

## License Agreement

**THIS LICENSE AGREEMENT** (this **Agreement**) is made as of 6/13/2023 2023 (the **Effective Date**) by and among the Medicines Patent Pool, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at rue de Varembe 7, Geneva 1202, Switzerland (**MPP**), and **M/S. HETERO LABS LIMITED** a company registered under the laws of **INDIA**, and having as principal place of business at **M/S. HETERO LABS LIMITED, 7-2-A2, INDUSTRIAL ESTATES, SANATH NAGAR, HYDERABAD - 500 018, TELANGANA, INDIA** (**Licensee**). Each of MPP and Licensee is referred to in this Agreement individually as a **Party** and collectively as the **Parties**.

### RECITALS

- (A) WHEREAS, in accordance with Shionogi-MPP Agreement (as hereinafter defined), MPP has beengranted by Shionogi & Co., Ltd. (registered in Japan, listed on the Tokyo Stock Exchange with stock code 4507) whose registered office is at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045, Japan (**Shionogi**), the right to sublicense certain Patents (as hereinafter defined) and Licensed Know-How (as hereinafter defined) regarding (a) the Compound (as hereinafter defined) used in Licensed Product (as hereinafter defined) and (b) the Licensed Product, in furtherance of its policy of improving access to COVID-19 medicines in the Territory (as hereinafter defined);
- (B) WHEREAS, MPP is a non-profit organization with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious, and affordable medicines by facilitating access to intellectual property on these medicines;
- (C) WHEREAS, Licensee desires to obtain a license from MPP to use the Patents and Licensed Know-How, and MPP is willing to grant to Licensee such a license, each in accordance with the terms and subject to the conditions of this Agreement; and
- (D) WHEREAS, the intent of this Agreement is to provide a license to Patents and Licensed Know-How solely as set forth herein.
- (E) NOW, THEREFORE, in consideration of the mutual covenants and obligations set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

### I. DEFINITIONS

**Affiliate** shall mean in relation to a Party or Shionogi, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with that Party or Shionogi (as applicable), but only for so long as such control continues. For the purposes of this definition, **control** (shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interests (whether directly or pursuant to any option, warrant, or other similar agreement) of such entity, and **controlled by** and **under common control with** shall be interpreted accordingly.

**Agency** shall mean, with respect to a country in the Territory, any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a regulatory approval or, to the extent required in such country, price approval, for a pharmaceutical product in such country.

**Agreed Dosage** shall mean 375mg on day 1 and 125mg on days 2 to 5 and any additional dosages included in Exhibit D.

**Agreed Formulation** shall mean an oral tablet and any additional formulations included in Exhibit D.

**Applicable Law** shall mean any and all laws, statutes, ordinances, regulations, permits, orders, decrees, judgments, directives, rulings or rules of any kind whatsoever that are promulgated by a federal, state, provincial, municipal, or Agency, in each case pertaining to any of the activities contemplated by this Agreement, including any regulations promulgated thereunder, all as amended from time to time.

**Approved Local Distributor** shall have the meaning given in Section 2.8 of this Agreement.

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

**Calendar Quarter** means: (a) the period starting on the Effective Date and ending on 30 June 2023; and (b) each period of three consecutive months starting on 1 January, 1 April, 1 July and 1 October following the Effective Date, except for the final Calendar Quarter, which shall start on 1 January, 1 April, 1 July or 1 October of the quarter in which termination or expiry of this Agreement occurs and end on the date of termination or expiry of this Agreement.

**cGMP** shall mean all applicable standards relating to current good manufacturing practices for fine chemical, intermediates, bulk products and/or finished pharmaceutical drugs, including (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, 21 C.F.R. Pars 210 and 211, (b) all applicable requirements detailed in the EMA's EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, and (c) all applicable laws promulgated by any Agency having jurisdiction over the manufacture of the applicable compound or pharmaceutical drug product, as applicable.

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

**Compound** shall mean that certain novel SARS-CoV-2 3CL<sup>pro</sup> small molecule inhibitor, known as ensitrelvir fumaric acid or S-217622 and described further in Exhibit A.

**Control** or **Controlled** shall mean, with respect to intellectual property rights, that Shionogi, a Party or one of their respective Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide or grant a license or sublicense to such intellectual property rights as provided for in this Agreement without violating the terms of any other agreement or other arrangement with or requiring any payment to any Third Party.

**Customer** shall mean the Third Party who is buying the Licensed Product from Licensee, but shall not include Shionogi, its Affiliates, or an MPP Licensee.

**Field** shall mean (i) for the period from the Effective Date until the Prevention Approval Date, the treatment of COVID-19 caused by SARS-CoV-2 and (ii) following the Prevention Approval Date, the treatment and/or prevention of COVID-19 caused by SARS-CoV-2.

**Government** or **Governmental Authority** is to be broadly interpreted and includes: (a) any national, federal, state, local, regional, or foreign government, or level, branch, or subdivision thereof; (b) any multinational or public international organization or authority; (c) any ministry, department, bureau, division, authority, agency, commission, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power; (d) any court, tribunal, or governmental arbitrator or arbitral body; (e) any government-owned or -controlled institution or entity; (f) any enterprise or instrumentality performing a governmental function; and (g) any political party.

**Government Official** is to be broadly interpreted and includes: (a) any elected or appointed Government official (eg, a legislator or a member of a ministry of health); (b) any employee or person acting for or on behalf of a Government, a Government department or agency, an institution or entity owned or controlled by a Government (eg, a healthcare professional employed by a Government-owned or -controlled hospital, or a person serving on a healthcare committee that advises a Government), or an enterprise or instrumentality performing a governmental function; (c) any candidate for public office, or officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) an employee or person acting for or on behalf of a public international organization (eg, the United Nations, the Red Cross, or the World Bank); (e) any member of a military or a royal or ruling family; and (f) any person otherwise categorized as a Government official under Applicable Law.

**Improvements** shall mean any (patentable or unpatentable) new or improved use, formulation, process, improvement, invention, development or finding related to any Compound and/or any Licensed Product, or any (patentable or unpatentable) other pharmaceutical product containing or otherwise using Compound, or any further invention (patentable or unpatentable) that relates to the development, manufacture, formulation or use of the Licensed Products and/or Compound or incorporate or are based on the Patents or Licensed Know-How, Controlled by Licensee or any of its Affiliates as of the Effective Date or during the term of the Sublicense. For the avoidance of doubt, "Improvements" shall include any patent rights, Know-How or other intellectual property rights related to any Compound and/or Licensed Product or that are necessary or useful for the development, manufacture and/or commercialization of Shionogi's pharmaceutical product(s) containing or otherwise using the Compound, in each case that are Controlled by Licensee or its Affiliates as of the Effective Date or at any time during the term of this Agreement.

**Key Approval** shall mean any technical, medical, scientific or other license, registration, authorization or approval of any Agency (including any approval of a New Drug Application or Biologic License Application) necessary for the development, manufacture or commercialization of a pharmaceutical product in any regulatory jurisdiction.

**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.

**Licensed Know-How** shall mean all Know-How that (a) is Controlled by Shionogi or any of its Affiliates as of the effective date of the Shionogi-MPP Agreement, (b) directly relates to the use of the Compound or Licensed Product in the Field, (c) is not in the public domain or otherwise generally known, and (d) is provided by Shionogi or any of its Affiliates to MPP or any Sublicensee in its sole discretion pursuant to this Agreement and necessary for the manufacture, registration and Commercialization of the Compound and/or Licensed Product for use in the Field. For the avoidance of doubt, Licensed Know-How shall not include any Know-How to the extent solely and directly related to any other Shionogi compound or to the extent related to the use of the Compound or Licensed Product outside the Field.

**Licensed Product** shall mean a pharmaceutical or biological composition or preparation containing the Compound as its sole active ingredient in the Agreed Formulation and with the Agreed Dosage, including any Improvements to the foregoing (provided such Improvements do not remain in the Agreed Formulation and with the Agreed Dosage), in each case (a) for sale or use by prescription, over-the-counter or any other method, or (b) for administration to, or use with, human patients in a human clinical trial (**Clinical Trial**) to the extent permitted pursuant to Section 3.3. For clarity, Licensed Product shall not include any pharmaceutical or biological composition or preparation containing both the Compound and another active ingredient in a single formulation.

For purposes of calculating Net Sales, when Licensed Product is sold for Stockpiling purposes in a form other than final form, Licensed Product will refer to Licensed Product in final or bulk form. "Stockpiling" shall mean activities conducted by a Governmental Authority or Public Purchasers to address public health emergencies by purchasing and maintaining inventories of Licensed Product for distribution and use in responding to such emergencies. Stockpiling may apply to purchases of finished or bulk form pharmaceutical Licensed Products or bulk forms of Compound used to make such Licensed Products.

For the avoidance of doubt, any sale of Licensed Products in bulk form or for a Clinical Trial may only take place if permitted and approved in advanced in writing by Shionogi.

**Local Distributor** shall have the meaning given in Section 2.8 of this Agreement.

**MPP Licensee(s)** shall mean any Third Party to whom MPP has granted a sublicense of the rights granted to MPP by Shionogi under and pursuant to the terms of the Shionogi-MPP Agreement.

**Net Sales** shall mean the gross amounts invoiced by Licensee or its Affiliate for sales of Licensed Products to Customers, less the sum of the following actual and customary deductions:

- (a) cash, trade, quantity and other discounts actually granted, including chargebacks, retroactive price reductions, rebates (whether or not Government- mandated), and discounts in the form of wholesaler inventory management fees;
- (b) sales, value added (only to the extent of amounts actually paid and not refunded, reimbursed, credited or otherwise recoverable), use, tariff, import/export duties or other excise taxes when included in the gross invoice price, but not value-added taxes assessed upon such sales that are not included in the gross invoice price or income taxes on income derived from such sales;
- (c) transportation and associated insurance, freight, packaging and customs charges when included in the gross invoice price;
- (d) allowances or credits to customers because of rejections, returns, or recalls; and
- (e) deductions for bad debts, not to exceed two percent (2%) of the total amount invoiced, in accordance with International Financial Reporting Standards principles, provided that such amounts will be included in Net Sales when recovered.

For purposes of calculating Net Sales, a sale to an Affiliate for end use by the Affiliate will be treated as a sale at list price. End use does not include: (a) use in a Clinical Trial if for no cost or for *de minimis* value, (b) charitable or compassionate use purposes if for no cost or for *de minimis* value, or (c) quantities provided for resale where royalties will be paid to Shionogi on the resale. For the avoidance of doubt, Net Sales shall not include (i) consideration paid or owed to Licensee for any sale to Shionogi, an Affiliate of Shionogi, or an MPP Licensee that is not for end use by each of such parties, or (ii) consideration paid or owed to Shionogi or its Affiliates for any use or sale by Shionogi or its Affiliates of Licensed Product sold to Shionogi or its Affiliates by Licensee. Net Sales and all deductions allowed in computing Net Sales shall be determined on an accrual basis in accordance with International Financing Reporting Standards principles, consistently applied.

**Non-Territory Patents** shall mean any Patents, granted or pending, in any country that is not included in the Territory (as hereinafter defined). For the avoidance of doubt, to the extent international and regional patent applications are included in Patents, such international and regional patent applications are Non- Territory Patents only with respect to countries that are not included in the Territory.

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

**Patents** shall mean any unexpired letters patent or any pending patent applications as set forth in Appendix 2 attached hereto, that are granted or pending, relating to the Compound and/or Licensed Product, 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 (eg, WIPO), regional (eg, EP or EA), and foreign national equivalents of the foregoing, in each case to the extent Controlled by Shionogi or any of its Affiliates.

**Prevention Approval Date** means the date on which Shionogi or any of its Affiliates receives any marketing authorisation outside the Territory with respect to the sale of Licensed Product for prevention of COVID-19 caused by SARS-CoV-2.

**Public Purchasers** shall mean with respect to a country in the Territory: (a) the following organizations to the extent that they are not for profit organizations and operate in such countries: (i) Non-Governmental Authorities to the extent that they are recognized by the applicable local government ministries from such country; (ii) UN-related organizations working for or in such country, including but not limited to UNDP and UNICEF; (iii) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC) to the extent that they are recognized by the applicable local government ministries from such countries; (iv) programs funded by funding mechanisms, including without limitation, UNITAID, PEPFAR, USAID, and Global Fund; and agencies based outside the Territory to the extent that they are supporting implementation of the organizations described in paragraph (i) through (iii) above locally in such country; and (b) nominally for profit procurement organizations but only to the extent that such procurements are supporting not-for-profit programs in such country as described in (a) of this definition within the Territory.

**Reference Listed Drug** shall mean the Compound in an oral pharmaceutical composition in a tablet form for use in the Field manufactured by or on behalf of Shionogi which has been approved by an SRA for use in the Field.

**Retail** shall mean sale, import, or export of the Licensed Product by Licensee to another MPP Licensee for the purpose of making the Licensed Product available in the Territory for the other MPP Licensee's Own Use.

**Shionogi Field** shall mean the treatment and/or prevention of diseases caused by coronaviruses.

**Shionogi-MPP Agreement** shall mean the license agreement entered into between Shionogi and MPP on 3 October 2022.

**Shionogi Trademarks** shall mean trademarks, service marks, logos, 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 Shionogi or its Affiliates.

**Stringent Regulatory Authority** or **SRA** shall mean an Agency which is:

- (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or

- (b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- (c) an Agency associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

**Territory** shall mean those countries set forth in Appendix 3 attached hereto.

**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.

**Third Party(ies)** shall mean any party other than MPP, Licensee, Shionogi and their respective Affiliates.

**Valid Claim** shall mean 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, finding, or decision of invalidity, unenforceability, or non-patentability by a court, Governmental Authority, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal.

**Vend** shall mean sale, import, or export of the Compound by Licensee to another MPP Licensee for the purpose of manufacturing the Licensed Product for such other MPP Licensee's Own Use.

**WHO** shall mean World Health Organization.

**Other Terms.** The definition of each of the following terms is set forth in the Section of this Agreement indicated below:

Defined Term	Section
Agency Action	9.1
Agreement	Preamble
BIS	8.4
Breach	8.5(g)
breaching party	12.2
Claims	9.3
Clinical Trial	1 (Licensed Product)
Confidential Information	13.1
Designated Officers	14.8(e)
Disclosure Right	4.7
Dispute	14.8(b)
EAR	8.4
Effective Date	Preamble
EUA	3.9
FCPA	8.5(c)
Improvement License	6.1
Indemnitees	9.3
LIC Territory	7.1

<b>Defined Term</b>	<b>Section</b>
Licensee	Preamble
Local Distributor	2.8
Losses	9.3
MPP	Preamble
non-breaching party	12.2
Notice	14.8(c)
OFAC	8.4
Option and ROFR	6.2
Out-of-Field License	6.2
Party or Parties	Preamble
Payments	8.5(b)
Person	8.4
Rules	14.8(f)
Shionogi	Recitals
Shionogi Consent Right	14.3(e)
Royalty Term	7.4
Sanctions	8.4
Sanctions Targets	8.4
Tax Action	7.6(c)
Temporary Waiver	3.8(a)
Trade Control Laws	8.4
VAT	7.6(b)

## **2. SCOPE OF LICENSE GRANT**

### **2.1 License Grant within the Territory**

Subject to the terms and conditions of this Agreement, MPP hereby grants to Licensee a non-exclusive, non-transferable, non-sublicensable (other than to its Affiliates or Approved Local Distributors, in each case, through one tier), royalty-bearing right and license under the Territory Patents and Licensed Know-How to:

- (a) manufacture the Compound and Licensed Product at a facility that is in the Territory (excluding involvement of any Sanctions Targets except as expressly permitted pursuant to Section 8.4 of this Agreement);
- (b) Commercialize the Licensed Product in the Field in the Territory (excluding involvement of any Sanctions Targets except as expressly permitted pursuant to Section 8.4 of this Agreement);
- (c) Retail the Licensed Product to other MPP Licensees for such other MPP Licensees' Own Use in the Territory;
- (d) register the Licensed Product in the Field in the Territory by itself or, subject to Section 2.7 of this Agreement, through its Affiliates for use in the Field for the purposes described and pursuant to the rights granted in Section 2.1(b) and or Section 2.1(e) of this Agreement;
- (e) sell the Licensed Product to Public Purchasers in the Territory for the sole purpose of enabling the Public Purchasers to supply the Licensed Product solely in the Territory for use in the Field; and

- (f) Vend the Compound.

## **2.2 License Grant Outside the Territory**

Subject to the terms and conditions of this Agreement, MPP hereby grants to Licensee a non-exclusive, non-transferable, non-sublicensable (other than its Affiliates, through one tier), royalty-bearing right and license under the Non-Territory Patents and Licensed Know-How to:

- (a) manufacture the Compound and Licensed Product at a facility that is in a non-Territory country (excluding any involvement of Sanctions Targets except as expressly permitted pursuant to Section 8.4 of this Agreement);
- (b) export Licensed Product manufactured outside the Territory (pursuant to the rights granted under Section 2.2(a) of this Agreement) to the Territory for their Own Use;
- (c) Retail Licensed Product manufactured outside the Territory (pursuant to the rights granted under Section 2.2(a) of this Agreement) in the Territory to other MPP Licensees for such other MPP Licensees' Own Use;
- (d) sell the Licensed Product to Public Purchasers outside of the Territory for the sole purpose of enabling such Public Purchasers to supply the Licensed Product in the Territory for use in the Field; and
- (e) Vend the Compound.

## **2.3 License Restrictions**

- (a) No rights are granted under this Agreement for any other purpose.
- (b) No license or right is granted by implication or otherwise with respect to the Compound and/or Licensed Product, except as expressly granted herein.
- (c) Subject to the above and except as expressly permitted in this Agreement, Licensee shall not be entitled, directly or indirectly, to manufacture, use, Commercialize, Retail, Vend, register with Agencies, distribute, offer for sale, sell and/or donate the Compound and/or the Licensed Product for any other purpose or in combination with any other substance, product, Licensed Product, intermediate, and/or active pharmaceutical ingredient (whether co-packaged, co-formulated or otherwise) (without the prior written approval of Shionogi in its sole discretion, in which event any such approval shall be subject to separate terms and conditions to be negotiated).

## **2.4 No Waiver**

For the avoidance of doubt, nothing in this Agreement shall be construed to prevent Licensee from engaging in activities inside or outside the Territory where such activities would not (a) infringe the Patents and/or any other intellectual property rights of Shionogi; (b) use or misappropriate Licensed Know-How; and/or (c) use or require the use of any of Shionogi's confidential information. Licensee acknowledges that Shionogi has expressly reserved all its rights under the Patents, except as expressly set forth in the Shionogi-MPP Agreement and this Agreement, and under any additional patents and/or patent applications Controlled (either as of the Effective Date or at any time during the term of this Agreement) by Shionogi or its Affiliates. For the avoidance of doubt, it shall not be deemed a breach by Licensee to supply Compound or Licensed Product outside the Territory into a country where the Government of such country has, to the extent permitted by applicable law, granted or required to be granted to Licensee a compulsory license under the Patents relating to such Compound, Product or Licensed Product allowing for the importation of such Compound or Licensed Product into such



country, provided that (a) Licensee's supply of Compound or Licensed Product into such country is solely within the scope and geographic range of such compulsory license and only for the duration that such compulsory license is in effect and (b) Licensee does not use or misappropriate Licensed Know-How and/or misappropriate, use or require the use of any of Shionogi's Confidential Information. Licensee also acknowledges that Shionogi does not waive any applicable statutory and/or regulatory exclusivities owned or controlled by Shionogi, except as expressly set forth in the Shionogi-MPP Agreement. Nothing in this Agreement shall provide a right to Vend, Retail, donate, offer for sale, sell or otherwise distribute the Compound or Licensed Product outside the Territory for further offer for sale, sale, donation or distribution of the Compound or Licensed Product outside or for use outside the Territory.

## **2.5 Retained Rights**

Licensee acknowledges that the licenses granted pursuant to Sections 2.1 and 2.2 of this Agreement are non-exclusive and that (a) MPP retains the right to grant licenses to other MPP Licensees, and (b) Shionogi retains the right in its sole discretion to (i) grant additional licenses or distribution rights for the Compound and/or Licensed Product to Third Parties and (ii) make, use, import, offer for sale, sell and/or donate the Compound and/or Licensed Product (or any other pharmaceutical product containing the Compound) on its own behalf.

## **2.6 Ex-Territory Restrictions**

- (a) Except as otherwise provided and solely in the manner permissible under this Agreement, the licenses granted are solely for the stated Territory.
- (b) Unless otherwise specified in this Agreement, no rights are granted under this Agreement permitting (i) manufacture or Commercialization of the Compound and/or Licensed Product outside the Territory or (ii) any other activity with respect to the Compound and/or any Licensed Product outside the Territory, and Licensee and its Affiliates agrees that they will not use the Patents or Licensed Know-How for any purpose outside the Territory.
- (c) Licensee and its Affiliates agree not to sell Compound and/or Licensed Product to any Third Party outside the Territory or to sell Compound and/or Licensed Product to any Third Party that Licensee or its Affiliates have reason to believe will resell Compound and/or Licensed Product outside the Territory in breach of this Agreement.
- (d) Licensee shall (i) include language on the packaging of any Licensed Product indicating that such Licensed Product is "not for resale" outside the initial country of sale and (ii) implement a system of batch control and tracing following the GS1 Global Traceability or comparable standards which will enable the identification and batch tracing of any such Licensed Product which are subsequently re-exported 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 Licensed Product in all countries of the Territory shall not sell, distribute, export or donate the Licensed Product or offer the Licensed Product for sale or donation outside the initial country of sale.
- (e) If MPP or Shionogi becomes aware of any Commercialization of Licensed Product outside the Territory in breach of this Agreement, MPP or Shionogi (itself or through MPP) 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.

## 2.7 Affiliate Performance

If Licensee wishes to register, manufacture, Commercialize, Retail or Vend the Compound or Licensed Product, as applicable, through an Affiliate of Licensee acting on Licensee's behalf, Licensee shall first provide prior written notification to MPP and Shionogi. Upon MPP's or Shionogi's request, Licensee will provide MPP or Shionogi with a written copy of Licensee's agreement(s) with such Affiliate and will certify to MPP and Shionogi in writing that such agreement(s) is/are consistent with the terms and conditions of this Agreement. MPP and Shionogi have 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, Shionogi, MPP or Shionogi 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. Notwithstanding any such review by MPP and Shionogi, Licensee shall remain responsible for ensuring that the terms and conditions of any such agreement(s) with such Affiliate is/are consistent with the terms and conditions of this Agreement, and Licensee shall be responsible for any liability arising from any inconsistency. Licensee shall be held responsible for the actions of any of its Affiliates in connection with this Agreement, and all obligations of Licensee under this Agreement in connection with the sale and Commercialization of the Licensed Product in the Territory will be deemed to apply to such activities conducted by any of its Affiliates. Any rights to register, manufacture, Commercialize, Retail or Vend the Compound or Licensed Product granted by Licensee to an Affiliate of Licensee shall automatically be terminated in the event that such Affiliate ceases to be an Affiliate of Licensee.

## 2.8 Local Distributor Performance

MPP acknowledges that in some countries of the Territory, for Licensed Product to be lawfully sold or otherwise supplied, regulatory approval (including, without limitation, any of the authorizations, registrations, or permits related to the Licensed Product) must be held in the name of a local entity registered in such country ("**Local Distributor**"). Where Licensed Product can only be lawfully sold or otherwise supplied in a country of the Territory by a Local Distributor, and an Affiliate of the Licensee cannot act as such Local Distributor pursuant to Section 2.7, the Licensee may submit a written request to MPP to use a Third Party that is not an Affiliate as a Local Distributor in such country. Such request shall be supported by appropriate documentation on (a) the need to use a Local Distributor and (b) due diligence on the Third Party. MPP, acting reasonably, shall consider the request and respond within 30 days of receipt of all appropriate supporting documents from the Licensee, with an approval or a written statement of why the request has not been approved. Any Third Party approved in writing by MPP pursuant to this Section 2.8 shall be referred to in this Agreement as an "**Approved Local Distributor**". The Licensee shall have the right, pursuant to the licence granted to it under Section 2.1, to grant a sublicense consistent with the terms and conditions of this Agreement to such Approved Local Distributor, solely to the extent necessary for such Approved Local Distributor to register and Commercialize the Licensed Product in the relevant country of the Territory.

## 2.9 No Other Licenses

The licenses granted under Sections 2.1 and 2.2 of this Agreement do not include a license to other intellectual property rights that Shionogi may possess with respect to any Compound and/or any Licensed Product, other than the Patents and Licensed Know-How, as expressly provided herein. For clarity, licenses granted under Sections 2.1 and 2.2 of this Agreement do not include a license to processes or procedures for the manufacture, production, packaging, labeling, warehousing, and quality control testing of the Compound and/or the Licensed Product that are not expressly included in the Patents and/or Licensed Know-How. Except as expressly set forth in this Agreement, (a) MPP does not grant any license to Licensee under any of Shionogi's intellectual property rights (including, without limitation, patents, patent applications, Know-How or rights to any Shionogi proprietary compounds or drug substances other than the Compound or for use of the Compound or Licensed

Product outside the Field or outside the Territory), and (b) Licensee shall not take any action which would constitute an infringement of any of the Patents.

## **2.10 License Purpose**

Notwithstanding anything to the contrary herein, Licensee acknowledges that the licenses granted under this Section 2 are granted solely under and with respect to the Patents and Licensed Know-How for the sole purpose of final supply of the Licensed Products in the Territory.

## **3. DEVELOPMENT, MANUFACTURE AND REGISTRATION**

### **3.1 Development Generally**

As of the Effective Date and subject always to Shionogi's retained rights to the Patents and Licensed Know-How and the limitations and restrictions set forth herein, Licensee shall have full control, responsibility (financial and otherwise) and authority, at Licensee's cost and expense, over development, registration, importation, manufacture, and Commercialization of the Licensed Products to be sold or supplied by Licensee in the Territory under this Agreement.

### **3.2 Data Package**

Upon Licensee's written request to MPP and submission of relevant access information requested by MPP, Shionogi shall make available to Licensee, on a confidential basis, a discrete data package related to the Compound, the contents of which shall have been determined by Shionogi in its sole discretion. Prior to receiving access to the data package, Licensee may request in writing from MPP, in which event MPP shall provide to Licensee, a high-level summary of topics included in the data package, provided that such summary shall not create any obligation on the part of Shionogi to include any specific piece of information in the data package. Shionogi shall not be required to provide any technical support or technical assistance to a Sublicensee for any reason.

### **3.3 Research and Studies**

Licensee shall not conduct basic research or pre-clinical, clinical or other studies (including Clinical Trials, non-clinical toxicology studies or any other study in humans or animals) with the Compound or Licensed Product without Shionogi's prior written approval (which may be provided or withheld in Shionogi's sole discretion). For the avoidance of doubt, Shionogi shall have the right to review the study design, specifications, protocol and related materials of any such proposed studies. In the event that any such studies have been approved by Shionogi, Licensee will pay for any necessary supplies, and Licensee agrees to fully comply with all Applicable Law in connection with such Clinical Trials. Unless specified otherwise in a writing signed by Shionogi, Shionogi will not be the sponsor or hold regulatory responsibility for such Clinical Trials and Licensee, pursuant to Section 9.3(a), shall indemnify Shionogi for any liability arising, directly or indirectly, from or based on the conduct of any Clinical Trial or study. Without limiting the foregoing, in the event Shionogi approves any such studies or trials in accordance with this Section 3.3, then, at the option of Shionogi, Shionogi may, but shall have no obligation to, have its representative review any approved studies, but in no event will such activities relieve the sponsor of such Clinical Trials from their oversight and monitoring obligations.

### **3.4 Research Data Reporting**

Upon completion of any such studies described in Section 3.3 of this Agreement, Licensee shall furnish free of charge to Shionogi and its Affiliates in the English language all data and information, including any adverse drug experiences, derived from any such studies (including Clinical Trials) carried out by Licensee relating to the Licensed Product, in such detail and at such times as Shionogi may reasonably request for regulatory purposes, use in connection with the exercise of the licenses granted to Shionogi

under Sections 6.1 or 6.2, other non-commercial and internal use and disclosure to any Third Party in compliance with the contractual obligations of Shionogi 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 Shionogi and its Affiliates want to use the data and information for any other purpose, Licensee and Shionogi shall negotiate in good faith.

### **3.5 Manufacturing Obligations**

Licensee agrees that it will manufacture the Compound and Licensed Product in a manner consistent with (a) WHO Prequalification standards; or (b) the standards of any SRA. Licensee will manufacture and sell the Compound and Licensed Products in accordance with all laws and regulations relevant to the manufacture and sale of the Compound and Licensed Product, including cGMP, and in accordance with good industry practice. Licensee agrees that it: (a) subject to Section 3.8, will not sell any Licensed Product without WHO Prequalification or SRA approval, or through any provisional or emergency use authorizations available through WHO or an SRA; and (b) will comply with applicable regulatory requirements in the country of manufacture and the country of sale.

### **3.6 Regulatory Generally**

Licensee shall be solely responsible for obtaining all regulatory approvals, including any Key Approvals and local regulatory approvals, necessary for Licensee to develop, manufacture, use, Retail, Vend and Commercialize the Compound and Licensed Product as permitted under this Agreement. Shionogi, to the extent necessary, will reasonably cooperate with limited administrative requests (eg, confirmatory letter of license grant) from Licensee to enable registration of the Licensed Product in the Territory.

### **3.7 Regulatory Approval**

Licensee shall submit a complete file for WHO Prequalification or any SRA approval within thirty-six (36) months after the Effective Date for any existing formulation of the Licensed Products, or within a period to be agreed among Shionogi, MPP and Licensee for any new formulation of the Licensed Product. Licensee will diligently pursue such applications following submission. Licensee agrees, where applicable and to the extent that it is able, to not seek and waive regulatory exclusivity in the Territory in relation to any data relating to the Licensed Products. Licensee acknowledges and agrees that it shall be permitted to use any such WHO Prequalification or SRA approval solely to support any filings to an Agency for Key Approval to Commercialize Licensed Product in the Field in the Territory and shall in no event be permitted to use any such WHO Prequalification or SRA approval as the basis of, or for a reference to, support for any filings to an Agency for Key Approval to Commercialize Licensed Product outside the Field and/or outside the Territory.

### **3.8 Temporary waiver**

- (a) If the Licensee has not obtained the approvals under Section 3.7, the Licensee may request a temporary waiver of that obligation in order to Commercialize the Licensed Product in a "Country of Manufacture" or "Country of Sale" by providing MPP and Shionogi:
  - (i) documentary proof that the Licensed Product has been filed for WHO Prequalification (or emergency use listing) or any SRA approval (or emergency use authorization);
  - (ii) documentary proof of marketing approval or registration or compassionate sale permit of the Licensed Product in the "Country of Manufacture" or "Country of Sale" before Commercialization of the Licensed Product in the "Country of Manufacture" or "Country of Sale";

- (iii) written certification that the Licensed Product is manufactured in a manner consistent with WHO Prequalification or SRA standards; and
- (iv) written certification that the product planned for Commercialization in the “Country of Manufacture” or “Country of Sale” and the product filed for WHO Prequalification or SRA approval are the same (including with respect to the composition, manufacturing process, manufacturing site, specifications and excipient grades),

(together, a **Temporary Waiver**).

- (b) If the Licensee requests a Temporary Waiver under Section 3.8(a), MPP and Shionogi may provide written approval (not to be unreasonably withheld) for the Licensee to Commercialize the Licensed Product under the Temporary Waiver for a period of up to six calendar months (or some other period agreed between MPP and Shionogi) from the date of MPP and Shionogi’s written approval.
- (c) If a Temporary Waiver is approved by MPP and Shionogi and WHO or an SRA denies WHO Prequalification or SRA approval or any provisional or emergency use authorizations available through WHO or an SRA, the Licensee shall immediately cease the Commercialization of the Licensed Product and MPP may terminate this Agreement with immediate effect by notice in writing to the Licensee.

### **3.9 Development and Regulatory Reporting**

For the period beginning from the Effective Date, within ten Business Days following the end of each Calendar Quarter, Licensee shall provide MPP with a quarterly written report covering all its activities related to the development and testing of all Licensed Products and/or Compound (as permitted and to the extent applicable) and the obtaining of necessary governmental approvals, including, but not limited to (and to the extent applicable and permitted) its (a) Licensed Products, and/or Compound in its development pipeline, (b) status of development of each Licensed Product and/or Compound in development, (c) regulatory filing plan for WHO Prequalification Programme and/or an SRA, and where applicable any local regulatory filings, for each Licensed Product, (d) a list of Agencies, including as applicable the FDA, WHO and authorities in the countries within the Territory for which such Key Approvals or other local approvals or authorizations have been filed and/or obtained for any Licensed Product, (e) summary of work completed and in progress, (f) current schedule of anticipated events and milestones, (g) anticipated market introduction dates, (h) all bioequivalence data generated by or on behalf of Licensee related to Licensed Product, and (i) other activities, if applicable. Licensee will also report to MPP and Shionogi the date of first commercial sale of each Licensed Product, whether such sale is to a Public Purchaser, Governmental Authority or private entity or person and whether such sale is made under an emergency use authorization (EUA) or Key Approval within five business days thereafter.

### **3.10 Development and Regulatory Meetings**

The Parties agree to meet on a quarterly basis or as reasonably requested by the MPP, to review development and filing status and also regarding such reports concerning Licensed Product and/or the Compound. MPP agrees that information contained in quarterly and other such reports shall be treated as Confidential Information of Licensee; provided, however, that such information may be shared with Shionogi (with Shionogi treating such reports as Confidential Information) and that aggregated data may be publicly disclosed by MPP. 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 Licensed Product in the Territory. Licensee will not sell Licensed Product in any country in the Territory prior to obtaining both local health Agency approval or authorization in the country in the Territory where the Licensed Product is sold and Commercialized and relevant approval or authorization for the manufacture of Licensed Product in the country of manufacture. Licensee shall provide quarterly written reports to MPP notifying MPP about the registration process and providing MPP with any other information in this regard that MPP may reasonably require which such reports may be shared with Shionogi (with Shionogi treating such reports as Confidential Information). Licensee shall not transfer, assign, or otherwise convey any of the authorizations, registrations, or permits related to the Licensed Product, as set forth above in this Section 3, to any Affiliate without the prior written notice to MPP and Shionogi.

### **3.11 Commercialization**

Licensee shall promote, Commercialize and sell the Licensed Product in strict adherence to regulatory, professional, and legal requirements in the Territory and solely to the extent permitted under, and consistent with, all applicable regulatory approvals (including, without limitation, Key Approvals). In no event shall Licensee, directly or indirectly, promote, market, offer for sale, sell, donate or otherwise distribute the Licensed Product for any use outside of the Field or otherwise perform any off-label promotion, marketing or Commercialization of the Licensed Product. Licensee shall do nothing which would jeopardize the goodwill or reputation of MPP or Shionogi or the reputation of the Compound and/or Licensed Product.

### **3.12 Pharmacovigilance**

Licensee shall maintain until the termination of this Agreement (or, as applicable, until the rights and obligations intended to survive termination of this Agreement have been fulfilled) pharmacovigilance and risk management systems, procedures and documentation needed to perform and comply with its regulatory obligations and its related obligations under this Agreement. Licensee shall ensure that it will comply with all Applicable Law regarding Licensed Product in the Territory, including, without limitation, those laws and regulations relating to risk management, drug safety and pharmacovigilance. If Licensee becomes aware of any adverse reaction relating to Licensed Product in connection with this Agreement, Licensee shall inform MPP and Shionogi within 24 hours of its becoming aware and cooperate with Shionogi in fulfilling Shionogi's reporting responsibilities under Applicable Law. Licensee will be responsible for fulfilling all pharmacovigilance activities pursuant to the local regulations and requirements for the Licensed Products in the Territory and provide MPP and Shionogi with a report containing information regarding all such activities. Such report shall be provided annually, on February 1 of each year, and otherwise on reasonable request by MPP or Shionogi to both MPP and Shionogi's pharmacovigilance contact as may be designated by Shionogi from time to time. Licensee shall notify MPP and Shionogi forthwith of the receipt of an enquiry from an Agency in the Territory relating to Licensed Product that concerns any safety issue. If Licensee becomes aware of any action that may be, will be or has been taken by an Agency for a safety reason connected with Licensed Product, it shall immediately, and in any event no later than 24 hours after receiving such notice from such Agency, notify MPP and Shionogi in writing (including, but not limited to, email communications) with available details regarding the same.

### **3.13 Recalls and Withdrawals**

Unless otherwise required by Applicable Law, Licensee shall not institute a recall or other market withdrawal of Licensed Product without first providing prior written notice to MPP and Shionogi, such notice to set forth the basis of the recall and market withdrawal. In the event that Licensee receives any notice from an Agency requesting or otherwise directing Licensee to initiate a recall or other market withdrawal of Licensed Product, Licensee shall immediately, but in any event within 24 hours of its receiving such notice, provide any such notice to MPP and Shionogi. Notwithstanding the obligations set forth herein, Licensee shall be solely responsible and liable for any recall or other

market withdrawal of Licensed Product in the Territory and in no event shall Shionogi or MPP have any liability with respect thereto.

### **3.14 Conflicts**

This Section 3 shall always be subject to the provisions of Section 4 of this Agreement. Where there is any inconsistency between this Section 3 and Section 4 of this Agreement, Section 4 of this Agreement shall prevail.

## **4. SUPPLY AND DISTRIBUTION**

### **4.1 Shionogi Supply Right**

Licensee hereby agrees to supply reasonable amounts of materials used in the synthesis of the Compound, the Compound, and/or Licensed Product, as requested by Shionogi in writing, to Shionogi or its Affiliates at the actual cost of goods (verifiable via Third Party audit) plus a ten percent (10%) markup under a supply agreement containing such other reasonable and customary terms and conditions as are agreed by Shionogi and Licensee in good faith. Such reasonable amounts of supply shall be determined by Shionogi taking into good faith consideration the total number of MPP Licensees and Shionogi's otherwise unmet twelve (12)-month forecasted demand.

### **4.2 Supply from Shionogi Affiliates and licensees**

If Licensee wishes to obtain the Compound and/or Licensed Product from Shionogi's Affiliates or Third Party licensees, Licensee shall notify Shionogi through MPP of the intended source prior to making any commitments to purchase the Compound and/or Licensed Product. Shionogi will determine at its sole discretion whether and on what terms to grant a license to the intended source to produce the Compound and/or Licensed Product or inform Licensee whether such license already exists.

### **4.3 Supply from MPP Licensees**

Subject to Sections 4.2 and 4.4 of this Agreement, Licensee shall have the right to source the Compound and/or Licensed Product from an MPP Licensee. Licensee's Commercialization of any Licensed Product sourced from an MPP Licensee shall be subject to the terms and conditions of this Agreement and be royalty-bearing in accordance with Section 7 of this Agreement.

### **4.4 MPP Licensee Supply Agreements**

Licensee shall not enter into any agreements with any other MPP Licensee with respect to Compound and/or Licensed Product without providing prior notice to Shionogi through MPP. All terms of the agreement between Licensee and an MPP Licensee must be consistent with this Agreement or written approval needs to be obtained by Shionogi. Licensee shall certify to Shionogi through MPP in writing that its arrangement(s) with each MPP Licensee with respect to Compound and/or Licensed Product is consistent with the terms and conditions of this Agreement. Shionogi 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 Shionogi, Shionogi shall have the right to require Licensee to terminate its agreement(s) with such MPP Licensee. Notwithstanding any such review by MPP and Shionogi, Licensee shall remain responsible for ensuring that the terms and conditions of any such agreement(s) with such Affiliate is/are consistent with the terms and conditions of this Agreement, and Licensee shall be responsible for any liability arising from any inconsistency.

**4.5 MPP Licensee Supply Reporting.**

Licensee shall not be obliged to disclose to MPP the financial terms of its agreement(s) with an MPP Licensee but shall provide MPP with quarterly reports in accordance with Section 7.5 of this Agreement that shall include the quantities of Compound and/or Licensed Product being supplied to Licensee by each MPP Licensee, which will be shared by MPP with Shionogi.

**4.6 Conditions to MPP Licensee Supply**

Licensee's right to source Compound and/or Licensed Product from, or sell Compound and/or Licensed Product to, a particular MPP Licensee hereunder shall remain in effect solely for so long as such MPP Licensee remains compliant with the terms and conditions of its agreement with MPP, and provided that such agreement between such MPP Licensee and MPP has not expired or been terminated.

**4.7 Disclosure Right**

Licensee hereby grants MPP the right to disclose its contact information to Shionogi or an MPP Licensee for the fulfilment of this Section 4 (**Disclosure Right**). Licensee shall receive reciprocal information of other MPP Licensees to the extent that the Disclosure Right has been similarly granted by such MPP Licensees.

**4.8 Anti-Competition**

Licensee confirms and warrants that it shall not engage in any anti-competitive behavior if it exercises its rights under this Section 4 and shall be fully compliant with all Applicable Law. Licensee further represents, warrants and covenants that it shall not enter into any agreement or other arrangement with a supplier of materials used in the synthesis of the Compound, the Compound, and/or Licensed Product that would prioritize supply to Licensee or de-prioritize or to reduce, in the case of an existing supplier, supply to Shionogi, or prevent, limit or otherwise restrict in any way (including, without limitation, as to amounts that may be purchased or pricing) such supplier from selling materials used in the synthesis of the Compound, the Compound, and/or Licensed Product to Shionogi.

**4.9 Distribution Diligence**

In each country of the Territory, the Licensee shall, acting in compliance with all Applicable Laws, use commercially reasonable endeavours to commercialise and maximise access to the Licensed Product(s) as soon as it has obtained relevant marketing authorisation(s) for such Product(s) in the relevant country.

**5. NON-DIVERSION**

**5.1 Diversion**

Licensee shall not, directly or indirectly, donate, distribute, sell, supply or otherwise make available Compound and/or Licensed Product outside the Territory except as expressly permitted (and solely to the extent expressly permitted) under this Agreement. Without limitation of the foregoing, except to the extent provided under this Agreement, Licensee shall not, directly or indirectly, sell or supply:

- (a) the Compound to any Third Party in the Territory that Licensee knows, believes or ought reasonably to suspect will sell or supply the Compound or use the Compound for manufacture of Licensed Product for sale or supply outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent; or



- (b) Licensed Product to any Third Party in the Territory that Licensee knows, believes or ought reasonably to suspect will sell or supply Licensed Product outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent.

## 5.2 Licensed Product Labelling

The labelling of all Licensed Products sold or offered for sale under this Agreement shall expressly state that:

- (a) the Licensed Product is manufactured under a license from the Medicines Patent Pool; and
- (b) any other use, beyond the Field, is not authorized.

## 5.3 Notice to Third Parties

Licensee shall give written notice, prior to the first sale of Licensed Product, to any Third Party to which it sells Licensed Product of the restrictions contained in this Section 5, and 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 Section 5 and will assist the MPP and Shionogi in securing compliance with this Section 5 and the restrictions which it contemplates.

## 5.4 Breach

Licensee shall promptly notify MPP and Shionogi in writing of any breach or suspected breach of this Section 5 and shall take all reasonable steps to mitigate such breach.

## 6. INTELLECTUAL PROPERTY

### 6.1 Improvements License

Licensee shall disclose, promptly and in English, to MPP and Shionogi, without charge, any Improvements. As to any such Improvements, Licensee shall grant, and hereby does grant, to Shionogi, its Affiliates, and MPP a perpetual, irrevocable, worldwide, non-exclusive, transferable, royalty-free and fully paid-up license, with the right to grant sublicenses through multiple tiers, under any and all Improvements (the **Improvement License**) for any and all purposes in the Shionogi Field, including the rights to use, have used, develop, have developed, manufacture, have manufactured, commercialize and have commercialized, offer for sale, sell, have sold, donate and distribute the Compound, Product and/or Licensed Product or any other product containing the Compound in the Shionogi Field. For the avoidance of doubt, the Improvement License shall not affect Licensee's ownership of any such Improvements. MPP shall not sublicense the Improvement License to any Third Party or to another MPP Licensee without the consent of Licensee and Shionogi.

### 6.2 Out-of-Field License

Licensee shall grant, and hereby does grant, to Shionogi and its Affiliates a perpetual, irrevocable, worldwide, non-exclusive, transferable, royalty-free and fully paid-up license, with the right to grant sublicenses through multiple tiers, under any and all Improvements for any use outside of the Shionogi Field (the **Out-of-Field License**). Licensee shall grant, and hereby does grant, to Shionogi and its Affiliates an option and right of first refusal to obtain a sole, sublicensable, worldwide license under any and all Improvements for any use outside the Field on reasonable financial terms to be negotiated by Shionogi and Licensee (the **Option and ROFR**). For the avoidance of doubt, the Out-of-Field License and Option and ROFR shall not affect the Licensee's ownership of any Improvements to the Licensed Product.

### 6.3 Patent Prosecution; Enforcement and Defense

Shionogi shall have the sole right (but not the obligation) to file, prosecute and maintain the Patents in the Territory in Shionogi's name and at Shionogi's own costs and expense. Shionogi will have the sole right (but not the obligation), at its own expense, to control enforcement and defense of the Patents and Licensed Know-How against any Third Party infringement or action, as applicable. If Licensee becomes aware of a possible infringement of the Patents by a Third Party in any country, Licensee will notify Shionogi, through MPP, immediately. The decision on whether any legal action is necessary or appropriate shall be made solely by Shionogi in its sole discretion. In the event that Shionogi institutes an action at its expense against alleged Third Party infringers with respect to Compound or any Licensed Product, or takes action to defend the Patents, Licensee agrees to cooperate in good faith with Shionogi in such action, upon the request of Shionogi and Shionogi shall reimburse Licensee for the reasonable out-of-pocket costs incurred by Licensee in providing such cooperation. Any recovery obtained by Shionogi as a result of such a proceeding or other action shall be retained by Shionogi.

### 6.4 Trademarks

No rights in any Shionogi Trademarks are granted to Licensee under this Agreement, and Licensee shall not appropriate or otherwise use, register to use or register any Shionogi Trademarks in connection with the Licensed Product in the Territory, including without limitation in connection with the sale, distribution, promotion, or marketing of the Licensed Product. A complete description of any trademark proposed to be used or registered by Licensee in connection with the sale of the Licensed Product in the Territory shall be submitted to MPP for Shionogi's written approval prior to use or filing an application to register such trademark. MPP shall promptly review such request and refer it to Shionogi. Licensee shall provide any additional information required by MPP in relation to such request. The response to Licensee for any request for approval shall be given within 30 days of receipt by Shionogi from MPP of all relevant documentation necessary to consider Licensee's request. Such approval may be withheld if the subject trademark is determined by Shionogi, in its sole discretion, to be identical to or confusingly similar to any Shionogi Trademark; provided, however, that any such approval shall not waive any rights of Shionogi or its Affiliates with respect to the Shionogi Trademarks. Notwithstanding the foregoing, in reviewing and/or granting approval to Licensee for use of any trademark in connection with the sale of any Licensed Product, Licensee acknowledges and agrees that Shionogi shall have no obligation to assess the availability or validity of, or the ability of the Licensee to use, the proposed trademark or whether the proposed trademark is the same or is similar to any trademark proposed to be used by and/or approved by Shionogi for use by any other MPP Licensee in connection with the Compound or any Licensed Product and Shionogi shall have no liability to Licensee where Licensee seeks to register or uses any trademark, logo or trade dress that is the same or similar to a that used by another MPP Licensee. In addition to the foregoing, for the avoidance of doubt, Licensee agrees that it shall not: (a) register, apply to register or, in connection with the sale of any Licensed Product, use any trademark, logo or trade name which is identical to or confusingly similar (as Shionogi shall determine in its sole discretion) to any Shionogi Trademark; (b) use trade dress, packaging (both internal and external), or labeling which is the same as or similar to (as Shionogi shall determine in its sole discretion) that of Shionogi or any Affiliate of Shionogi in connection with the sale of any Licensed Product; or (c) give the impression to the public, to physicians or to the trade that the Licensed Product is manufactured by or in any way connected with Shionogi or any of its Affiliates.

## 7. ROYALTY AND TAXES

### 7.1 No LIC Territory Royalty

No royalty shall be due and payable by Licensee for any sales of Licensed Product in any low-income country as designated in Appendix 3 (the **LIC Territory**).

## 7.2 Royalties

Subject to Section 7.3 of this Agreement, Licensee will pay to Shionogi a royalty at the rate of (a) five percent (5%) of aggregate Net Sales of Licensed Products sold by Licensee or its Affiliates to a Governmental Authority or Public Purchaser in each country in the Territory, other than the LIC Territory, during the Royalty Term, to the extent (i) a Valid Claim of Patent exists in the country of manufacture and/or sale of such Licensed Product or (ii) regulatory exclusivity exists for such Licensed Product in such country of sale, and (b) ten percent (10%) of aggregate Net Sales of Licensed Products sold by Licensee or its Affiliates to a commercial entity in a country in the Territory, other than the LIC Territory, during the Royalty Term, to the extent (i) a Valid Claim of Patent exists in the country of manufacture and/or sale of such Licensed Product or (ii) regulatory exclusivity exists for such Licensed Product in such country of sale, such royalties to be recorded in the manner further described in Appendix 4 attached hereto.

## 7.3 Suspension of Royalty

Notwithstanding the foregoing, the royalty obligation with respect to all countries in the Territory shall be suspended until the end of the month in which the WHO declares the end of the Public Health Emergency of International Concern regarding COVID-19, and royalties shall only be payable as set forth in Section 7.2 of this Agreement with respect to any sales made by Licensee or its Affiliates thereafter.

## 7.4 Royalty Term

On a country-by-country and Licensed Product-by-Licensed Product basis, royalty payments in the Territory shall commence upon the first commercial sale of such Licensed Product, whether such sale is to a Public Purchaser, Governmental Authority or private entity or person and whether such sale is made under an EUA or Key Approval, in such country in the Territory and will terminate upon the later of: (a) the expiration, invalidation or abandonment date of the last Valid Claim of the Patents in the country of sale or manufacture of such Licensed Product in the Territory or (b) expiration of regulatory exclusivity of such Licensed Product in such country of sale in the Territory (the **Royalty Term**).

## 7.5 Royalty Payments

Royalties accruing to Shionogi will be paid to Shionogi quarterly within 45 days after the end of each Calendar Quarter. Licensee will make all payments under this Agreement by wire transfer to an account of Shionogi designated by written notice from Shionogi. All royalties due to Shionogi will be payable in United States dollars. When Licensed Products are sold for monies other than United States dollars, the earned royalties will first be determined in the foreign currency of the country in which the sale was made and then converted into equivalent United States funds. The exchange rate will be that rate quoted in The Wall Street Journal on the last Business Day of the reporting period. Licensee shall bear the expense of any bank charges or any other transaction costs incurred in connection with payment under this Section 7 and will effect payment of such amount that will result in Shionogi receiving the full amount calculated for any payment with no deduction of any type. Each royalty payment shall be accompanied by a statement setting forth the elements and calculation of the royalty amount in the format specified by Shionogi. For clarity, any sale of Compound, Product and/or Licensed Product between Licensee and other MPP Licensee(s) other than for end use by such other MPP Licensee(s) shall be exempt from any royalty payment.

## 7.6 Taxes

- (a) Payments due for sales occurring in any country will not be reduced by any fees or other charges imposed by the Government of such country on the remittance of royalty income, provided that if laws

or regulations require that taxes be withheld with respect to any royalty payments by Licensee to Shionogi under this Agreement, Licensee will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, (c) send evidence of the obligation together with proof of tax payment to Shionogi on a reasonable and timely basis following that tax payment, and (d) Licensee will reasonably assist Shionogi in seeking an exemption to such withholding to the extent available.

- (b) It is understood and agreed that any payments made under this Agreement are exclusive of any value added or similar tax (VAT), which shall be added thereon as applicable. In the event any payments made by Licensee to Shionogi pursuant to this Agreement become subject to withholding taxes under Applicable Law, Licensee shall deduct and withhold the amount of such taxes for the account of Shionogi to the extent required by Applicable Law and such amounts payable to the Shionogi shall be reduced by the amount of taxes deducted and withheld, which shall be treated as paid to Shionogi in accordance with this Agreement. To the extent that Licensee is required to deduct and withhold taxes on any payments under this Agreement, Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Shionogi an official tax certificate or other evidence of such withholding sufficient to enable Shionogi to claim such payments of taxes. Shionogi shall provide any tax forms to Licensee that may be reasonably necessary in order for Licensee not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Licensee shall provide Shionogi with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit Shionogi.
- (c) Notwithstanding anything in this Agreement to the contrary, if an action, including, but not limited to, any assignment or transfer of its rights or obligations under this Agreement, or any failure to comply with Applicable Law or filing or record retention requirements (a **Tax Action**) by Licensee leads to the imposition of withholding tax liability or VAT on Shionogi that would not have been imposed in the absence of a Tax Action or in an increase in such liability above the liability that would have been imposed in the absence of such Tax Action, then (i) the sum payable by Licensee (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Shionogi receives a sum equal to the sum which it would have received had no Tax Action occurred and (ii) the sum payable Licensee (in respect of which such deduction or withholding is required to be made) shall be made to Shionogi after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with Applicable Law. For the avoidance of doubt, Licensee shall only be liable for increased payments pursuant to this Section 7.6 to the extent Licensee engaged in a Tax Action that created or increased a withholding tax or VAT on Shionogi.
- (d) Licensee agrees to cooperate and produce on a timely basis any tax forms or reports reasonably requested by Shionogi in connection with any payment made by Licensee to Shionogi under this Agreement.

## 7.7 Interest

If monies owed to Shionogi under this Agreement are not received by Shionogi when due, Licensee will pay to Shionogi interest charges at a rate of three percent (3%) above the WSJ rate up to a maximum of ten percent (10%) per annum. Such interest will be calculated from the date payment was due until actually received by Shionogi. Such accrual of interest will be in addition to, and not in lieu of, enforcement of any other rights of Shionogi related to such late payment. Acceptance of any late payment will not constitute a waiver under Section 14.10 of this Agreement.

## **8. REPRESENTATIONS, WARRANTIES, AND COVENANTS**

### **8.1 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;
- (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 Governmental Authority having jurisdiction over such Party; and
- (d) it has not and will not employ or otherwise use in any capacity the services of any person or entity that is a Sanctions Target or is debarred by any Agency or the subject of debarment proceeding by any Agency in performing any activities under this Agreement. Each Party shall notify the other Party, in writing, immediately if any such sanctions or debarment occurs or comes to its attention, and shall, with respect to any person or entity so sanctioned or debarred, promptly remove such person or entity from performing any further activities under this Agreement, as applicable.

### **8.2 Additional Licensee Representations and Warranties**

Licensee represents and warrants that:

- (a) all information provided by Licensee during the selection process, including information provided in the Expression of Interest system, is complete, truthful, and accurate in all respects;
- (b) it has the experience, ability and capacity to manufacture Licensed Product for the purposes of sale in the Territory; and
- (c) it has the experience, capability and capacity to Commercialize Licensed Product in the Territory.

### **8.3 Law Compliance**

- (a) General

Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all Applicable Law, including, without limitation, with respect to anti-corruption, anti-competition, recalls, safety and reporting requirements and export controls and sanctions, and shall obtain, have and maintain all necessary regulatory approvals (including, without limitation, Key Approvals), marketing authorizations, export licenses, and other permits and licenses, at Licensee's expense for the manufacture and sale of the Compound and/or Licensed Product and any other Licensee activities contemplated hereby. Licensee further agrees that it shall not export, re-export, transfer, transmit, or release (including to a foreign national within the United States and Germany) any goods, materials, software, or technology (including technical data) without first obtaining all necessary authorizations from the relevant Governmental Authorities. 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

Neither Party 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, or penalizable under, any Applicable Law.

#### 8.4 Trade Control Laws

(a) The Parties shall comply with all applicable economic sanctions and export control laws in the performance of this Agreement, including without limitation the sanctions programs administered by the U.S. Department of Treasury's Office of Foreign Assets Control (**OFAC**) and the Export Administration Regulations (**EAR**) administered by the U.S. Department of Commerce's Bureau of Industry and Security (**BIS**) (collectively **Trade Control Laws**). Licensee represents that neither Licensee nor, to the knowledge of Licensee, any director, officer, employee, or agent of Licensee, is an individual or entity (**Person**) that is, or is fifty percent (50%) or more owned or controlled by Persons that are: (a) the target of any sanctions administered or enforced by the U.S. Government, including by OFAC, or by the governments of Japan, Switzerland, the EU, or the United Kingdom (**Sanctions**) or listed on any denied party lists maintained by OFAC, BIS or on the European Union's Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions, or (b) located, organized or resident in a country or territory that is, or whose government is, the target of Sanctions (including, without limitation, Cuba, Iran, North Korea, Venezuela, and Syria) ((a) and (b) collectively, **Sanctions Targets**).

(b) Licensee further warrants that in relation to this Agreement it will not, directly or indirectly, use, transfer, sell, donate, lend, contribute or otherwise make available any rights (including intellectual property rights) or Know-How, or the Compound, or Licensed Product, to any Sanctions Target, nor to any Person to engage in any activities or business of or with any Sanctions Target or in any country or territory, that, at the time of such transfer or other transaction, is, or whose government is, the target of Sanctions (including, for the avoidance of doubt, any country listed in Appendix 3) without prior written approval from MPP and Shionogi. Licensee covenants that it shall notify MPP and Shionogi in writing immediately if any of the preceding representations and warranties becomes incorrect during the term of this Agreement. In case of an inaccuracy or breach in the representations, warranties or covenants in this Section 8.4 during the term of this Agreement, MPP shall be entitled to terminate this Agreement immediately and without penalty to MPP.

(c) Notwithstanding anything to the contrary in this Agreement, including Appendix 3, the Parties acknowledge that the grant of any rights or Know-How under this Agreement through Shionogi in the Shionogi-MPP Agreement relating to the Compound or Licensed Product for, in, or to the Sanctions Targets require prior authorization, in the form of general licenses, specific licenses, and/or other authorizations, from OFAC and/or BIS. Accordingly, nothing in this Agreement, including Appendix 3 shall be construed as a grant of rights or Know-How under this Agreement with respect to Sanctions Targets. MPP and Licensee shall, to the extent required, comply with applicable Trade Control Laws and shall not cause Shionogi to violate any applicable Trade Control Laws.

#### 8.5 Ethical Business Practices.

(a) By signing this Agreement, Licensee agrees to conduct the business contemplated herein in a manner which is consistent with both Applicable Law and good business ethics.

(b) Specifically, Licensee warrants that none of the employees, agents, officers, or other members of the management of Licensee or its Affiliates or Approved Local Distributors are or will become during

the term of this Agreement Government Officials having governmental authority to make or participate in any decisions regarding the Licensed Product in the Territory. Licensee has not and shall not make any payment or promise of payment, either directly or indirectly, of money or any other thing of value, including but not limited to any compensation derived from this Agreement (hereinafter collectively referred to as a **Payment**), to Government Officials or representatives of other businesses or persons acting on behalf of any of the foregoing where such Payment would constitute a violation of any Applicable Law. In addition, regardless of legality, Licensee has not and shall not make any Payment either directly or indirectly to Government 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 Licensee's, MPP's or Shionogi's business.

- (c) Licensee has complied and shall comply with, and has not and will not cause its Affiliates, associates, directors, officers, shareholders, employees, representatives, or agents worldwide to be in violation with any applicable anti-corruption law or regulation and notably without limiting the foregoing to any provision of the United States Foreign Corrupt Practices Act (the **FCPA**), U.K. Bribery Act 2010 and any equivalent laws in Japan. In light of the aforementioned, Licensee has not and shall not, directly or indirectly, pay any money to, or offer or give anything of value to, any Government Official in order to obtain or retain business or to secure any commercial or financial advantage for Licensee, Shionogi or the MPP or any of their respective Affiliates. Licensee has not bribed and undertakes not to bribe Government Officials or any private companies or individuals, bribes having the following definition: offering, promising, or giving a financial or other advantage to another person where: (i) it is intended to bring about the improper performance of a relevant function or activity, or to reward such "Improper Performance" (as that term is used in the FCPA); or (ii) acceptance of the advantage offered, promised or given in itself constitutes improper performance of a relevant function or activity.
- (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, and will maintain an internal accounting controls system to ensure the proper authorization, recording and reporting of all transactions and to provide reasonable assurances that any breaches of this Section 8.5 will be prevented, detected and deterred.
- (e) Licensee further acknowledges that no employee of Shionogi and MPP or their respective Affiliates shall have the authority to give any direction, either written or oral, relating to any Payment by Licensee or its agents, employees, officers, subcontractors, sublicensees (for clarity, Licensee shall have no sublicensees under this Agreement), or Affiliates, to any Third Party in violation of this Agreement.
- (f) 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.
- (g) MPP may, in the event that it determines that Licensee has breached any provision of this Section 8.5, provide written notice to Licensee of its intention to terminate this Agreement, along with any evidence supporting its claim of breach (**Breach**) to the extent that it is possible to provide. The Parties will discuss any mitigation plans to the Breach but in the event that no consensus can be reached, MPP shall have the sole right to terminate this Agreement. These measures are in addition and without prejudice to any other remedies that may be available.
- (h) In addition to all other remedies and indemnities provided for in this Agreement, Licensee and its Affiliates shall indemnify and hold MPP and Shionogi 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 Third Parties acting on Licensee's behalf which would constitute a violation of this Section 8.5.

#### **8.6 Licensee Acknowledgement**

Licensee acknowledges that Shionogi's willingness to approve the selection of Licensee and execution of this Agreement is based, in part, upon the representations, warranties and covenants made by Licensee to MPP under this Agreement, and that such representations, warranties and covenants constitute a material inducement for Shionogi's approval of Licensee and this Agreement.

#### **8.7 DISCLAIMER**

EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE SHIONOGI-MPP AGREEMENT, MPP AND SHIONOGI (IN THE SHIONOGI-MPP AGREEMENT) 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 MPP AND SHIONOGI (IN THE SHIONOGI-MPP AGREEMENT) HEREUNDER, OR WITH RESPECT TO THE COMPOUND OR LICENSED PRODUCT, 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 MPP'S OR LICENSEE(S)'S USE OF THE PATENTS, LICENSED KNOW-HOW, COMPOUND OR LICENSED PRODUCT AS CONTEMPLATED HEREUNDER WILL NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. MPP AND SHIONOGI (IN THE SHIONOGI-MPP AGREEMENT) ALSO MAKE NO REPRESENTATION OR WARRANTY THAT LICENSEE(S)'S USE OF THE COMPOUND OR LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS (OTHER THAN THE PATENTS AND LICENSED KNOW-HOW) OF SHIONOGI OR ITS AFFILIATES. MPP AND SHIONOGI (IN THE SHIONOGI-MPP AGREEMENT) ALSO DO NOT GIVE ANY WARRANTY, EXPRESS OR IMPLIED, WITH REGARD TO THE SAFETY OR EFFICACY OF THE COMPOUND OR LICENSED PRODUCT AND IT SHALL BE THE SOLE RESPONSIBILITY OF LICENSEE TO ENSURE SUCH SAFETY OR EFFICACY.

### **9. QUALITY CONTROL, REGULATORY COMPLIANCE, LIABILITY, AND INDEMNITY**

#### **9.1 Quality Control; Regulatory Compliance**

Licensee agrees that the Licensed Product sold by it and the processes for manufacturing, storage and handling of such Licensed Product shall strictly comply with all Applicable Law (including cGMP) and Licensee's manufacturing standards (such standards to be no less stringent than industry standards used by companies that manufacture similar products for sales in countries that are regulated by SRAs) relating to any operations involved in the manufacture, packaging, labeling, quality control, testing, receipt, storage of, warehousing, and shipping, of Licensed Product, including but not limited to regulations for protection of worker health and safety. Licensee shall immediately notify MPP in writing 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 9.1 for the manufacture and handling of the Licensed Product (**Agency Action**), such notice to set forth in reasonable detail all such failures and observations made by such Agency. If at any time, during the term of this Agreement, MPP is made aware of any Agency Action other than by Licensee pursuant to the preceding sentence, MPP shall promptly provide Licensee with a notice of the same. Licensee shall within a period of 30 days from becoming aware of an Agency Action provide MPP with a plan



for remedying the same within a timeline to be mutually agreed by the Parties, such agreement by either Party not to be unreasonably withheld or delayed. If Licensee is unable to remedy the same within the mutually agreed timeline (or, in the absence of such a mutually agreed timeline, within a reasonable period of time not to exceed 90 days), MPP 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 MPP; provided however, that in the event that Licensee has already received a prior notice of any such violation, then MPP shall have the right to terminate this Agreement immediately without any notice.

## 9.2 No MPP or Shionogi Liability

Neither Shionogi nor MPP shall be responsible to Licensee or to any Third Party for any damages or losses resulting, directly or indirectly from Licensee's or its Affiliates' or Approved Local Distributors' manufacture, packaging, labeling, receipt, shipping, handling, storage, use, importation, marketing, or sale of the Licensed Product or any other acts or omissions of Licensee arising out of this Agreement.

## 9.3 Indemnity

Licensee shall jointly and severally indemnify, hold harmless and defend MPP, Shionogi, inventors of any patents and patent applications within the Patents, its and their respective Affiliates, Third Parties to whom Shionogi, and each of their respective Affiliates may directly or indirectly owe an indemnity, and each of their respective directors, officers, employees, contractors and agents and its and their respective directors, officers, employees, contractors and agents (collectively, the **Indemnitees**), from and against any and all claims, demands, actions and proceedings (whether criminal or civil or in contract, tort or otherwise) (**Claims**) for losses, damages, liabilities, costs and expenses (including, without limitation, attorneys' fees, witness fees, damages, judgments, fines, and amounts paid in settlement), and any amounts an Indemnitee becomes legally obligated to pay (**Losses**), directly or indirectly, arising out of, resulting from or related to: (a) the development (including, but not limited to, the conduct of any Clinical Trials), manufacture, use or sale of the Compound or any Licensed Product by or on behalf of Licensee, its Affiliates and their respective directors, officers, employees, contractors and agents (including any product liability, liability for death, illness, personal injury, improper business practice or any other statutory liability or any other liability under any law or regulation to the extent arising or resulting therefrom), (b) any breach of the terms and conditions of this Agreement by Licensee, its Affiliates and their respective directors, officers, employees, contractors and agents, (c) any breach of any of the representations, warranties or covenants made by Licensee under this Agreement, any negligence, recklessness or willful misconduct or wrongful intentional omissions of Licensee, its Affiliates and their respective directors, officers, employees, contractors and agents, (d) violation of Applicable Law by Licensee, its Affiliates and their respective directors, officers, employees, contractors and agents, (e) breach by Licensee of the scope of the licenses set forth in Section 2.1 of this Agreement, or (f) the alleged or actual infringement or misappropriation of any Third Party's intellectual property rights; provided, however, that the indemnification obligations set forth herein shall not apply to the extent such Losses directly result from the willful misconduct of the Indemnitees.

In connection with any Claim for which an Indemnitee seeks indemnification from Licensee pursuant to this Agreement, such Indemnitee shall: (i) give Licensee prompt written notice of the Claim, provided that failure to provide such notice shall not relieve Licensee from its liability or obligation hereunder except to the extent of any material prejudice as a direct result of such failure; (ii) cooperate with Licensee, at Licensee's expense, in connection with the defense and settlement of the Claim; and (iii) permit Licensee to control the defense and settlement of the Claim, provided that Licensee may not settle the Claim without such Indemnitee's (and Shionogi's where Shionogi is not the Indemnitee) prior written consent, which shall not be reasonably withheld or delayed, in the event that such settlement admits wrongdoing on the part of any Indemnitee, admits that any Patent is invalid, unenforceable or not infringed or that imposes any financial obligations on Indemnitee or otherwise

materially adversely impacts such Indemnitee's or Shionogi's rights or obligations. Further, such Indemnitee shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and its own expense. Notwithstanding the foregoing, Shionogi, directly or through any of its Affiliates, may elect to assume control of the defense of a Claim at any time if, in Shionogi's sole discretion: (A) Licensee fails to timely assume the defense of or reasonably defend such Claim in good faith to the satisfaction of Shionogi or its Affiliates; or (B) Shionogi or its Affiliates believes in good faith that a bona fide conflict exists between Indemnitee(s) and Shionogi with respect to such Claim. Upon written notice of such election, Shionogi shall have the right to assume control of such defense (directly or through either one of its Affiliate), and Licensee shall pay (as incurred and on demand), all Losses, including, without limitation, the reasonable attorneys' fees and other expenses incurred by Indemnitee(s), in connection with the Claim. In all events, Licensee shall cooperate with Indemnitee(s) in the defense, settlement or compromise of the Claim.

Costs and expenses, including, without limitation, fees and disbursements of counsel, incurred by the Indemnitee(s) in connection with any Claim shall be reimbursed on a quarterly basis by Licensee, without prejudice to Licensee's right to refund in the event that Licensee is ultimately held in a final, non-appealable judgment or award to be not obligated to indemnify the Indemnitee(s).

#### **9.4 Assumption of Liability**

Notwithstanding any provision in this Agreement to the contrary, Licensee shall be solely responsible for any product liability, liability for death, illness, personal injury, improper business practice or any other statutory liability or any other liability under any law or regulation in respect of the Compound, Product and/or Licensed Product.

#### **9.5 Insurance Recovery**

Notwithstanding anything expressed or implied to the contrary in this Section, the amount of any losses subject to indemnification shall be reduced by the amount of any insurance proceeds received by the indemnified party from Licensee's insurer with respect to such Losses, and there shall be no obligation under this Agreement for Licensee to indemnify such indemnified party for the amount of losses so reduced by such payment by Licensee's insurer to such indemnified party.

#### **9.6 LIMITATION OF LIABILITY**

SUBJECT ALWAYS TO SECTION 9.7, NOTWITHSTANDING ANYTHING ELSE TO THE CONTRARY CONTAINED IN THIS AGREEMENT OR THE SHIONOGI-MPP AGREEMENT, IN NO EVENT SHALL SHIONOGI, MPP OR ANY OF THEIR RESPECTIVE AFFILIATES BE LIABLE TO LICENSEE FOR ANY DAMAGES, WHETHER CHARACTERIZED AS DIRECT OR INDIRECT DAMAGES, INCLUDING, BUT NOT LIMITED TO, ANY SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, LOSS OF BUSINESS OR PROFITS), RELATED TO THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, AND NEITHER SHIONOGI NOR MPP NOR ANY OF THEIR RESPECTIVE AFFILIATES SHALL HAVE ANY RESPONSIBILITIES OR LIABILITIES WHATSOEVER WITH RESPECT TO PATENTS, LICENSED KNOW-HOW, COMPOUND OR LICENSED PRODUCT, EVEN IF, IN ANY SUCH CASE, LICENSEE IS ADVISED OF THE POSSIBILITY OF SUCH CLAIMS OR DEMANDS, REGARDLESS OF THE FORM OF ACTION OR LEGAL THEORY, WHETHER UNDER CONTRACT LAW, TORT LAW (INCLUDING, WITHOUT LIMITATION, NEGLIGENCE), STRICT LIABILITY, STATUTE, WARRANTY OR OTHERWISE. IN NO INSTANCE SHALL SHIONOGI, MPP OR ANY OF THEIR RESPECTIVE AFFILIATES BE LIABLE TO LICENSEE (WHETHER ARISING IN WARRANTY, TORT (INCLUDING, WITHOUT LIMITATION, NEGLIGENCE), CONTRACT, STRICT LIABILITY OR OTHERWISE) FOR ANY LIABILITIES OF LICENSEE TO ANY THIRD PARTY, INCLUDING, WITHOUT LIMITATION, THROUGH

CONTRIBUTION, INDEMNITY, OR FOR ANY CLAIM FOR WHICH LICENSEE WOULD HAVE TO INDEMNIFY SHIONOGI OR MPP IF THAT CLAIM WERE BROUGHT DIRECTLY AGAINST SHIONOGI OR MPP.

**9.7 Liability – General**

Notwithstanding the foregoing provisions of this Section 9, nothing in this Agreement shall limit or exclude the liability of either Party for death or personal injury resulting from negligence or fraud or fraudulent misrepresentation or other matters, the exclusion of liability for which is not allowable under Applicable Laws.

**10. INSURANCE**

10.1 No later than 60 days before the anticipated date of market introduction of any Licensed Product, whether such market introduction is made under an EUA or Key Approval, 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 and product liability insurance (contractual liability included) with limits as follows:

- (a) Each occurrence \$10,000,000;
- (b) Products/completed operations aggregate \$50,000,000;
- (c) Personal and advertising injury \$5,000,000; and
- (d) General aggregate (commercial form only) \$10,000,000.

**10.2 Term**

If the above insurance is written on a claims-made form, it shall continue for three (3) years following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date of this Agreement.

**10.3 Policy Conditions**

Sublicensee's insurance obligations can be met through a combination of insurance or self-insurance. The coverage and limits referred to in Section 10.1 will not in any way limit the liability of Licensee under this Agreement. Upon the execution of this Agreement, subsequently at the time of each of the further triggers stated above requiring increased coverage, Licensee will furnish MPP with certificates of insurance evidencing compliance with all requirements herein. Shionogi shall be named as an additional insured on each insurance policy. Licensee will promptly notify MPP of any material modification of the insurance coverages or cancellation notice it receives of any such insurance policies. All insurance coverage required under this Agreement shall be primary to any coverage carried by Shionogi or MPP. Shionogi, the MPP and their respective Affiliates, and their respective directors, officers, agents, and employees will be named as loss payees under such commercial general liability and product liability insurance. Upon request by MPP or Shionogi, Licensee shall provide to Shionogi and MPP evidence of its insurance coverage.

**11. STATEMENTS, REPORTING AND RIGHT TO AUDIT**

**11.1 Books and Records; Audit Right**

Licensee will keep full, true, and accurate books and records containing all particulars that may be necessary for the purpose of showing the amount of royalties payable to Shionogi and Licensee's compliance with other obligations under this Agreement and Applicable Law. 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 15 days' advance written notice, for five 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 Shionogi and MPP, individually or together and reasonably acceptable to Licensee for the purpose of verifying Licensee's royalty reports or compliance in other respects with this Agreement and Applicable Law. 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 Shionogi and/or MPP. The fees and expenses of the certified public accountants performing such an examination will be borne by Shionogi and/or MPP. However, if an error in underpaid royalties to Shionogi of more than five percent (5%) of the total royalties due for any twelve month period is discovered, then the fees and expenses of these representatives will be borne by Licensee.

## **11.2 Royalty Reporting**

After the first sale anywhere in the Territory, within 10 Business Days following the end of each Calendar Quarter, Licensee shall deliver to MPP a statement accounting for, inter alia, all royalties calculations, Licensed Products and/or Compound (in terms of smallest units and patient packs for each formulation) sold or supplied by Licensee under this Agreement during such Calendar Quarter in the reporting template as set forth in Appendix 4. For the avoidance of doubt, such royalty reports shall include sales for which no royalty payment may be due and payable. MPP 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 Shionogi (with Shionogi treating such reports as Confidential Information).

## **12. TERM AND TERMINATION**

### **12.1 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 on a country-by-country basis until the later of (a) the expiration, invalidation or abandonment date of the last Valid Claim of the Patents in both the country of sale and the country of manufacture of a Licensed Product (including, without limitation, the manufacture of Compound contained in such Licensed Product) or (b) expiration of the last regulatory exclusivity for a Licensed Product in a country of sale of such Licensed Product.

### **12.2 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 12.2 will not (a) relieve either Party of any obligation or liability accrued; (b) impair any accrued rights of either Party; or (c) 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.

### 12.3 MPP Right to Terminate

MPP shall have the right to terminate this Agreement, either in whole or in relation to a particular Patent, with immediate effect by notice in writing to the Licensee if:

- (a) Licensee breaches any of the anti-diversion provisions of Section 5 of this Agreement;
- (b) MPP becomes aware of any action (including any official notifications or communications) taken by any Agency involving a determination of Licensee's failure to comply with cGMP in connection with for the manufacture and handling of the Licensed 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 9.1, Licensee is unable to reliably and consistently manufacture Compound or Licensed Product in accordance with such quality requirements;
- (c) Licensee fails to comply with the obligations contained in Section 3.7 of this Agreement;
- (d) Licensee fails to comply with the obligations contained in Section 3.12 of this Agreement;
- (e) a Temporary Waiver is approved by MPP and Shionogi and WHO or an SRA denies WHO Prequalification or SRA approval or any provisional or emergency use authorizations available through WHO or an SRA;
- (f) Licensee repeatedly fails to comply with, or to timely provide MPP with the reports contemplated under this Agreement, including, but not limited to, the reports required under Sections 3.4, 3.9, 3.10. 4.5 and 11.2 of this Agreement;
- (g) Licensee fails to file for WHO Prequalification of the Licensed Product within six months of a WHO Expression of Interest for the Licensed Product or such other time as may be mutually agreed between the Parties;
- (h) any material safety issue that Shionogi or MPP reasonably believes makes it inadvisable to proceed or continue with the Commercialization of Licensed Product in the Territory;
- (i) the legal or beneficial ownership of Licensee or any of its Affiliates changes, directly or indirectly, without the prior written consent of Shionogi and MPP in accordance with Section 14.9;
- (j) any serious or intentional violation of any Applicable Law or misappropriation of a Third Party's intellectual property rights by Licensee anywhere in the world, which in Shionogi's and MPP's judgement, may reflect unfavorably on Shionogi, MPP, their reputation or Licensed Product; or
- (k) Licensee is in breach of Section 8.3, Section 8.4 or Section 8.5 of this Agreement.

### 12.4 Failure to Promote Access

If, in the reasonable opinion of the MPP, Licensee fails to promote access or appears in MPP's reasonable opinion, will fail to promote access to the Licensed Products in the Territory in accordance with this Agreement, the MPP shall give notice to Licensee requiring it to cure such failure. If, in the reasonable opinion of the MPP, 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 MPP shall have the right to terminate this Agreement with immediate effect by giving written notice to Licensee. In making such determination of reasonable progress, the MPP shall take into account the period within which the relevant authorities provide the necessary approvals and normal development

lead time for the Licensed Products, and progress reported by Licensee in its quarterly reports and meetings provided under Section 3.9 of this Agreement.

#### **12.5 Misrepresentations in Expression of Interest**

Licensee acknowledges that it was offered to enter into this Agreement on the basis of certain representations and projections that it made through MPP's Expression of Interest system. In the event that MPP discovers any material misrepresentations made therein, or if Licensee fails to substantially meet its projections (including, without limitation, projections regarding the countries in which Licensee intends to Commercialize Licensed Product, the efforts and resources that Licensee intends to devote to the Commercialization of Licensed Product in each country and the extent to which Licensee's supply is sufficient to meet demand in each country), MPP shall have the right, upon 30 days' notice, to terminate this Agreement.

#### **12.6 Conversion to Direct License with Shionogi**

Subject always to the termination provisions of the Shionogi-MPP Agreement, in the event that the Shionogi-MPP Agreement is terminated prior to its term, this Agreement shall be converted into a direct license between Shionogi and Licensee, provided that (a) Licensee is in good standing under, and not in breach of, this Agreement, (b) Shionogi reserves its rights to terminate this Agreement on the same grounds as those having led to termination of the Shionogi-MPP Agreement or pursuant to any rights of termination specified in this Agreement and (c) the terms of this Agreement (as converted) shall be no more onerous upon Shionogi than the terms of the Shionogi-MPP Agreement. In the event of such conversion and upon Shionogi's request, Licensee shall agree in writing to such conversion and to perform all of its obligations under such direct license.

#### **12.7 Termination by Licensee**

Licensee may terminate this Agreement at any time by providing 30 days written notice to MPP. Any termination pursuant to this Section 12.7 by Licensee will not relieve Licensee of any obligation or liability accrued hereunder prior to such termination or rescind anything done by Licensee or any payments made to Shionogi hereunder prior to the time such termination becomes effective, and such termination will not affect in any manner any rights of MPP arising under this Agreement prior to such termination.

#### **12.8 Insolvency**

Either Party may terminate this Agreement immediately by written notice to the other, if any step, process, application, filing in court, order, proceeding, notice or appointment is taken or made by or in respect of the other party for a moratorium, composition, compromise or arrangement with creditors (by way of voluntary arrangement, scheme of arrangement or otherwise), administration, liquidation (other than for the purposes of amalgamation or reconstruction), dissolution, receivership (administrative or otherwise), distress or execution, or the other party becomes insolvent or is deemed unable to pay its debts as they fall due, or anything analogous to the foregoing occurs in any applicable jurisdiction.

#### **12.9 Effects of Termination**

Upon termination of this Agreement other than expiration of this Agreement pursuant to Section 12.1 of this Agreement, (a) all rights and licenses granted to Licensee under Section 2 of this Agreement shall terminate and Licensee shall cease all use of the Patents and the Licensed Know-How, (b) the Parties will cooperate with each other to provide for an orderly wind-down of the transactions contemplated herein and (c) Shionogi shall have the right to purchase from Licensee materials used in the synthesis of the Compound, the Compound and/or Licensed Product at the actual cost of goods

(verifiable via Third Party audit) plus a ten percent (10%) markup under a supply agreement containing such other reasonable and customary terms and conditions as are agreed by Shionogi and Licensee in good faith. Any termination or expiration of this Agreement will not relieve Licensee of its obligations to pay any monies 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.

#### **12.10 Survival**

Sections 1, 2.7 (with respect to Licensee's responsibility and liability for its Affiliates), 2.8, 2.9, 3.3 (with respect to Licensee's indemnity obligation), 3.4, 3.12, 3.13, 3.14, 4.4 (with respect to the last sentence), 4.8, 6.1, 6.2, 6.3, 6.4, 7 (with respect to any sales of Licensed Product sold or manufactured prior to termination), 8.7, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 10 (for the period set forth in Section 10.2), 11.1 (for the period set forth therein), 11.2 (with respect to any sales of Licensed Product sold or manufactured prior to termination), 12.6, 12.9, 13, 14 and this Section 12.10 shall survive termination or expiry of this Agreement.

### **13. CONFIDENTIALITY AND PUBLICATIONS**

#### **13.1 Confidential Information**

Each Party 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 or Shionogi (**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 (a) Shionogi in order to comply with the Shionogi-MPP Agreement and (b) any Agency as may be required by Applicable Law. For the avoidance of doubt, Shionogi shall have the right to such Confidential Information and wherever Shionogi has a contractual obligation towards a Third Party to disclose information regarding the Licensed Product or Compound, Shionogi may disclose Confidential Information to that Third Party under obligations of confidentiality no less stringent than contained herein. The obligations imposed by this Section 13.1 shall not apply to any information that the receiving Party can demonstrate by competent written evidence:

- (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 other than as a result of any breach of this Agreement by the receiving Party;
- (c) is subsequently disclosed to the receiving Party on a non-confidential basis by a Third Party who may lawfully do so; or
- (d) is independently discovered or developed by the receiving Party without the use of, or reference to, Confidential Information of the disclosing Party, as documented by the receiving Party's business records.

#### **13.2 Licensed Know-How**

Licensee will keep Licensed Know-How confidential subject to Section 13.1 of this Agreement.

#### **13.3 Return and Destruction**

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.

**13.4 Confidentiality Term**

The obligations of confidentiality set forth in this Section 13 shall survive for a period of ten years after the expiration, cancellation, or other termination of this Agreement.

**13.5 No Public Statements**

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

**14. MISCELLANEOUS**

**14.1 Third Party Beneficiary**

- (a) Except as expressly stated in this Section 14.1, a person who is not a Party to this Agreement may not enforce any of its terms under the Contracts (Rights of Third Parties) Act 1999.
- (b) The Parties acknowledge and agree that Shionogi is intended to be and constitutes a third-party beneficiary of the representation, warranties, covenants, and agreements of Licensee, and Shionogi is entitled to enforce, without any obligation to consult with, or obtain approval from, MPP, the terms and provisions of this Agreement on its own behalf to the same extent as MPP, including, without limitation, any termination right that MPP may have hereunder.
- (c) In no event shall Shionogi be deemed a party to this Agreement.

**14.2 Agency**

Neither Party is, nor will be deemed to be, an employee, agent, or representative of the other Party for any purpose and nothing in this Agreement shall be deemed to constitute a partnership between the Parties. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to nor shall, explicitly or implicitly, represent that they have the authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party.

**14.3 Whole Agreement**

- (a) This Agreement and the documents referred to in it contain the whole agreement between the Parties relating to the transactions contemplated by this Agreement and supersede all previous communications, representations or understandings, and agreements, whether oral or written, between the Parties relating to these transactions. Except as required by statute, no terms shall be implied (whether by custom, usage or otherwise) into this Agreement.
- (b) Each Party acknowledges that, in agreeing to enter into this Agreement, it has not relied on any express or implied representation, warranty, collateral contract or other assurance (except those set out in this Agreement).
- (c) Each Party waives all rights and remedies which, but for Section 14.3(b), might otherwise be available to it in respect of any such express or implied representation, warranty, collateral contract or other assurance.



- (d) Nothing in this Section 14.3 limits or excludes any liability for fraud.
- (e) In each instance under this Agreement where Shionogi's consent, approval, permission, acquiescence or other form of acceptance is required (**Shionogi Consent Right**), it shall be read and understood to mean that Shionogi may withhold such Shionogi Consent Right at its sole and absolute discretion unless a contrary standard is expressly stated therein with respect to such Shionogi Consent Right.

#### **14.4 Severability**

The provisions contained in each Section of this Agreement shall be enforceable independently of each of the others and their validity shall not be affected if any of the others are invalid. 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.

#### **14.5 Notices.**

- (a) Any notice or other document to be served under this Agreement will be in writing and will be delivered by hand or internationally recognized express courier with tracking capabilities or mailed postage prepaid by first class, registered, or certified mail, in any case addressed as set forth below unless changed by notice so given. The Parties may also for information purposes provide a copy of any such notifications to the email addresses set forth below:

**In the case of MPP:**

Medicines Patent Pool  
Rue de Varembe 7  
Geneva 1202  
Switzerland  
Attention: General Counsel  
E-mail: [legal@medicinespatentpool.org](mailto:legal@medicinespatentpool.org)

**In the case of Licensee:**

**M/S. HETERO LABS LIMITED**  
**607/608, Matharu Arcade, Plot no: 32, Subhash Road,**  
**Vile Parle (E), Mumbai - 400 057, INDIA**

**Attention: MR. BHAVESH SHAH & MR. SUDERSHAN PALLAP - AVP LEGAL**

**E-mail: [bhavesh@hetero.com](mailto:bhavesh@hetero.com) / [legal@heterodrugs.com](mailto:legal@heterodrugs.com)**

- (b) Any such notice will be deemed delivered on the date received. A Party may add, delete, or change the person or address to whom notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section.

#### **14.6 Language**

Any notice given or document provided in connection with this Agreement must be in English.

#### 14.7 Governing Law

This Agreement and any non-contractual obligations arising out of or in connection with it will be governed by the laws of England, without regard to its choice of law principles.

#### 14.8 Dispute Resolution.

- (a) This Section 14.8 shall be governed by English law.
- (b) Any dispute, claim, difference or controversy arising out of, relating to or having any connection with this Agreement, including any dispute as to its existence, validity, interpretation, performance, breach or termination or the consequences of its nullity and any dispute relating to any non-contractual obligations arising out of or in connection with it (a **Dispute**), shall be finally resolved pursuant to the following provisions of this Section 14.8.
- (c) Either Party may, by notice in writing to the other Party at the address given for the sending of notices under this Agreement at Section 14.5, and in a manner provided for in that Section, give notice that a Dispute has arisen (**Notice**).
- (d) Once the Notice is received, the Parties agree that they shall first attempt in good faith to settle the Dispute by negotiation and consultation between their respective operational teams.
- (e) In the event that such Dispute is not resolved on an informal basis within 30 days after such Notice is received, either Party may, by written to the other Party, refer the Dispute to the **DIRECTOR & AVP LEGAL** of **HETERO LABS LIMITED** and to the Executive Director of MPP (together, the **Designated Officers**) for attempted resolution by good faith negotiation.
- (f) If any such Dispute is not resolved by the Designated Officers within 30 days after the receipt of the notice referring such Dispute to the Designated Officers, then either Party may refer the Dispute for final resolution by arbitration under the Arbitration Rules of the London Court of International Arbitration as amended from time to time (the **Rules**), except as those rules may be modified herein or by mutual agreement of the Parties.
- (g) The Rules are incorporated by reference into this Section 14.8 and capitalised terms used in this Section 14.8 that are not otherwise defined in this Agreement have the meaning given to them in the Rules.
- (h) The arbitration shall be conducted by three arbitrators in accordance with the Rules. The Claimant (or Claimants jointly) shall nominate one arbitrator for appointment by the LCIA Court in its request for arbitration. The Respondent (or Respondents jointly) shall nominate one arbitrator for appointment by the LCIA Court within 30 days of the receipt of the request for arbitration. The two arbitrators so nominated by the Parties shall nominate the presiding arbitrator to be appointed by the LCIA Court, within 30 days after the confirmation of the later-nominated arbitrator. If any of the three arbitrators are not nominated within the time prescribed above, then the LCIA Court shall appoint the arbitrator(s).
- (i) The seat or legal place of the arbitration shall be London, United Kingdom.
- (j) The language used in the arbitral proceedings shall be English. All documents submitted in connection with the proceedings shall be in the English language, or, if in another language, accompanied by an English translation.
- (k) Notwithstanding Section 14.5, any Request pursuant to this Section 14.8 shall be delivered by email to the address given by the relevant party for the receipt of Requests, as follows:

- (i) to Licensee at: **bhavesh@hetero.com / legal@heterodrugs.com**; and
  - (ii) to MPP at **legal@medicinespatentpool.org**.
- (l) The jurisdiction of the English courts under s.45 and s.69 of the Arbitration Act 1996 is excluded.
- (m) The Emergency Arbitrator provisions in the Rules shall not apply.
- (n) Notwithstanding any provision to the contrary in the Rules, the Parties agree that any arbitrator (including the presiding arbitrator) may have the same nationality as any Party to the arbitration.
- (o) This Section 14.8 is without prejudice to each Party's right to seek interim relief against the other Party (such as an injunction) through the courts of England to protect its rights and interests, or to enforce the obligations of the other party.
- (p) Service of process
  - (i) Within ten (10) days of the Effective Date, Licensee will appoint an agent under this Agreement for service of process in the event that recourse is sought to the English courts in relation to any arbitral proceedings contemplated by this Section 14.8, and notify MPP thereof.
  - (ii) Within ten (10) days of the Effective Date, MPP will appoint an agent under this Agreement for service of process in the event that recourse is sought to the English courts in relation to any arbitral proceedings contemplated by this Section 14.8, and notify MPP thereof.
  - (iii) If any person appointed as process agent under this Section 14.8(p) is unable for any reason to so act, the appointing Party must immediately (and in any event within 10 Business Days of the event taking place) appoint another agent. Failing this, the other Party may appoint another process agent for this purpose.
  - (iv) Each Party agrees that failure by a process agent to notify it of any process will not invalidate the relevant proceedings or render service of those proceedings ineffective.
  - (v) This Section 14.8 does not affect any other method of service allowed by law.
- (q) In the event that Shionogi elects to enforce any rights of MPP under this Section 14.8 pursuant to Section 14.1 of this Agreement, or, in the event that Licensee has any dispute involving, in whole or in part, Shionogi, then, without implying any obligation or liability of Shionogi under this Agreement or waiving any of its potential defenses, including, but not limited to, any defense regarding a lack of contractual privity between Licensee and Shionogi, the terms and conditions of this Section 14.8 shall apply. For the purposes of Section 14.8(d), Shionogi shall be represented by the Senior Executive Officer, Senior Vice President, R&D Supervisory Unit of Shionogi.

#### **14.9 Assignment**

Neither Party is entitled to transfer or assign this Agreement or the rights and obligations under this Agreement without the other Party's and Shionogi's prior written consent. For the avoidance of doubt, Shionogi, as a third party beneficiary, shall have the right to assign, or transfer its benefits and rights under this Agreement or any part thereof without the prior written consent of MPP or Licensee. Any attempted assignment or delegation in violation of this Section 14.9 shall be null and void. Subject to

the foregoing, this Agreement will inure to the benefit of, and be binding on, the Parties' successors and assigns.

#### **14.10 Amendments and Waivers**

- (a) No amendment or modification hereof shall be valid or binding upon the Parties unless made in writing and signed by both Parties and consented to in writing by Shionogi.
- (b) No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver; provided, however, that no waiver by MPP shall be effective unless consent to in writing has been given by Shionogi.
- (c) The rights of each Party under this Agreement:
  - (i) may be exercised as often as necessary;
  - (ii) are cumulative and not exclusive of rights or remedies provided by law; and
  - (iii) may be waived only in writing and specifically.

Delay in exercising or non-exercise of any such right is not a waiver of that right.

#### **14.11 Privacy Laws**

Licensee and MPP shall comply with all Applicable Law 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 Licensee and MPP 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.

#### **14.12 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.

#### **14.13 Costs**

Each Party shall pay the costs and expenses incurred by it in connection with the entering into of this Agreement.

*[signatures appear on following page]*

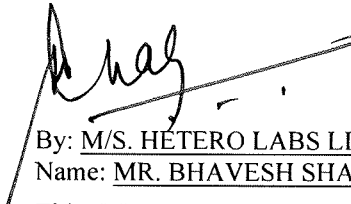
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

**MEDICINES PATENT POOL:**

**Medicines Patent Pool**

By <sup>DocuSigned by:</sup> Charles Gore  
Name: Charles Gore  
Title: Executive Director

**LICENSEE:**

  
By: M/S. HETERO LABS LIMITED  
Name: MR. BHAVESH SHAH  
Title: DIRECTOR - INTERNATIONAL MARKETING

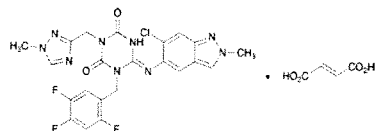


**APPENDIX 1**

**COMPOUND**

Name of the Active Ingredient: ensitrelvir fumaric acid (S-217622)

Structure of Active Ingredient:



## APPENDIX 2

## PATENTS

## PATENT APPLICATIONS

Application number	Country	Application date	Applicant
PCT/JP2022/6495	WO	17/02/2022	Shionogi & Co Ltd and Hokkaido University
202280000918.9	China	17/02/2022	Shionogi & Co Ltd and Hokkaido University
202210742186.2	China	17/02/2022	Shionogi & Co Ltd and Hokkaido University
202210983564.6	China	17/02/2022	Shionogi & Co Ltd and Hokkaido University
17/790358	US	17/02/2022	Shionogi & Co Ltd and Hokkaido University
PCT/JP2022/6496	WO	17/02/2022	Shionogi & Co Ltd and Hokkaido University
2022-7018680	Korea	17/02/2022	Shionogi & Co Ltd and Hokkaido University
17/733366	US	17/02/2022	Shionogi & Co Ltd and Hokkaido University
1343	Lebanon	13/04/2022	Shionogi & Co Ltd and Hokkaido University
111113943	Taiwan	13/04/2022	Shionogi & Co Ltd and Hokkaido University
PCT/JP2022/35803	WO	27/09/2022	Shionogi & Co Ltd and Hokkaido University
111136544	Taiwan	27/09/2022	Shionogi & Co Ltd and Hokkaido University
2021-191635	Japan	26/11/2021	Shionogi & Co Ltd
2021-189932	Japan	24/11/2021	Shionogi & Co Ltd
2022-046304	Japan	23/03/2022	Shionogi & Co Ltd
2022-006725	Japan	19/01/2022	Shionogi & Co Ltd
2022-012386	Japan	28/01/2022	Shionogi & Co Ltd

2022-017132	Japan	07/02/2022	Shionogi & Co Ltd
2022-027629	Japan	25/02/2022	Shionogi & Co Ltd
2022-120325	Japan	28/07/2022	Shionogi & Co Ltd
2022-149666	Japan	09/21/2022	Shionogi & Co Ltd
2022-142767	Japan	08/09/2022	Shionogi & Co Ltd
To be determined	China	09/21/2022	Shionogi & Co Ltd

**GRANTED PATENT RIGHTS**

<b>Patent number</b>	<b>Country</b>	<b>Applicant</b>
7105430	Japan	Shionogi & Co Ltd and Hokkaido University
9150546	US	Shionogi & Co Ltd
5692747	Japan	Shionogi & Co Ltd
EP2399910	Belgium	Shionogi & Co Ltd
EP2399910	Switzerland	Shionogi & Co Ltd
EP2399910	Germany	Shionogi & Co Ltd
EP2399910	Spain	Shionogi & Co Ltd
EP2399910	France	Shionogi & Co Ltd
EP2399910	United Kingdom	Shionogi & Co Ltd
EP2399910	Ireland	Shionogi & Co Ltd
EP2399910	Italy	Shionogi & Co Ltd
EP2399910	Liechtenstein	Shionogi & Co Ltd
EP2399910	Netherland	Shionogi & Co Ltd
EP2399910	Poland	Shionogi & Co Ltd
EP2399910	Sweden	Shionogi & Co Ltd
EP2399910	Turkey	Shionogi & Co Ltd
2010214356	Australia	Shionogi & Co Ltd
2752269	Canada	Shionogi & Co Ltd
201080016705.2	China	Shionogi & Co Ltd



289831	India	Shionogi & Co Ltd
315392	Mexico	Shionogi & Co Ltd
173647	Singapore	Shionogi & Co Ltd
I457328	Taiwan	Shionogi & Co Ltd
5765753	Japan	Shionogi & Co Ltd

**APPENDIX 3****TERRITORY**

LIC : Low-Income Country  
 LMIC : Lower Middle-Income Country  
 UMIC : Upper Middle-Income Country  
 HIC : High-Income Country

<b>Country</b>	<b>Classification</b>
Afghanistan	LIC
Algeria	LMIC
Angola	LMIC
Armenia	UMIC
Azerbaijan	UMIC
Bangladesh	LMIC
Belize	LMIC
Benin	LMIC
Bhutan	LMIC
Bolivia	LMIC
Botswana	UMIC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cambodia	LMIC
Cameroon	LMIC
Central African Republic	LIC
Chad	LIC
Comoros	LMIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Costa Rica	UMIC
Côte d'Ivoire	LMIC
Cuba	UMIC
Djibouti	LMIC
Dominica	UMIC
Dominican Republic	UMIC
Ecuador	UMIC
Egypt, Arab Rep.	LMIC
El Salvador	LMIC
Equatorial Guinea	UMIC
Eritrea	LIC
Eswatini	LMIC
Ethiopia	LIC
Fiji	UMIC
Gabon	UMIC

<b>Country</b>	<b>Classification</b>
Gambia, The	LIC
Georgia	UMIC
Ghana	LMIC
Grenada	UMIC
Guatemala	UMIC
Guyana	UMIC
Guinea	LIC
Guinea-Bissau	LIC
Haiti	LMIC
Honduras	LMIC
India	LMIC
Iran	LMIC
Iraq	UMIC
Jamaica	UMIC
Jordan	UMIC
Kazakhstan	UMIC
Kenya	LMIC
Kiribati	LMIC
Korea, Dem. People's Rep.	LIC
Kosovo	UMIC
Kyrgyz Republic	LMIC
Lao PDR	LMIC
Lesotho	LMIC
Liberia	LIC
Libya	UMIC
Madagascar	LIC
Malawi	LIC
Maldives	UMIC
Mali	LIC
Marshall Islands	UMIC
Mauritania	LMIC
Mauritius	UMIC
Micronesia, Fed. Sts.	LMIC
Moldova	UMIC
Mongolia	LMIC
Morocco	LMIC
Mozambique	LIC
Myanmar	LMIC
Namibia	UMIC
Nepal	LMIC
Nicaragua	LMIC
Niger	LIC
Nigeria	LMIC
Pakistan	LMIC

<b>Country</b>	<b>Classification</b>
Papua New Guinea	LMIC
Paraguay	UMIC
Peru	UMIC
Philippines	LMIC
Rwanda	LIC
Saint Lucia	UMIC
Saint Vincent and the Grenadines	UMIC
Samoa	LMIC
São Tomé & Príncipe	LMIC
Senegal	LMIC
Seychelles	HIC
Sierra Leone	LIC
Solomon Islands	LMIC
Somalia	LIC
South Africa	UMIC
South Sudan	LIC
Sri Lanka	LMIC
Sudan	LIC
Suriname	UMIC
Syrian Arab Republic	LMIC
Tajikistan	LIC
Tanzania	LMIC
Timor-Leste	LMIC
Togo	LIC
Tonga	UMIC
Tunisia	LMIC
Tuvalu	UMIC
Uganda	LIC
Ukraine	LMIC
Uzbekistan	LMIC
Vanuatu	LMIC
Venezuela	UMIC
Vietnam	LMIC
West Bank and Gaza	LMIC
Yemen, Rep.	LIC
Zambia	LMIC
Zimbabwe	LMIC

## APPENDIX 4

## QUARTERLY REPORTING TEMPLATE

Each reporting template shall include the following but may be subject to change from time to time:

## Reporting Template for Royalties

Country	Local Currency (LC)	Customer	Gross revenue from Sale of Licensed Products (in LC)	Allowable Deductions (in LC)	Net Sales pursuant to Section 7.2 of the License Agreement, itemized detail of details against gross sales to compute net sales (LC)	Exchange Rate (USD per LC)	Net Sales pursuant to Section of 7.2 of the License Agreement, itemized Detail of details against gross Sales to compute net sales (USD)	Royalty Rate	Total Royalties due to Shionogi (USD)
Eg India	INR	Gov. Entities/Public Purchasers	80,000,000	5,000,000	75,000,000	0.0133	1,000,000	5%	50,000
	INR	Commercial Entities	20,000,000	1,000,000	19,000,000	0.0133	253,333.33	10%	25,333.33

Compliance Certification:	I hereby certify that all activities performed under the License Agreement have been conducted in accordance with all Applicable Law (as defined in the License Agreement), including, without limitation, with respect to anti-corruption, anti-competition, recalls, safety and reporting requirements, and export controls and sanctions.
	Name: _____ Date: _____ Title: _____

## Reporting Template for Licensed Products

Country	Licensed Product manufactured and sold	Strength	Formulation (Tablet/granules/liquid/powder for suspension)	Pack Size	Quantity (number of packs)	Total Value in USD(FOB) *	Country of Origin


\* Please mention FOB (Free on Board) price basis country of origin  
 Note: this format is to be filled and sent to MPP on a quarterly basis, ten Business days from end of each calendar quarter.

Compliance Certification:	I hereby certify that all activities performed under the License Agreement have been conducted in accordance with all Applicable Law (as defined in the License Agreement), including, without limitation, with respect to anti-corruption, anti-competition, recalls, safety and reporting requirements, and export controls and sanctions.
	Name: _____ Date: _____ Title: _____

### Reporting Template for Compounds

Month	Country	Purchaser	Licensed Product	Quantity (kg)	Total Value (USD)

\* Please mention FOB (Free on Board) price basis country of origin

Note: this format is to be filled and sent to MPP on a quarterly basis, ten Business days from end of each calendar quarter.

Compliance Certification:	I hereby certify that all activities performed under the License Agreement have been conducted in accordance with all Applicable Law (as defined in the License Agreement), including, without limitation, with respect to anti-corruption, anti-competition, recalls, safety and reporting requirements, and export controls and sanctions.
	Name: _____ Date: _____ Title: _____

**APPENDIX 5**

**ADDITIONAL AGREED DOSAGES AND AGREED FORMULATIONS**