensee and its Affiliates agree not to sell the Substance and/or the Product to any Third Party outside the Territory or to sell Substance and/or Product to any Third Party that Licensee or its Affiliates have reason to believe will resell the Substance and/or the Product outside of the Territory in breach of this Agreement. Licensee shall (a) include language on the packaging of such Product indicating that such Product is "not for resale" outside of the initial country of sale and (b) implement a system of batch control and tracing which will enable the identification and batch tracing of

any such Product which are subsequently reexported outside the Territory. In addition, Licensee shall use its best efforts, including but not limited to including provisions in its customer contracts and purchase orders, to ensure that all of its customers and any subsequent purchasers of the Product in all countries of the Territory shall not sell the Product or offer the Product for sale outside of the initial country of sale. If COMPANY becomes aware of any Commercialization of Product outside the Territory in breach of this Agreement, COMPANY shall provide the relevant information to Licensee, and Licensee shall promptly take all possible steps to prevent any further re-exports through the distribution channel or channels identified in such information.

2.6 If Licensee wishes to Commercialize or sell the Product through an Affiliate of the Licensee acting on Licensee's behalf, Licensee shall first provide prior written notification to COMPANY. Upon COMPANY's request, Licensee will provide COMPANY with a written copy of Licensee's agreement(s) with such Affiliate and will certify to COMPANY in writing that such agreement(s) is/are consistent with the terms and conditions of this Agreement. COMPANY has the right to review all such agreements to verify consistency with the terms and conditions of this Agreement. In the event that any inconsistency is found which had not been specifically discussed with, and agreed to in writing by COMPANY, COMPANY shall have the right to require Licensee to amend such agreement with such Affiliate to be consistent with the terms and conditions of this Agreement. Licensee shall be held responsible for the actions of any of its Affiliates or any other permitted assignees/transferees in connection with this Agreement, and all obligations of Licensee under this Agreement in connection with the sale and Commercialization of the Product in the Territory will be deemed to apply to such activities conducted by any of its Affiliates and permitted assignees/transferees.

2.7 The license granted under Sections 2.1 to 2.2 above does not include a license to other intellectual property that COMPANY may possess with respect to the Substance and/or the Product, other than the Territory Patents, and COMPANY Know-How, as expressly provided herein. For clarity, license granted under Sections 2.1 to 2.2 above does not include a license to processes or procedures for the manufacture, production, packaging, labeling, warehousing, and quality control testing of the Substance and/or the Product that are not included in the Patents and/or COMPANY Know-How.

2.8 Except as expressly set forth in this Agreement, (1) COMPANY does not grant any license to Licensee under any of COMPANY intellectual property rights (including, without limitation, patents or rights to any COMPANY proprietary

compounds or drug substances other than the Substance), and (2) Licensee shall not take any action which would constitute an infringement of any of the Patents.

3. DEVELOPMENT AND REGISTRATION

3.1. As of the Effective Date and subject always to COMPANY's retained rights to the Patents, the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture, and commercialisation of the Products to be sold or supplied by the Licensee in the Territory under this Agreement.

3.2. Licensee agrees that it will manufacture the Substance and the Product in a manner consistent with (i) WHO Pre-qualification standards; or (ii) US FDA Tentative Approval Standards. Licensee shall not sell any Product without WHO Prequalification or US FDA Tentative approval, and shall comply with applicable regulatory and legal requirements in the country of manufacturing and the country of sale.

3.3. For the period beginning from the Effective Date, within 10 Business Days following the end of each Agreement Quarter, Licensee shall provide COMPANY with a quarterly written report covering all its activities related to the development and testing of all Products and/or Substance (as permitted and to the extent applicable) and the obtaining of necessary governmental approvals; these shall include (but is not limited and to the extent applicable and permitted) to its (a) Products and/or Substance in its development pipeline, (b) status of development of each Product and/or Substance in development, (c) regulatory filing plan for WHO Pre-qualification Program (d) a list of regulatory authorities, including as applicable the FDA, WHO and authorities in the countries within the Territory for which such regulatory approvals or authorizations have been filed and/or obtained for any Product, (e) summary of work completed and in progress, (f) current schedule of anticipated events and milestones, (g) anticipated market introduction dates and (h) its activities, if applicable. Licensee will also report to COMPANY the date of first commercial sale of each Product within five (5) business days thereafter.

3.4. The Parties agree to meet on a quarterly basis or as reasonably requested by the COMPANY, to review development and filing status and also regarding such reports concerning Products and/or Substance. COMPANY agrees that information contained in quarterly and other such reports shall be treated as Confidential Information; provided, however, that such information may be shared with COMPANY and or its Affiliates.(with COMPANY treating such reports as

Confidential Information); and that aggregated data may be publicly disclosed by COMPANY and or its Affiliates. Licensee shall, at its own expense and using its own resources, and using all due care in accordance with the prevailing standard of professional competence in a regulatory function in the pharmaceutical industry, obtain, maintain and operate in compliance with (a) the Key Approvals and (b) all other authorizations, licenses, permits, registrations, and regulations which may from time to time be required by any Agency for Licensee to import, manufacture, promote, and sell the Product in the Territory. Licensee will not sell Product in any country in the Territory prior to obtaining both local health Agency approval or authorization in the country where the Product is manufactured and/or local health Agency approval or authorization in the country in the Territory where the Product is sold and Commercialized. Licensee shall provide quarterly written reports to COMPANY notifying COMPANY about the registration process and providing COMPANY with any other information in this regard that COMPANY may reasonably require. Licensee shall not transfer, assign, or otherwise convey any of the authorizations, registrations, or permits related to the Product, as set forth above in this Section, to any Affiliate without the prior written notice to COMPANY.

3.5. Licensee will manufacture and sell the Substance and Products in accordance with all laws and regulations relevant to the manufacture and sale of the Substance and Products and in accordance with good industry practice in addition to provisions contained in 3.2.

3.6. Licensee shall not transfer, assign, or otherwise convey any of the authorizations, registrations, or permits related to the Product, as set forth above in this Section, to any Third Party without the prior permission of COMPANY, and which may be withheld at COMPANY's sole discretion in the case of a proposed transfer to a Third Party.

3.7. Licensee shall promote, Commercialize and sell the Product in strict adherence to regulatory, professional, and legal requirements in the Territory and shall do nothing which would jeopardize the good will or reputation of COMPANY or the reputation of the Product.

3.8. Upon request of the applicable health authorities, COMPANY shall directly provide to such health authorities the relevant data contained in the Common Technical Document (CTD) sections of the initial new drug application including the clinical, non-clinical and toxicology sections and shall provide necessary support to Response to Questions (RTQs).

3.9. This Section 3 shall always be subject to the provisions of Section 3B. Where there is any inconsistency between the two Sections, Section 3B shall prevail.

3A. **TRADEMARKS**

3A.1 No rights in any COMPANY Trademarks are granted to Licensee under this Agreement, and Licensee shall not appropriate or otherwise use or register any COMPANY Trademarks in connection with the Product in the Territory, including without limitation in connection with the sale, distribution, promotion, or marketing of the Product. A complete description and representation of any trademark, logo or branding proposed to be used or registered by Licensee in connection with the sale of the Product in the Territory shall be submitted for COMPANY's written approval prior to use or filing an application to register such trademark. The Licensee shall provide any additional information required by COMPANY in relation to such request. The response to the Licensee for any request for approval shall be given within 30 days of receipt by COMPANY from Licensee of all relevant documentation necessary to consider the Licensee's request. Such approval may be withheld if the subject trademark is determined by COMPANY, in its sole discretion, to be inappropriate, having a negative connotation, or identical to or confusingly similar to any COMPANY Trademark, however any such approval shall not waive any rights with respect to the COMPANY Trademarks.

3A.2 In addition to the foregoing, for the avoidance of doubt, Licensee agrees that it shall not: (i) register or, in connection with the sale of any Product, use any trademark or trade name which is identical to or confusingly similar (as COMPANY shall determine in its sole discretion) to any COMPANY Trademark; (ii) use trade dress, packaging (both internal and external), or labeling which is the same as or similar to (as COMPANY shall determine in its sole discretion) that of COMPANY or any Affiliate of COMPANY in connection with the sale of any Product; and (iii) give the impression to the public, to physicians or to the trade that the Product is manufactured by or in any way connected with COMPANY or any of its Affiliates. Copies of all labels and packaging artwork to be used in connection with the Products shall be submitted to COMPANY for written approval prior to use. Such approval may be withheld if the subject label or packaging artwork is determined by COMPANY at its sole discretion to be not in compliance with any of the requirements of this Section 3A.

3B. PURCHASE OF SUBSTANCE OR PRODUCT

3B.1 Licensee hereby agrees to supply the Substance and/or the Product, as requested by COMPANY in writing, to COMPANY or its Affiliates at the actual cost of goods (verifiable via Third Party audit) plus a reasonable markup (to be negotiated) under

a supply agreement containing such other reasonable and customary terms and conditions as are agreed by the Parties in good faith.

3B.2 If Licensee wishes to obtain Substance and/or Product from a Third Party source, Licensee shall notify COMPANY of the intended source prior to making any commitments to purchase the Substance and/or Product. COMPANY will determine at its sole discretion whether and on what terms to grant a license to the intended source to produce the Substance and/or Product or inform Licensee whether such license already exists.

Subject to Sections 3B.2 and 3B.4 below, the Licensee shall have the right to source the Substance and/or Product in its finished form from an Authorized Supplier or COMPANY Licensee. Licensee's Commercialization of any Product sourced from an Authorized Supplier or COMPANY Licensee shall be subject to the terms and conditions of this Agreement.

3B.3 Licensee shall not enter into any agreements with an Authorized Supplier or COMPANY Licensee with respect to Substance and/or Product without providing prior notice to COMPANY. All terms of the agreement between Licensee and Authorized Supplier or COMPANY Licensee must be consistent with this Agreement or written approval needs to be obtained by COMPANY. Licensee shall certify to COMPANY in writing that its arrangement(s) with each Authorized Supplier with respect to Substance and/or Product is consistent with the terms and conditions of this Agreement. COMPANY shall have the right to review all such agreements to verify consistency with the terms and conditions of this Agreement. If any inconsistency is found which had not been specifically discussed and agreed with COMPANY, COMPANY shall have the right to require Licensee to terminate its agreement(s) with such Authorized Supplier.

3B.4 Licensee shall not be obliged to disclose to COMPANY the financial terms of its agreement(s) with Authorized Suppliers, but shall provide COMPANY with quarterly reports in accordance with the Agreement that shall include the quantities of Substance and/or Product being supplied to Licensee by each Authorized Supplier (on an Authorized Supplier-by-Authorized Supplier basis), which will be shared with COMPANY.

3B.5 Licensee's right to source from and sell to, Substance and,or Product to a particular Authorized Supplier hereunder shall remain in effect solely for so long as such Authorized Supplier remains compliant with the terms and conditions of the agreement between such Authorized Supplier and COMPANY, and provided that

such agreement between such Authorized Supplier and COMPANY has not expired or been terminated.

3B.6 The Licensee shall disclose its contact information to COMPANY, an Authorized Supplier or a COMPANY Licensee for the fulfilment of Section 3B of this Agreement ("**Disclosure Right**"). Licensee shall receive reciprocal information of other Authorized Supplier or COMPANY Licensee to the extent that the Disclosure Right had been similarly granted by such Authorized Suppliers or a COMPANY Licensee.

3B.7 The Licensee confirms and warrants that it shall not engage in any anti-competitive behavior if it exercises its rights under this Section 3B and shall be fully compliant of all applicable laws.

4. NON-DIVERSION

4.1. Diversion. Licensee shall not, directly or indirectly, divert Substance and/or Product outside the Territory. Without limitation of the foregoing, except to the extent provided under this Agreement, the Licensee shall not, directly or indirectly, sell, or supply:

(a) Products or Substance outside the Territory;

(b) Substance to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Substance outside the Territory ; and/or

(c) Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products outside the Territory.

4.2. Product Labelling. The labelling of all Products sold or offered for sale under this Agreement shall expressly state that the Product is for sale in the relevant country within the Territory only; and any other use, beyond the Field, is not authorized.

4.3. Notice to Third Parties. The Licensee shall give written notice, prior to the first sale of Products, to any Third Party to which it sells Products of the restrictions contained in this Clause 4 and the Licensee shall use its best endeavors, without prejudice to any other provision of this Agreement, to ensure that such Third Parties will undertake to abide by the restrictions contained in this Clause 4 and will assist COMPANY in securing compliance with this Clause 4 and the restrictions which it contemplates.

5. INTELLECTUAL PROPERTY

5.1. The Licensee shall have no rights in relation to the conduct of any matter relating to the Patents, including the filing, prosecution, and maintenance thereof.

5.2. If Licensee becomes aware of a possible infringement of the Patents by a Third Party in any country, Licensee will notify COMPANY immediately. The decision on whether any legal action is necessary or appropriate shall belong to COMPANY.

5.3. In the event that COMPANY institutes an action at its expense against alleged third-party infringers with respect to Substance or any Product, or takes action to defend the Patents, Licensee agrees to cooperate in good faith with COMPANY in such action, upon the request of COMPANY and at COMPANY's cost. Any recovery obtained by COMPANY as a result of such a proceeding or other action shall be retained by COMPANY.

5.4. LICENSEE agrees to disclose promptly to COMPANY in English, without charge, any Improvements, whether patentable or not, relating to the Product or Substance that are made or conceived by LICENSEE during the term of this Agreement. As to any such Improvements, LICENSEE hereby grants to COMPANY and its Affiliates a worldwide, non-exclusive (except as to LICENSEE) license to use any such Improvements to make, have made, use and/or sell the Products or Substance or any other pharmaceutical product using Substance, with the right to sublicense upon a royalty fee / development fee to be agreed between the parties in good faith Provided that LICENSEE has fully complied with the provisions of this Section 5.4, LICENSEE may use such Improvements to make, have made, use, and sell the Products in the Territory, but may not disclose such Improvements to Third Parties other than by a Patent Office publication that results from the LICENSEE's filing of a patent application in accordance with Section 5.5.

5.5. At the time of any disclosure to COMPANY as set forth in Section 5.4, LICENSEE shall also advise COMPANY whether or not LICENSEE has filed or intends to file one or more patent applications for any of the disclosed inventions or Improvements. In the event LICENSEE does not intend to file patent application(s), LICENSEE shall assign the rights to said invention(s), in each country in which LICENSEE has elected not to file, to COMPANY or its designee, which shall have the option, at its sole discretion, to file and prosecute patent applications based upon such assigned rights in COMPANY's name and at COMPANY's cost. Upon request by COMPANY, and at COMPANY's cost, for any such patent application(s),

LICENSEE shall supply COMPANY with all information including data required to prepare such patent application(s) and assist COMPANY in the prosecution of any such patent application(s) by supplying COMPANY with information, including data as required, and by signing documents and ensuring the availability and cooperation of any inventors employed by LICENSEE at the time of invention in connection with such patent applications as COMPANY may reasonably request.

5.6. License will be royalty free in the Territory during the Term of the Agreement.

6. REPRESENTATIONS, WARRANTIES, AND COVENANTS

6.1. Ability to Perform. Each of the Parties hereby represents and warrants that:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of their incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) this Agreement has been duly executed and delivered, and constitutes a legal, valid, and binding obligation, enforceable against it in accordance with the terms hereof; and

(c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party.

(d) it has not and will not employ or otherwise use in any capacity the services of any person or entity debarred under 21 U.S.C. § 335a (or equivalent foreign provisions) in performing any activities under this Agreement. Each Party shall notify the other Party, in writing, immediately if any such debarment occurs or comes to its attention, and shall, with respect to any person or entity so debarred, promptly remove such person or entity from performing any further activities under this Agreement, as applicable.

(e) shall comply with all applicable laws, regulations and codes relating to data privacy, personal data, trans-border data flow, and data protection involved in handling any personal data and information related to each other and their representatives. It shall be the duty of the Licensee to ensure that no personally identifiable information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means is shared with each other under any circumstances without complying with

applicable privacy laws. This obligation shall survive the expiry of this Agreement.

6.2. Law and Trade Compliance

(a)General. Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all applicable laws and regulations, including, without limitation, with respect to anti-competition, recalls, safety and reporting requirements and export controls and sanctions, and shall obtain, have and maintain all necessary regulatory approvals, marketing authorizations, export licenses, and other permits and licenses, at Licensee's expense for the manufacture and sale of the Substance and/or Product and any other Licensee activities contemplated hereby. Licensee further agrees that it shall not export, re-export, transfer, transmit, or release any goods, materials, software, or technology (including technical data) without first obtaining all necessary authorizations from the relevant government agencies. Notwithstanding anything herein to the contrary, any delay or failure to perform any part of this Agreement by either Party resulting from a denial, delay, or withdrawal of any required export authorization shall not constitute a breach of this Agreement nor expose either Party to liability hereunder.

(b) Conflicts. None of the Parties shall be required to take any action or perform any obligation under this Agreement to the extent that such action or obligation is in direct conflict with any applicable law, rule, or regulation.

(c)Licensee represents and warrants that as of the Effective Date and during the term of this Agreement that neither Licensee nor any of its directors, officers, employees or other legal representatives ("Representatives"), as applicable, is listed on any of the Denied Parties Lists. Licensee further represents and warrants that it is not 50% or more owned, directly or indirectly, by one or more persons listed on any Denied Parties List.

(d) Licensee shall comply with all applicable U.S. and local export control (dual-use trade control) laws and regulations relating to the performance of Licensee's obligations under this Agreement. Licensee represents and covenants that it will not, directly or indirectly, use, transfer, lend, contribute or otherwise make available the Licensed Rights/Technology/Products to any to any person or entity (1) listed on any Denied Parties List, (2) owned 50% or more by one or more parties listed on any Denied Parties List, or (3) headquartered, located, or incorporated under the laws of Cuba, Iran, North Korea, Russia, Syria, Venezuela or the Crimea, Donetsk or Luhansk, Regions of Ukraine ("Sanctioned Countries") without prior written approval from COMPANY. Licensee also represents and covenants that it will not make or have made the Substance or Product in a

Sanctioned Country without prior written approval from COMPANY.

(e) Licensee covenants that Licensee shall notify COMPANY in writing immediately if any of the preceding representations and warranties becomes incorrect during the term of this Agreement. In case of an inaccuracy in or a breach of the representations, warranties and covenants provided for above in (c) and/or if Licensee fails to comply with its obligations under (c) and (d) COMPANY has the right, in its sole discretion, to terminate this Agreement immediately and without penalty to COMPANY. Licensee agrees to indemnify and hold harmless COMPANY for any inaccuracy or breach of the representations and warranties provided for above in (c) and/or for Licensee's non-compliance with its obligations under (d). This provision shall survive termination and expiration of this Agreement.

(f) As used in this Section, "**Denied Parties List**" means any denied parties list issued by the U.S., the E.U., or any other jurisdiction, that is applicable to this Agreement, including but not limited to the U.S. Treasury Department's Office of Foreign Asset Controls' ("**OFAC**") List of Specially Designated Nationals and Blocked Persons (the "**SDN List"**) (https://www.treasury.gov/ofac/downloads/sdnlist.pdf), the OFAC Consolidated Sanctions List (https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/consolidated.aspx), the U.S. Commerce Department's Denied Persons List (https://www.bis.doc.gov/index.php/the-denied-persons-list) and Entity List (https://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern/entity-list), and the EU's Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions ("**EU Sanctions List**"):

https://data.europa.eu/data/datasets/consolidated-list-of-persons-groups-and-entities-subject-to-eu-financial-sanctions?locale=en

Anti-Boycott Compliance.

Notwithstanding any provision of this Agreement, neither party shall take or agree to take any action that is prohibited or penalized under the antiboycott laws and regulations of the United States.

6.3. Ethical Business Clause.

(a) By signing this Agreement, Licensee agrees to conduct the business contemplated herein in a manner which is consistent with both laws, regulations and good business ethics, including the U.S. Foreign Corrupt Practices Act and, where applicable, the U.K. Bribery Act 2010, and as otherwise communicated to Licensee

by COMPANY or one of its Affiliates from time to time.

(b) Specifically, Licensee represents, warrants and covenants, that in connection with this Agreement and the business contemplated hereby, its Affiliates, their respective Representatives, and anyone acting on their behalf shall not offer, make or promise any payment, either directly or indirectly, of money or other assets or any other thing of value, including but not limited to any compensation derived from this Agreement (collectively, a "Payment"), to any government, political party, political party official, international organization official, candidate for public office, or any person acting on behalf of or directly associated with any of the foregoing, including their employees, business partners, relatives, and family members (collectively, "Officials"), where such Payment would constitute a violation of any applicable law. In addition, regardless of legal permissibility, Licensee shall not make any Payment, either directly or indirectly, to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement or the business activities of COMPANY or its Affiliates.

(c) Licensee represents, warrants, and covenants that none of its employees, agents, officers, or other members of management are, and that none of the employees, agents, officers, or other members of management of Licensee, its Affiliates, or permitted assignees/transferees are or will become during the Term of this Agreement, officials, officers, agents, or representatives of any government or international public organization, or of any government or political party having governmental authority to make or participate in decisions regarding the Product in the Territory.

(d) Licensee will maintain proper and accurate books, records, and accounts which accurately and fairly reflect any and all payments made, expenses incurred and assets disposed of in connection with its performance of this Agreement. Licensee shall also maintain an adequate system of internal accounting controls and a compliance program designed to ensure the proper authorization, recording and reporting of all transactions and to provide reasonable assurances that any breaches of this Section 6.3 will be prevented, detected and deterred. Licensee further represent, warrant, and undertake that no "off-book" or similar funds will be maintained or used in connection with this Agreement. Licensee shall ensure that its and its Affiliates' Representatives, agents, subcontractors, and other personnel involved in performance of this Agreement are specifically made aware of, and comply with, the requirements of this Section, including through appropriate training and periodic certifications of compliance in such form as COMPANY may reasonably require. Licensee shall implement and maintain and shall cause any of its agents or subcontractors to implement and/or sustain a compliance program to

comply with the requirements of this Section and to maintain adequate records of such compliance program.

(e) The Licensee represents and warrants that it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity) and aims to achieve greater equity along those lines in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates

(f) The Licensee's failure to abide by the provisions of this Section shall be deemed a material breach of this Agreement. COMPANY may in such case and with immediate effect terminate this Agreement at its sole discretion upon written notice to Licensee and without prejudice to any other remedies that may be available to COMPANY.

(g) The Licensee shall indemnify and hold COMPANY and any of its Affiliates harmless from and against any and all liabilities (including all costs and reasonable attorneys' fees associated with defending against such claims) that may arise by reason of the acts or omissions of Licensee or its agents or other Third Parties acting on Licensee's behalf which would constitute a violation of this Section.

6.4. Privacy Laws: COMPANY and Licensee shall comply with all applicable laws, regulations and codes relating to data privacy, personal data, trans-border data flow and data protection involved in handling any personal data and information related to each other and their representatives. It shall be the duty of the COMPANY and LICENSEE to ensure that no personally identifiable information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means is shared with each other under any circumstances. This obligation shall survive the expiry of this Agreement.

6.5. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, COMPANY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE PATENTS OR ANY LICENSE GRANTED BY COMPANY HEREUNDER, OR WITH RESPECT TO THE SUBSTANCE OR THE PRODUCTS, OR ANY OTHER MATTER. FURTHERMORE, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS

INCLUDED IN THE PATENTS IS VALID OR ENFORCEABLE OR THAT THE LICENSEE(S)'S USE OF THE PATENTS, SUBSTANCE OR PRODUCT AS CONTEMPLATED HEREUNDER WILL NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. COMPANY ALSO DOES NOT GIVE ANY WARRANTY, EXPRESS OR IMPLIED, WITH REGARD TO THE SAFETY OR EFFICACY OF THE SUBSTANCE OR THE PRODUCT AND IT SHALL BE THE SOLE RESPONSIBILITY OF THE LICENSEE TO ENSURE SUCH SAFETY OR EFFICACY.

7. QUALITY CONTROL, REGULATORY COMPLIANCE, LIABILITY, AND INDEMNITY

7.1. Licensee agrees that the Product sold by it and the processes for manufacturing, storage and handling of such Product shall strictly comply with all applicable laws, guidelines (including current good manufacturing practices), regulations, and Licensee's manufacturing standards relating to any operations involved in the manufacture, packaging, labeling, quality control, testing, receipt, storage of, warehousing, and shipping, of Product, including but not limited to regulations for protection of worker health and safety. If at any time, during the term of this Agreement, COMPANY is made aware of any action (including any official notifications or communications) taken by any Agency in the Territory in connection with Licensee's failure to meet the standards set forth in this Section 7.1 for the manufacture and handling of the Product, COMPANY shall promptly provide Licensee with a notice of the same and the Licensee shall within a period of thirty (30) days from receipt of such notice, provide COMPANY with a plan for remedying the same within a mutually agreed timeline. If Licensee is unable to remedy the same within the mutually agreed timeline, COMPANY may, after giving Licensee written notice, terminate this Agreement at its sole discretion and without prejudice to any other remedies that may be available to COMPANY; provided however, that in the event that Licensee has already received a prior notice of any such violation, then COMPANY shall have the right to terminate this Agreement immediately without any notice.

7.2. COMPANY shall not be responsible to Licensee or to any Third Party for any damages or losses resulting from Licensee's or its Affiliates' or permitted assignees'/transferees' manufacture, packaging, labeling, receipt, shipping, handling, storage, use, importation, marketing, or sale of the Product or any other acts or omissions of Licensee arising out of this Agreement.

7.3. Licensee shall defend COMPANY, its Affiliates and its directors, officers, employees, and agents, and inventors of any patents and patent applications within the Patents

(each and collectively a "**Indemnified Party**"), at Licensee's cost and expense, and shall indemnify and hold any Indemnified Party harmless from and against any and all liabilities, losses, costs, damages, fees, or expenses (including reasonable legal expenses and attorneys' fees incurred by a Indemnified Party) arising out of any claim, action, lawsuit or other proceeding brought against such Indemnified Party by a Third Party resulting directly or indirectly from the manufacture, packaging, labeling, receipt, shipping, handling, storage, use, importation marketing, Commercialization, or sale of Product or Substance or any other activity under this Agreement by Licensee or permitted assignees/transferees relating to: (a) any breach of this Agreement by Licensee or its Affiliates, or (b) the gross negligence, willful misconduct, or violation of applicable law by or of Licensee, its Affiliates or their respective directors, officers, employees or agents or any of them in performing under this Agreement; except, in each case, to the extent caused by the negligence, willful misconduct, violation of applicable law, or breach of this Agreement of or by COMPANY, its Affiliates, or any of the other Indemnified Parties. Licensee shall immediately notify COMPANY of any such suits and shall confer with COMPANY prior to the settlement of such claims.

Licensee shall immediately notify COMPANY of any such suits and shall confer with COMPANY prior to the settlement of such claims.

7.4. Notwithstanding anything expressed or implied to the contrary in this clause, the amount of any losses subject to indemnification shall be reduced by the amount of any insurance proceeds received by the indemnified Party with respect to such Losses; and there shall be no obligation under this Agreement to indemnify such indemnified Party for the amount of losses so reduced.

7.5. NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS OR ROYALTIES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION.

8. INSURANCE

Licensee, at its sole cost and expense, shall insure its activities in connection with this Agreement and obtain, keep in force, and maintain comprehensive or commercial form general liability insurance (contractual liability included) with adequate limits.

9. STATEMENTS, REPORTING AND RIGHT TO AUDIT

9.1. Licensee will keep full, true, and accurate books and records for the purpose of showing Licensee's compliance with other obligations under this Agreement and applicable laws. Said books and records will be kept at Licensee's principal place of business or the principal place of business of the appropriate division of Licensee to which this Agreement relates. Said books and records and the supporting data will be open at all reasonable times during normal business hours upon at least fifteen (15) days' advance written notice, for three (3) years following the end of the calendar year to which they pertain, to the inspection and audit (on site if Licensee so requests) by independent certified public accountants hired by COMPANY and reasonably acceptable to Licensee for the purpose of verifying Licensee's quarterly reports or compliance in other respects with this Agreement and applicable laws. Such certified public accountants will be bound to hold all information in confidence except as necessary to communicate Licensee's non-compliance with this Agreement to COMPANY .

9.2. The fees and expenses of the certified public accountants performing such an examination will be borne by COMPANY. After the first sale anywhere in the Territory, within 20 Business Days following the end of each Agreement Quarter, the Licensee shall deliver to COMPANY a statement accounting for, *inter alia*, , Products and/or Substance (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter in the Reporting Template as set forth in Appendix 4. COMPANY agrees that information contained in quarterly and other such reports shall be treated as Confidential Information, however, that such information may be aggregated data may be publicly disclosed by COMPANY.

10. TERM AND TERMINATION

10.1. Term. Unless otherwise terminated by the operation of law or by acts of the parties in accordance with the terms of this Agreement, this Agreement will be in force from the Effective Date and will remain in effect until 31 March 2035, unless sooner terminated as provided in this Agreement or by mutual agreement between COMPANY and Licensee.

10.2. Termination for Breach. A Party ("**non-breaching party**") shall have the right to terminate this Agreement in the event the other Party ("**breaching party**") is in material breach of any of its material obligations under this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party

shall have a period of 30-days after such written notice is provided to cure such breach, or to provide a timeline to cure such breach to the satisfaction of the non-breaching party. If such breach is not cured within the 30-day period or in accordance with the timeline, the non-breaching party shall have the right to terminate this Agreement immediately in the sole discretion. Any termination pursuant to this Section 10.2 will not (1) relieve either Party of any obligation or liability accrued; (2) impair any accrued rights of either Party (3) or rescind anything done by either Party hereunder prior to the time of such termination becoming effective. In the case where the breaching party is Licensee, such termination shall not relieve Licensee of its obligation to pay any royalty or other fees owing at the time of such termination.

10.3. COMPANY Right to Terminate.

COMPANY shall have the right to terminate this Agreement, without any liability, either in whole or in relation to a particular Patent, with immediate effect by giving written notice to Licensee if:

(a) Licensee breaches any of the anti-diversion provisions of Section 4;

(b) COMPANY becomes aware of any action (including any official notifications or communications) taken by any regulatory authority involving a determination of Licensee's failure to comply with good manufacturing practices as prescribed in the applicable legal or regulatory standards in connection with for the manufacture and handling of the Products, or otherwise reasonably determines that, due to material deficiencies in Licensee's compliance, or repeated failure to comply, with the quality requirements of Section 3.2, Licensee is unable to reliably and consistently manufacture Substance or Product in accordance with such quality requirements;

(c) Licensee fails to file for US FDA Tentative Approval for the Substance and Product within 36 months from the date of this Agreement;

(d) Licensee repeatedly fails to comply with or to timely provide COMPANY with the reports contemplated under Sections 3.4 and 9.2 of this Agreement;

(e) Licensee fails to file for WHO Pre-Qualification of the Substance and Product within six months of a WHO Expression of Interest for the Product or such other time as may be mutually agreed between the Parties;

(f) The legal or beneficial ownership of Licensee or any of its Affiliates changes in such a manner as COMPANY after consulting with Licensee reasonably determines to be significant and adversely impacts the ability of the Parties to

achieve the objectives of this Agreement; or

(g) Licensee, its subsidiaries or Affiliates challenges the validity, enforceability or scope of any claim within the Patent in a court or other governmental agency of competent jurisdiction, including in a re-examination or opposition proceeding, or as a defense to enforcement of this Agreement or the terms of this Agreement, including applicable payment obligations.

(h) if COMPANY no longer retains the rights necessary to sell the Product in the Territory or to license such rights to third parties

(i) With respect to the Product, COMPANY reasonably determines that the continued sale of such Product would not be medically appropriate or would otherwise harm COMPANY's business reputation.

10.4. Failure to Promote Access. If, in the reasonable opinion of the COMPANY, the Licensee fails to promote access or appears in COMPANY's reasonable opinion, will fail to promote access to the Products in the Territory in accordance with this Agreement, the COMPANY shall give notice to the Licensee requiring it to cure such failure. If, in the reasonable opinion of the COMPANY, the Licensee fails to present an acceptable plan within 60 days and report reasonable progress within 180 days after receiving written notice with respect to the default, the COMPANY shall have the right to terminate this Agreement without any obligation to pay any compensation or any penalty, with immediate effect by giving written notice to the Licensee. In making such determination of reasonable progress, the COMPANY shall take into account the period within which the relevant authorities provide the necessary approvals and normal development lead time for the Products, and progress reported by Licensee in its quarterly reports and meetings provided under Section 3.4 of this Agreement.

10.5. Misrepresentations in Expression of Interest. Licensee acknowledges that it was offered to enter into this Agreement on the basis of certain representations that it made to the COMPANY. In the event that the COMPANY discovers any material misrepresentations made therein, the COMPANY shall have the right, upon 30 days' notice, to terminate this Agreement without any obligation to pay any compensation or any penalty.

10.6. Insolvency. Either Party may terminate this Agreement in the event that the other Party becomes insolvent, makes an assignment to the benefit of creditors, or has a petition in bankruptcy filed for or against it.

10.7. Rights on Termination. Any termination of this Agreement will not relieve Licensee

of its obligations to make any payment due or owing at the time of such termination and will not relieve any obligations, of either to the other Party, established prior to termination.

10.8. Survival. All sections of this Agreement that are expressly or by implication meant to survive this Agreement, including but not limited to the sections 3A, 6, 7.3, 8, 11, will remain in full force and effect upon expiration or termination of this Agreement.

11. CONFIDENTIALITY AND PUBLICATIONS

11.1. Licensee may conduct clinical studies, or other trials with the Product, provided that Licensee has obtained COMPANY's prior written consent, which may be withheld at COMPANY's sole discretion. A response by COMPANY should be provided within 90 business days after receiving the suggested study protocol from the Licensee. In the event COMPANY approves any such studies or trials in accordance with this Section 11, then, at the option of COMPANY, COMPANY may have its representative monitor any approved studies or trials.

11.2. In the event that any such studies or trials have been approved by COMPANY, Licensee will pay for any necessary supplies and, upon completion of such studies or trials, Licensee shall furnish free of charge to COMPANY and its Affiliates in the English language all data and information, especially any adverse drug experiences, derived from any such studies, pre-clinical or clinical trials carried out by Licensee relating to the Product, in such detail and at such times as COMPANY may reasonably request for non-commercial and internal use and disclosure to any Third Party in compliance with the contractual obligations of COMPANY and its Affiliates. Any such Affiliates which are recipients of such information pursuant to the foregoing shall be under the same obligation of confidentiality as set forth in this Section. If COMPANY and its Affiliates want to use the data and information for any other purpose, the Licensee and COMPANY shall negotiate in good faith.

11.3. Each Party hereto agrees to keep secret and confidential any and all business information, Know-How, quarterly reports, technology, or any other confidential information disclosed by one Party ("**Confidential Information**") to the other Party pursuant to this Agreement (including any discussions or correspondence relating to the preparation of this Agreement), and not to disclose such information to any Third Party other than to any Agency as may be required by applicable law or regulations. For the avoidance of doubt, COMPANY shall have the right to such Confidential Information and wherever COMPANY has a contractual obligation towards a Third Party to disclose information regarding the Product or Substance, COMPANY may

disclose Confidential Information to that Third Party under obligations of confidentiality no less stringent than contained herein. The obligations imposed by this Section 12.3 shall not apply to any information:

(a) which, at the time of disclosure, is in the public domain; or

(b) which, after disclosure, becomes part of the public domain by publication or otherwise, through no fault of the receiving Party; or

(c) which, at the time of disclosure, is already in the receiving Party's possession from a source owing no obligation of confidentiality to the disclosing Party, and such possession can be properly demonstrated by the receiving Party; or

(d) which is rightfully made available to the receiving party from sources independent of the disclosing Party; or

(e) which is developed independently without the use or reference to the information received from the receiving Party and without making reference to Substance and/or Product.

11.4. Licensee will keep COMPANY Know-How confidential subject to Section 11.3 above.

11.5. Within 30 days after any expiration or termination of this Agreement, either Party shall destroy (and certify to the other Party such destruction) or return all Confidential Information provided by the other Party except as otherwise set forth in this Agreement. One copy of the other Party’s Confidential Information may be retained solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement.

11.6. The obligations of confidentiality set forth in this Section 11 shall survive for a period of ten (10) years after the expiration, cancellation, or other termination of this Agreement.

11.7. Subject always to Agreement, COMPANY and Licensee agree that no public release or announcement concerning the Agreement shall be issued without the prior written consent of COMPANY, except if such release or announcement may be required by law (including without limitation information to any Agency), in which case the Licensee shall allow COMPANY reasonable time to comment on such release or announcement in advance of such issuance.

11.8. Save as otherwise provided in this Agreement, the Parties agree that COMPANY shall not be required to provide any technical support or technical assistance to Licensee for any reason except that COMPANY shall provide only a technical package for drug product development and analytical testing support, and no other technical assistance whatsoever. COMPANY and its Affiliates make no representations that Licensee or its Affiliates will be able to obtain or maintain marketing authorizations, licenses, permits, or registration for the Product in the Territory or that the Licensee will be able to manufacture the Product.

12. MISCELLANEOUS

12.1. Agency. Neither Party is, nor will be deemed to be, an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Nothing contained in this Agreement shall be deemed to establish or otherwise create a relationship of joint venture or distributorship between the Parties. Licensee acknowledges that it is an independent contractor and that it shall have no authority to enter into any contract or commitment binding upon COMPANY or an Affiliate of COMPANY, or to obligate COMPANY or its Affiliates in any matter whatsoever. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

12.2. Entire Understanding. This Agreement embodies the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous communications, representations or understandings, and agreements, whether oral or written, between the Parties relating to the subject matter hereof.

12.3. Severability. The Parties hereby expressly state that it is not their intention to violate any applicable rule, law, or regulation. If any of the provisions of this Agreement are held to be void or unenforceable with regard to any particular country by a court of competent jurisdiction, then, to the extent possible, such void or unenforceable provision shall be replaced by a valid and enforceable provision which will achieve as far as possible the economic business intentions of the Parties. The provisions held to be void or unenforceable shall remain, however, in full force and effect with regard to all other countries. All other provisions of this Agreement shall remain in full force and effect.

12.4. Notices Any legal notice or other communication to be given under this Agreement, unless otherwise specified, shall be in writing, in English and shall be deemed to have

been provided when delivered to the addressee at the address listed below (i) on the date of delivery if delivered in person or email (receipt confirmed) or (ii) three days after mailing by registered or certified mail, postage paid:

In the case of the COMPANY:

Merck Sharp and Dohme LLC
120 E Lincoln Avenue
Rahway, NJ 07065
The United States of America
Attention: Office of Secretary

In the case of Licensee:

Attention: _____
E-mail: _____

Any Party may change its address for communications by a notice in writing to the other Party in accordance with this Section.

12.5. Language; Governing Law. This Agreement is entered into and will be governed by and construed in accordance with the English language. This Agreement is made in accordance with and shall be governed and construed under the laws of New York, without regard to its choice of law principles.

12.6. Dispute Resolution.

(a) 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 (a "Dispute"). Any Party shall give the other Party written notice of any Dispute not resolved in the normal course of business. Within 20 days from the date of delivery of such notice, the receiving Party shall submit to the other Party a written response. The notice and response shall include (a) a statement of that Party's position and a summary of arguments supporting that position, and (b) the name and title of the executive who will represent that Party and of any other person who will accompany the executive. Within 45 days from the date of delivery of the initial notice, the executives of both Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. These executives shall have the authority to settle the Dispute and shall be at a higher level of management than the persons with direct responsibility for administration of

this Agreement. All negotiations pursuant to this paragraph are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

(b) If the Parties do not fully settle following the procedure in Section (a) , and a Party wishes to pursue the matter, each dispute, controversy or claim arising from or related to this Agreement or the breach thereof that is not an Excluded Claim shall be brought in the New York courts. Each of the Parties hereby submits to the exclusive jurisdiction of such courts for the purpose of any such litigation; provided that a final judgment in any such litigation shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each Party irrevocably and unconditionally agrees not to assert (a) any objection which it may ever have to the laying of venue of any such litigation in such courts, (b) any claim that any such litigation brought in any such court has been brought in an inconvenient forum, and (c) any claim that such court does not have jurisdiction with respect to such litigation. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO A TRIAL BY JURY AND AGREES THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY LITIGATION.

(c) Without prejudice to the foregoing, nothing in this Agreement shall prevent or restrict COMPANY from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country outside the United States, to which election COMPANY and the Licensee hereby agrees.

12.7. Assignment. Neither Party is entitled to transfer or assign this Agreement or the rights and obligations under this Agreement without the other Party's prior written consent except that COMPANY shall have the right, to the extent possible, assign, or transfer the benefits, rights and obligations under this Agreement or any part thereof to an Affiliate without consent .

12.8. Amendment. No amendment or modification hereof shall be valid or binding upon the Parties unless made in writing and signed by all of the Parties.

12.9. Entire Agreement. This Agreement contains the entire agreement between the Parties hereto in respect of the subject matter hereof, and supersedes and cancels all previous agreements, negotiations, commitments, and writings in respect of the subject matter hereof, except that any previous confidentiality agreements shall remain in full force and effect. This Agreement may not be changed or modified in any manner, or

released, discharged, abandoned, or otherwise terminated orally or otherwise, unless in writing and signed by the duly authorized officers or representatives of the Parties.

12.10. 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 (i) be valid only if set forth in written instrument duly executed by authorized representative(s) of the Party to be bound thereby and (ii) 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. Any delay in exercising any right under this Agreement shall not constitute a waiver of such right.

12.11. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile, pdf, or through DocuSign, and that any such e-signature shall be given the same legal force and effect as the physical delivery of this Agreement, bearing original handwritten signatures without affecting the validity thereof.

This Agreement consists of 12 (twelve) Articles and 4 (four) appendices and is hereby executed on this [day] of [month] [year] by the duly authorized representatives of the Parties, who are authorized to represent and bind the Parties.

[signatures appear on following page]

Appendix 1 - Countries in the Territory

No.	Country	No.	Country
1	Afghanistan	41	Gabon
2	Algeria	42	Gambia
3	Angola	43	Georgia
4	Anguilla	44	Ghana
5	Antigua & Barbuda	45	Grenada
6	Armenia	46	Guatemala
7	Aruba	47	Guinea
8	Azerbaijan	48	Guinea-Bissau
9	Bahamas, The	49	Guyana
10	Bangladesh	50	Haiti
11	Barbados	51	Honduras
12	Belarus	52	India
13	Belize	53	Indonesia
14	Benin	54	Iran
15	Bhutan	55	Iraq
16	Bolivia	56	Jamaica
17	Botswana	57	Jordan
18	British Virgin Islands	58	Kazakhstan
19	Burkina Faso	59	Kenya
20	Burundi	60	Kiribati
21	Cabo Verde	61	Korea, Dem. People's Rep.
22	Cambodia	62	Kyrgyz Republic
23	Cameroon	63	Lao PDR
24	Central African Republic	64	Lebanon
25	Chad	65	Lesotho
26	Comoros	66	Liberia
27	Congo, Dem. Rep.	67	Libya
28	Congo, Rep.	68	Madagascar
29	Cote d'Ivoire	69	Malawi
30	Cuba	70	Malaysia
31	Djibouti	71	Maldives
32	Dominica	72	Mali
33	Dominican Republic	73	Marshall Islands
34	Egypt	74	Mauritania
35	El Salvador	75	Mauritius
36	Equatorial Guinea	76	Micronesia, Fed. Sts.
37	Eritrea	77	Mongolia

No.	Country	No.	Country
38	Eswatini	78	Montserrat
39	Ethiopia	79	Morocco
40	Fiji	80	Mozambique
81	Myanmar	106	Sudan
82	Namibia	107	Suriname
83	Nauru	108	Syria
84	Nepal	109	Tajikistan
85	Nicaragua	110	Tanzania
86	Niger	111	Thailand
87	Nigeria	112	Timor-Leste
88	Pakistan	113	Togo
89	Palau	114	Tonga
90	Papua New Guinea	115	Trinidad & Tobago
91	Philippines	116	Tunisia
92	Rwanda	117	Turkmenistan
93	Samoa	118	Turks & Caicos
94	Sao Tome and Principe	119	Tuvalu
95	Senegal	120	Uganda
96	Seychelles	121	Ukraine
97	Sierra Leone	122	Uzbekistan
98	Solomon Islands	123	Vanuatu
99	Somalia	124	Venezuela
100	South Africa	125	Viet Nam
101	South Sudan	126	West Bank and Gaza
102	Sri Lanka	127	Yemen, Rep.
103	St. Kitts and Nevis	128	Zambia
104	St. Lucia	129	Zimbabwe
105	St. Vincent & G.		