

LICENSE AGREEMENT

This LICENSE AGREEMENT (the "Agreement") is made as of December 17, 2018 (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 Varembé 7, Geneva 1202, Switzerland ("Licensor"), and MYLAN LABORATORIES LIMITED a company registered under the laws of INDIA, and having a registered office at PLOT NO. 564/A/22, Road No. 92, J.Hills, Hyd ("Licensee").

Each of Licensor and Licensee is referred to in this Agreement as a **Party**. Licensor and Licensee are collectively referred to in this Agreement as the **Parties**.

RECITALS

WHEREAS, the Licensor has been granted by AbbVie Inc. and AbbVie Deutschland GmbH & Co KG (collectively, "AbbVie") the right to sublicense certain patents and patent applications, which relate to the antiviral compounds known as glecaprevir and pibrentasvir (the "AbbVie-MPP Agreement");

WHEREAS, the Licensor 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;

WHEREAS, the Licensee desires to obtain a license from the Licensor to use the aforesaid patents and the Licensor is willing to grant to the Licensee such a license in accordance with the terms and subject to the conditions of this Agreement;

WHEREAS, the purpose of this Agreement is to promote access to antiviral drugs in various low and middle-income countries;

WHEREAS, the intent of this Agreement is to provide access to AbbVie Patents, and not to create any non-patent-related barriers where AbbVie Patents do not exist;

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and other good and valuable considerations, the receipt of which is hereby acknowledged, the parties hereto mutually agree as follows:

1. Definitions

1.1 **AbbVie-MPP HCV Agreement** shall mean the License Agreement entered into between AbbVie and Licensor on 12 November 2018.

1.2 **AbbVie Patents** shall mean Territory Patents and Non-Territory Patents.

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



corporation, firm, partnership or other entity.

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

1.5 **Change of Control** shall mean (i) the acquisition, directly or indirectly, beneficially or of record, by any person or group (within the meaning of the Securities Exchange Act of 1934 and the rules of the Securities and Exchange Commission thereunder as in effect on the date hereof) consisting of or including a competitor, of equity interests representing a controlling stake of a party; or (ii) the acquisition of direct or indirect control of a party by any person or group consisting not previously in such control of a party.

1.6 **Commercialization** shall mean any and all activities directed to the preparation for sale of, offering for sale of, having sold, or sale of a Licensed Product, including activities related to marketing, promoting, distributing, and importing such Licensed Product. When used as a verb, "to **Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.7 **Development** shall mean all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of applications to regulatory authorities, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a regulatory authority as a condition or in support of obtaining or maintaining a regulatory approval. When used as a verb, "**Develop**" means to engage in Development.

1.8 **Exploit** or **Exploitation** shall mean to make, have made, import, use, sell, have sold, or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of.

1.9 **Field** shall mean the treatment of Hepatitis C (HCV).

1.10 **Licensed Compounds** shall mean the antiviral compounds known as glecaprevir and pibrentasvir in a fixed dose combination bioequivalent to Maviret™/Mavyret™ manufactured or sold for the sole purpose of use in Licensed Product solely for Exploitation in the Field in the Territory.

1.11 **Licensed Products** shall mean products for use in the Field containing the Licensed Compounds.

1.12 **Manufacture** and **Manufacturing** shall mean all activities related to the production, manufacture, having manufactured, processing, filling, finishing, packaging, labeling, shipping, and holding of the Licensed Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.



1.13 **Manufacturing-Only Countries** shall mean those countries set forth in Exhibit B.

1.14 **New Formulation** shall mean any Licensed Product that has not been approved for use in the Field as of the Effective Date.

1.15 **New Glecapravir/Pibrentasvir Formulation** shall mean those New Formulations containing the Licensed Compounds.

1.16 **Non-Territory Eligible Purchasers** shall mean: (a) the following organizations to the extent that they are not-for-profit organizations: (i) NGOs including without limitation those recognized by the applicable local government ministry; (ii) UN-related organizations working for or within the Territory, 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); and (iv) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and agencies based outside the Territory to the extent that they are supporting implementation locally within the Territory, and (b) nominally for-profit procurement organizations but only to the extent that such procurements are supporting not-for-profit treatment programs as described in (a) of this provision.

1.17 **Non-Territory Patents** shall mean those patents and patent applications listed in Exhibit D and any continuation, continuation-in-part divisional applications and foreign equivalents thereof.

1.18 **Sole License** shall mean a non-exclusive license granted solely to AbbVie and to no other party.

1.19 **Territory** shall mean those countries set forth in Exhibit A.

1.20 **Territory Patents** shall mean those patents and patent applications as set forth in Exhibit C, and any continuation, continuation-in-part, divisional applications and foreign equivalents thereof.

1.21 **Third Party** means any individual or entity other than Licensor and Licensee.

2. License Grants

2.1 Subject to the other terms and conditions of this Agreement, the AbbVie-MPP Agreement, and AbbVie's Collaborative and License Agreement related to the Licensed Compounds ("Collaboration Agreement"), Licensor hereby grants to Licensee:

(a) a non-exclusive, non-transferable license under the Territory Patents to Exploit the Licensed Products in the Field and in the Territory;

(b) a non-exclusive, non-transferable license under the AbbVie Patents to Manufacture and Develop the Licensed Compounds and Licensed Products in the Territory solely for the purpose of Commercialization of Licensed Products in the Field and in the Territory;



(c) a non-exclusive, non-transferable license under the AbbVie Patents to Manufacture and Develop the Licensed Compounds and Licensed Products in the Manufacturing-Only Countries solely for the purpose of Commercialization of Licensed Products in the Field and in the Territory;

(d) a non-exclusive, non-transferable license under the AbbVie Patents to sell, have sold, offer to sell, or otherwise distribute Licensed Products to Non-Territory Eligible Purchasers solely for the purpose of Commercialization of Licensed Products in the Field and in the Territory; and

(e) a non-exclusive, non-transferable license under the AbbVie Patents to sell, have sold, offer to sell, or otherwise distribute Licensed Compounds solely for the purpose of Commercialization of Licensed Products in the Field and in the Territory.

2.2 The licenses granted hereunder do not include any license or other right to use any AbbVie trademark, trade name, logo or service mark (each, an "AbbVie Mark") or any word, logo or any expression that is similar to or alludes to any AbbVie Mark. Licensee agrees not to Exploit any Licensed Products or Licensed Compounds that contain AbbVie Marks, including without limitation the brand name Maviret™ or Mavyret™ or any name confusingly similar thereto, or the same or confusingly similar color scheme used by AbbVie for its Mavyret™/Maviret™ pills and packaging. Licensee shall obtain AbbVie's prior written approval, such approval not to be unreasonably withheld, of Licensees' proposed trademark, trade dress, product markings or the color or shape of the proposed Licensed Products and will supplement with updated samples and color photographs in the event Licensee changes packaging or pill colors. If in AbbVie's reasonable opinion, Licensee proposes to use marks, packaging, or a color scheme that is the same or confusingly similar to AbbVie's Mavyret™/Maviret™ products, Licensee shall change its marks, packaging, or color scheme (including pill color), as applicable, and provide AbbVie with confirmation and new samples and photographs confirming the change. AbbVie's consent shall be understood as provided unless otherwise notified by AbbVie within thirty (30) days of Licensee's initial written request.

2.3 Nothing in this Agreement shall be construed to prevent Licensee from engaging in any activities where such activities would not infringe AbbVie Patents granted and in force, including, without limitation, where a country has issued a compulsory license on AbbVie Patent(s).

2.4 Except as expressly set forth in this Agreement, Licensor does not grant any license to Licensee under any of AbbVie intellectual property rights (including, without limitation, AbbVie Patents or rights to any AbbVie proprietary compounds or drug substances other than Licensed Compounds). Licensee may provide sublicenses of the rights set forth in this Agreement to its Affiliates, for only so long as any such Affiliate remains an Affiliate of Licensee and only where Licensee causes such Affiliate to comply with the terms and conditions of this Agreement. Licensee agrees to be liable to Licensor and AbbVie for all acts and omissions by its Affiliates which receive a sublicense hereunder, each such Affiliate's acts and omissions will be deemed the acts and omissions of Licensee for the purposes of enforcement of Licensor's and AbbVie's rights pursuant to this Agreement. Except as explicitly permitted by this Section 2.4, Licensee shall not further sublicense any of the rights set forth in this Agreement. Nothing in this Agreement obligates Licensor or AbbVie to provide to Licensee any information related to the composition or formulation of, or the method of making or using, the Licensed Compounds or Licensed Products.



2.5 Notwithstanding anything to the contrary herein, Licensee acknowledges and agrees that the license granted under this Section 2 is granted solely under and with respect to AbbVie Patents Rights for the purposes of supplying Licensed Compounds and Licensed Products for ultimate use in Licensed Products used in the Field and in the Territory. Nothing in this Agreement will be construed as granting Licensee any rights under any patents, know-how or otherwise to use or sell the Licensed Product for ultimate use outside of the Field or outside of the Territory.

2.6 New Glecaprevir/Pibrentasvir Formulations. Licensee agrees to grant to AbbVie an option to and right of first refusal for:

(a) (1) the sole right to purchase New Glecaprevir/Pibrentasvir Formulations from the Licensee developing such formulation for sale in the United States and European Union under terms to be agreed upon by Licensee and AbbVie; or (2) a Sole License to any patents and know-how necessary or useful in exploiting such New Glecaprevir/Pibrentasvir Formulations in the United States and European Union under terms to be agreed upon by Licensee and AbbVie; *provided*, in the event that AbbVie chooses option (2), the term of such Sole License shall last until the termination or expiration of this Agreement, whereupon such Sole License will be converted into a license under royalty and terms to be agreed upon by Licensee and AbbVie, and AbbVie will pay Licensee a royalty of 4% of the Net Sales of the New Glecaprevir/Pibrentasvir Formulation, payable at the end of each Agreement Quarter for such Sole License; and

(b) a non-exclusive right to commercialize and otherwise exploit the New Glecaprevir/Pibrentasvir Formulations outside the United States and the European Union and outside the Territory through purchase or royalty-free non-exclusive license.

AbbVie will have ninety (90) days from the date of notification to AbbVie of a New Glecaprevir/Pibrentasvir Formulation in which it may provide notice of its intent to exercise the option provided in this section, failing which the option(s) will have been deemed to be declined.

3. Development and Registration

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

3.2 Licensee will be solely responsible at its expense for making or having made all of its respective requirements for the Licensed Products in conformity with all applicable specifications in the Territory and will hold all relevant authorizations and permits required in this respect.

3.3 Licensee agrees that it will manufacture Licensed Compounds and Licensed Product in a manner consistent with (i) World Health Organization ("WHO") pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority, as defined by the WHO. Where such approvals are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel.

3.4 The Licensee will obtain from the relevant authorities in the Territory and maintain in force all health registrations, permissions, consents and regulatory authorisations



relating to the importation, manufacture and sale of the Licensed Products which are necessary to enable the Licensed Products to be sold or supplied in the Territory in accordance with this Agreement. Licensor and Licensee shall, as soon as practicable after the Effective Date, confer to agree upon reasonable milestones towards the registration of Licensed Products. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Licensed Products.

3.5 Within 10 Business Days following the end of each Agreement Quarter, Licensee shall provide Licensor with a quarterly written report setting forth the status of development and regulatory filing, in any country, of the Licensed Compound and Licensed Product, in accordance with the reporting template as set forth in Exhibit F. The Parties agree to meet on a quarterly basis regarding such reports and also review development and filing status of Licensed Products. Licensor 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 AbbVie (with AbbVie treating such reports as Confidential Information); and that aggregated data may be publicly disclosed by Licensor.

3.6 The Licensee will manufacture and sell the Licensed Products and Licensed Compounds in accordance with all laws and regulations relevant to the manufacture and sale of the Licensed Products and Licensed Compounds and in accordance with good industry practice.

4. Pharmacovigilance

4.1 Licensee undertakes that it will 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.

4.2 If Licensee becomes aware of any adverse reaction relating to the Licensed Products in connection with this Agreement, Licensee shall inform Licensor and AbbVie within 1 day of its becoming aware and cooperate with AbbVie in fulfilling AbbVie's reporting responsibilities under applicable laws and regulations.

4.3 Licensee undertakes that it will ensure that it will comply with all applicable laws and regulations regarding the Licensed Products in the Territory including without limitation those laws and regulations relating to risk management, drug safety and pharmacovigilance.

4.4 Licensee will be responsible for fulfilling all pharmacovigilance activities as per the local regulations and requirements for the Licensed Products in the Territory and provide Licensor with a report containing information regarding all such activities. Such report shall be provided annually and otherwise on reasonable request by the Licensor.

5. Non-Diversion

5.1 Save as otherwise provided under this Agreement, Licensee shall not Exploit Licensed Product outside of the Field or outside of the Territory where such Exploitation would infringe an AbbVie Patent granted and in force. Save as otherwise provided under this Agreement, Licensee shall not Exploit Licensed Compounds except in the course of activities



supporting the Exploitation of Licensed Product where such Exploitation of Licensed Compounds would infringe an AbbVie Patent granted and in force.

5.2 The Licensee shall not, directly or indirectly, sell or supply:

(a) Licensed Products or Licensed Compounds to any Third Party that the Licensee knows, believes or ought reasonably to suspect will Commercialize Licensed Products or Licensed Compounds outside the Territory where such Commercialization would infringe an AbbVie Patent granted and in force;

(b) Licensed Products or Licensed Compounds to any Third Party that the Licensee knows, believes or ought reasonably to suspect will Commercialize Licensed Products or Licensed Compounds outside the Field where such Commercialization would infringe an AbbVie Patent granted and in force; nor

(c) Licensed Compounds to any Third Party that the Licensee knows, believes or ought reasonably to suspect will Commercialize the Licensed Compounds other than in a Licensed Product, where such Commercialization would infringe an AbbVie Patent granted and in force.

5.3 Product Labeling. The labeling of all Licensed Products sold or offered for sale under this Agreement shall expressly state that the Licensed Product is manufactured under a license from the Medicines Patent Pool.

5.4 Audit. Licensee shall permit Licensor and AbbVie, individually or together, to: (i) inspect and audit the performance of, and compliance with, this Agreement and the AbbVie-MPP Agreement and applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of this Agreement. Licensee will cooperate with and provide all reasonable assistance to AbbVie or Licensor and their officers, employees, agents, advisors, representatives or contractors exercising the rights of AbbVie and Licensor under this Section 5.4. AbbVie or Licensor will provide Licensee with a commercially reasonable period of notice of the proposed audit; *provided, however*, dispute as to such notice shall not limit Licensee's obligations under this section. AbbVie and Licensor, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Licensee to perform in compliance with this Agreement, the AbbVie-MPP Agreement or applicable laws.

5.5 The terms governing product diversion in this Agreement and the right of Licensor to terminate pursuant to Section 10.3(b) will apply only with respect to Licensed Product or Licensed Compound that is Manufactured or Developed pursuant to the rights granted to Licensee under this Agreement and Commercialized outside of the Field or the Territory. This Agreement does not modify any Party's rights or obligations with respect to any other agreement between the Parties or between a Party and AbbVie.

6. Representations, Warranties and Covenants

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

(a) it is duly organized, validly existing and in good standing under the laws



of the jurisdiction of their incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

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

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

6.2 Law Compliance

(a) General. Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all applicable laws and regulations, including, without limitation, with respect to (i) recalls, safety and reporting requirements and shall obtain, have and maintain all necessary regulatory approvals (including in India), marketing authorizations, permits and licenses, at Licensee's expense for the manufacture and sale of the Licensed Compound or Licensed Product and any other Licensee activities contemplated hereby, and (ii) all applicable anti-bribery and corruption laws (including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010) and, in particular, Licensee will not, directly or indirectly, offer, promise or give any financial or other advantage and or pay money or anything of value to government officials, political parties, candidates and any other person for the purposes of corruptly obtaining or retaining business. Licensee will certify to Licensor in writing, at the frequency requested by Licensor (and at least once annually), compliance with their obligations under this Agreement (including compliance with the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010).

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

6.3 OFAC. The Licensee represents that neither the Licensee nor, to the knowledge of the Licensee, any director, officer, employee of the Licensee, is an individual or entity ("**Person**") that is, or is owned or controlled by Persons that are the target of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control ("**Sanctions**") or located, organized or resident in a country or territory that is the target of country-wide or territory-wide Sanctions (collectively, "**Sanctions Target**"). The Licensee represents and covenants that, prior to making the Patents or any Licensed Product available, directly or indirectly, to any Person that is a Sanctions Target, it will obtain a license or other authorization, either directly or through Licensor, from OFAC.

6.4 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, LICENSEE ACKNOWLEDGES AND AGREES THAT (I) THE ABBVIE PATENTS ARE LICENSED TO LICENSEE "AS IS" AND (II) NEITHER LICENSOR NOR ABBVIE MAKE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE LICENSED COMPOUNDS, LICENSED PRODUCTS, ABBVIE PATENTS OR ANY OTHER MATTER UNDER THIS AGREEMENT INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT. IN PARTICULAR, AND WITHOUT LIMITING THE FOREGOING, ABBVIE WILL HAVE NO LIABILITY IN THE EVENT THE EXERCISE



BY LICENSEE OF ITS RIGHTS UNDER THIS AGREEMENT INFRINGES THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. Licensors also does not give any warranty, express or implied, with regard to the safety or efficacy of any Licensed Compound or Licensed Product and it shall be the sole responsibility of the Licensee to ensure such safety or efficacy.

7. Liability and Indemnity

(a) **Licensee Indemnity.** Licensee shall jointly and severally indemnify, hold harmless and defend Licensors and AbbVie and its Affiliates, licensors, which licensors include AbbVie's Collaboration Agreement partner, directors, officers, employees and agents (together, the "Indemnitees"), from and against any and all losses, damages, expenses, cost of defense (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 because of any Third Party claim against it (i) arising out of any breach by Licensee of the terms and conditions of this Agreement, or (ii) for any product liability, liability for death, illness, personal injury or improper business practice, or any other statutory liability or any other liability under any law or regulation, to the extent that such claim or claims are due to reasons caused by or on behalf of Licensee related to this Agreement or a Licensed Product (including, without limitation, their manufacture, use or sale). The indemnification obligations of Licensee stated in this Section 7(a) shall apply only in the event that Licensors or AbbVie, as applicable, provides Licensee with prompt written notice of such claims, grants Licensee the right to control the defense or negotiation of settlement, and makes available all reasonable assistance in defending the claims; *provided, however*, no settlement of such a claim shall be binding upon Licensors or AbbVie without their prior written consent.

(b) **Product Liability.** Licensee shall be solely responsible for any product liability or any other statutory liability under any regulation, in respect of any Licensed Product or aspect thereof.

(c) **Licensors Liability.** NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, IN NO EVENT SHALL LICENSORS BE LIABLE TO LICENSEE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOSS OF BUSINESS OR PROFITS) RELATED TO THIS AGREEMENT, AND SHALL NOT HAVE ANY RESPONSIBILITIES OR LIABILITIES WHATSOEVER WITH RESPECT TO LICENSED COMPOUNDS OR LICENSED PRODUCTS, EVEN IF, IN ANY SUCH CASE, 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.

8. Insurance

Within 30 days prior to the first commercial launch by Licensee of a Licensed Product, and each year thereafter for so long as this Agreement is in effect, Licensee shall provide to Licensors certificates of insurance by insurers acceptable to Licensors evidencing comprehensive general liability coverage, including products liability, with a combined limit of no less than 10 million dollars (\$10,000,000.00) for bodily injury, including personal injury, and property

damage. Licensee shall not cancel any such policy without at least 60 days prior written notice to Licensor, and agrees that such policy shall be maintained (or have an extended reporting period) of at least 7 years after the termination of this Agreement.

9. Statements and Remittances

9.1 At all times the Licensee shall keep, and shall require its Affiliates and any third party manufacturers and third parties making sales on its behalf to keep, complete and accurate records for the previous two years (or for the period from the Effective Date to the then current date if such period is less than two years) of all quantities of Licensed Compounds and Licensed Products manufactured or sold under the licenses granted by this Agreement, together with that information contemplated by Section 9.2. The Licensor shall have the right (and the Licensee shall procure such right), at its expense, through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the term of this Agreement and for six months after its termination or expiry; *provided, however*, that such examination shall not take place more often than twice in any calendar year and shall not cover such records for more than the preceding two calendar years and provided further that such accountant or like person shall report to Licensor only as to:

(a) the accuracy of the manufacturing and sales statements of the Licensee (and its Affiliates and its third party manufacturers contemplated by this Agreement) in relation to such manufacture and sales

(b) the appropriateness of quantities of Licensed Compounds and Licensed Products imported or manufactured pursuant to this Agreement by reference to what quantities of Licensed Compounds and Licensed Products would reasonably be required to meet demand for actual sales made and sales forecasted by the Licensee;

(c) verification that all sales and other supplies of Licensed Compounds and Licensed Products made by the Licensee have been made in the Territory, except for Licensed Compounds and Licensed Products made outside the Territory as expressly provided for in this Agreement;

(d) verification that all sales and other supplies of Licensed Compounds and Licensed Products made by Third Party manufacturers contemplated by this Agreement have been made to the Licensee in accordance with this Agreement.

9.2 Within 10 Business Days following the end of each Agreement Quarter, the Licensee shall deliver to Licensor a statement accounting for all Licensed Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee in the Territory under this Agreement during such Agreement Quarter in the Reporting Template as set forth in Exhibit E, as well as the amount of Licensed Compound manufactured under this Agreement for the purpose of making Licensed Products. Licensor 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 AbbVie (with AbbVie treating such reports as Confidential Information); and that aggregated data may be publicly disclosed by Licensor.



10. Term and Termination

10.1 Term. This Agreement shall enter into force upon the Effective Date and, unless earlier terminated as provided herein, shall continue until the expiration of the last-to-expire AbbVie Patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of Licensed Compound or the Licensed Product in the Field in the Territory.

10.2 Termination for Breach. A Party ("non-breaching party") shall have the right to terminate this Agreement in the event the other Party ("breaching party") is in material breach of any of its material obligations under this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party shall have a period of 30 days after such written notice is provided to cure such breach. If such breach is not cured within the 30 day period, this Agreement shall effectively terminate.

10.3 Licensor Right to Terminate. Licensor shall have the right to immediately terminate this Agreement if:

(a) upon a Change of Control of Licensee, Licensor reasonably determines, after conferring with Licensee, that the Change of Control is significant and adversely impacts the ability of the parties to achieve the objectives of this Agreement;

(b) Licensee breaches any of the anti-diversion provisions of Section 5;

(c) Licensor reasonably determines that, due to material deficiencies in Licensee's compliance, or repeated failure to comply, with the quality requirements of Section 3.2, Licensee is unable to manufacture Licensed Compound or Licensed Product in accordance with such quality requirements;

(d) Licensee repeatedly fails to meet the milestones as contemplated in Section 3.4 of this Agreement; or

(e) Licensee repeatedly fails to comply with or to timely provide Licensor with the reports contemplated under Sections 3.5 and 9.2 of this Agreement;

(f) Licensee breaches Section 2.2 herein, but only after a failure of Licensee to change its marks, packaging, or color scheme (including pill color), as applicable, to be different and non-confusingly similar.

10.4 Failure to Promote Access. If, in the reasonable opinion of the Licensor, the Licensee fails to promote access to the Licensed Products in the Territory in accordance with this Agreement, the Licensor shall give notice to the Licensee requiring it to cure such failure. If, in the reasonable opinion of the Licensor, the Licensee fails to present an acceptable plan within 60 days and report reasonable progress within 180 days after receiving written notice with respect to the default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee. In making such determination of reasonable progress, the Licensor 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 Sections 3.5 and 9.2 of this Agreement.



10.5 Conversion to Direct License with AbbVie. In the event that the AbbVie-MPP Agreement is terminated or expires, this Agreement shall be converted into a direct license between AbbVie and the Licensee, provided that Licensee is not in breach of this Agreement and subject to AbbVie's rights pursuant to the AbbVie-MPP Agreement.

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

10.7 Waiver. The waiver by any party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

10.8 Survival. Sections 6.4, 7, 8, 9, 10.8, 11.1, 12.3 and 12.7 shall survive termination or expiry of this Agreement.

11. Confidentiality and Publications

11.1 Confidential Information. All technology, know-how, business information, quarterly reports or any other confidential information disclosed by one party (the "**Disclosing Party**") to the other party (the "**Receiving Party**") hereunder ("**Confidential Information**") shall be used solely and exclusively by Receiving Party in a manner consistent with the rights granted hereunder and the purposes of this Agreement as stated in the preamble and recitals hereto; maintained in confidence by the Receiving Party; and shall not be disclosed to any non-party or used for any purpose except to exercise its rights and perform its obligations under this Agreement without the prior written consent of the Disclosing Party, except to the extent that the Receiving Party can demonstrate by competent written evidence that such information: (a) is known by the Receiving Party without obligations of confidentiality 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 Confidential Information provided by the Disclosing Party as documented by the Receiving Party's business records. Within 30 days after any expiration or termination of this Agreement, Receiving Party shall destroy (and certify to the Disclosing Party such destruction) or return all Confidential Information provided by the Disclosing Party except as otherwise set forth in this Agreement. One copy of the Confidential Information may be retained in the Receiving Party's files solely for archival purposes as a means of determining any continuing or surviving obligations under this Agreement. The confidentiality obligations under this Agreement shall survive this Agreement for a period of five (5) years. The Receiving Party may disclose Confidential Information belonging to the other Party to AbbVie to the extent such is reasonably necessary in connection with the performance of the this Agreement.

11.2 Press Release. Each party may disclose to third parties or make public statements, by press release or otherwise, regarding the existence of this Agreement, the identity of the parties, the terms, conditions and subject matter of this Agreement, or otherwise in reference to this Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.

11.3 Publications. Licensee shall not present or publish, or submit for publication, any work resulting from the Agreement or relating to the Licensed Products or the Licensed Compounds.

11.4 Other use of Names. Except as otherwise set forth herein, including in Section 11.2, Licensee shall not use AbbVie's name, trademark, servicemark or logo in any publicity, advertising or announcement, without AbbVie's prior written consent.

12. Miscellaneous

12.1 Agency. Neither Party is, nor will be deemed to be, an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other party in any way without prior written authority from the other Party.

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

12.3 Third Party Beneficiary. The parties hereto acknowledge that AbbVie is intended to be and constitutes a third party beneficiary of the representation, warranties, covenants and agreements of Licensee and AbbVie is entitled to enforce the terms and provisions of this Agreement on its own behalf to the same extent as Licensor.

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

12.5 Notices

(a) Any notice or other communication to be given under this Agreement, unless otherwise specified, shall be in writing and shall be deemed to have been provided when delivered to the addressee at the address listed below (i) on the date of delivery if delivered in person or by facsimile (receipt confirmed) or email (receipt confirmed) or (ii) three days after mailing by registered or certified mail, postage paid:

In the case of Licensor:

Medicines Patent Pool
Rue de Varembe 7
Geneva 1202
Switzerland



Attention: General Counsel
E-mail: office@medicinespatentpool.org

In the case of Licensee:

Plot No. 564/A/22, Road No. 92

Jubilee Hills, Hyderabad - 500096

Attention: General Counsel - India & E.M.
Facsimile:

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

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

12.7 Dispute Resolution. The parties agree that in the event of a dispute they shall first attempt in good faith to resolve such dispute. In the event that such dispute is not resolved on an informal basis, either Party may refer the dispute to the Executive Director of the MPP, and to [Licensee DO] (together, the Designated Officers). If such dispute is not resolved by the Designated Officers within 30 days, the Parties shall submit such dispute to mediation in accordance with the WIPO Mediation Rules. In the event that the dispute remains outstanding after 60 days from the date when it was first discussed (in any manner) between the parties, either party may commence court proceedings. The foregoing however shall not prevent any person from seeking and obtaining injunctive relief at any time.

12.8 Assignment. Neither Party is entitled to transfer or assign this Agreement or the rights and obligations under this Agreement without the other Party's prior written consent.

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


[signatures appear on following page]



IN WITNESS WHEREOF, the parties hereto have executed this License Agreement as of the Effective Date.

LICENSOR:

Medicines Patent Pool

By Charles Gore  Medicines Patent Pool
Name: CHARLES GORE Rue de Varembé 7
Title: EXECUTIVE DIRECTOR 1202 Geneva
Switzerland

LICENSEE:

_____ 
By Arvind Kanda
Name: ARVIND KANDA
Title: HEAD COMMERCIAL - ARV, SA, SAS API

APPROVED AS TO FORM
MYLAN LEGAL DEPT.
DATE: 17/12/2019
By: [Signature]

Exhibit A
Territory

Afghanistan	Fiji	Namibia	Timor-Leste
Angola	Gabon	Nauru	Togo
Antigua and Barbuda	Gambia	Nepal	Tunisia
Bangladesh	Georgia	Niger	Turkmenistan
Belize	Ghana	Nigeria	Tuvalu
Benin	Grenada	Niue	Uganda
Bhutan	Guinea	Pakistan	Vanuatu
Bolivia	Guinea-Bissau	Palau	Vietnam
Botswana	Guyana	Papua New Guinea	West Bank and Gaza
Burkina Faso	Haiti	Philippines	Yemen
Burundi	Indonesia	Rwanda	Zambia
Cambodia	Jordan	Saint Kitts and Nevis	Zimbabwe
Cameroon	Kenya	Saint Lucia	
Cape Verde	Kiribati	Saint Vincent & the Grenadines	
Central African Republic	Laos	Samoa	
Chad	Lesotho	Sao Tome and Principe	
Comoros	Liberia	Senegal	
Cook Island	Libya	Seychelles	
Cote d'Ivoire	Madagascar	Sierra Leone	
Democratic Republic of the Congo	Malawi	Solomon Islands	
Congo, Rep.	Maldives	Somalia	
Djibouti	Mali	South Africa	
Dominica	Marshall Islands	South Sudan	
Egypt	Mauritania	Sri Lanka	
Equatorial Guinea	Mauritius	Sudan	
Eritrea	Micronesia	Suriname	
Ethiopia	Morocco	Swaziland	
	Mozambique	Tanzania	
	Myanmar		

Exhibit B
Manufacturing-Only Countries

India



Exhibit C

Territory Patents

Title	Country	Application Number	Patent Number	Status
ANTI-VIRAL COMPOUNDS	Bolivia	SP-0314-2011-F1		Filed
ANTI-VIRAL COMPOUNDS	Bolivia	SP-00314-2011	6565	Granted
ANTI-VIRAL COMPOUNDS	Egypt	611/2013PCT		Filed
ANTI-VIRAL COMPOUNDS	Indonesia	W00201301506	IDP000042760	Granted
ANTI-VIRAL COMPOUNDS	Philippines	1-2013-500708	1-2013-500708	Granted
ANTI-VIRAL COMPOUNDS	Pakistan	645/2013		Filed
ANTI-VIRAL COMPOUNDS	Pakistan	752/2011		Filed
ANTI-VIRAL COMPOUNDS	Turkmenistan	201390538	024100	Granted
COMPOUNDS INHIBITING REPLICATION OF HEPATITIS C VIRUS AND PHARMACEUTICAL COMPOSITIONS CONTAINING THE COMPOUNDS	Vietnam	1-2014-03573		Filed
COMPOUNDS INHIBITING REPLICATION OF HEPATITIS C VIRUS AND PHARMACEUTICAL COMPOSITIONS CONTAINING THE COMPOUNDS	Vietnam	1-2013-01449	15857	Granted
ANTI-VIRAL COMPOUNDS	South Africa	2013/06888	2013/06888	Granted
ANTI-VIRAL COMPOUNDS	South Africa	2017/05519		Filed
ANTI-VIRAL COMPOUNDS	South Africa	2013/02269		Filed
METHODS FOR TREATING HEPATITIS C	South Africa	2015/01752	2015/01752	Granted
COMBINATION OF TWO ANTIVIRALS FOR TREATING HEPTATITIS C	South Africa	2015/05880	2015/05880	Granted
COMBINATION OF DIRECT ACTING ANTIVIRAL AGENTS AND RIBAVIRIN FOR TREATING HCV PATIENTS	South Africa	2017/05080		Filed
COMBINATION OF DIRECT ACTING ANTIVIRAL AGENTS AND RIBAVIRIN FOR TREATING HCV PATIENTS	South Africa	2015/06031	2015/06031	Granted
NUCLEOTIDE AND NUCLEOSIDE THERAPEUTICS COMPOSITIONS AND USES	Bolivia	SP-0226-2014		Filed



RELATED THERETO				
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Egypt	PCT 2175/2017		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Egypt	PCT84/2018		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Indonesia	P00201800608		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Indonesia	P00201801161		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Philippines	1-2017-502426		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Philippines	1-2018-500132		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Vietnam	1-2018-00320		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	Vietnam	1-2018-00634		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	South Africa	2018/00533		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	South Africa	2018/01082		Filed
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Bolivia	SP-0292-2011-F1		Filed
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Bolivia	SP-00292-2011	63968	Granted
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Egypt	481/2013		Filed



MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Indonesia	W00201301596		Filed
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Philippines	1-2013-500533	1-2013-500533	Granted
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Pakistan	683/2011		Filed
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	Turkmenistan	201500728	029145	Granted
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS AND A PHARMACEUTICAL COMPOSITION FOR USE IN TREATING A VIRAL INFECTION	Turkmenistan	201390425	023009	Granted
HCV PROTEASE INHIBITORS AND PHARMACEUTICAL PRODUCTS CONTAINING THEREOF (MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS)	Vietnam	1-2013-01552		Filed
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	South Africa	2013/08655	2013/08655	Granted
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	South Africa	2013/02317	2013/02317	Granted

Exhibit D**Non-Territory Patents**

Title	Country	Application No.	Application Date	Patent No.	Status
ANTI-VIRAL COMPOUNDS	India	201818021052	6/5/2018		Filed
ANTI-VIRAL COMPOUNDS	India	1310/DELNP/2013	10/12/2011		Filed
MACROCYCLIC PROLINE DERIVED HCV SERINE PROTEASE INHIBITORS	India	2891/DELNP/2013	9/20/2011		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	India	201817002543	6/24/2016		Filed
SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV	India	201817004313	7/18/2016		Filed



Exhibit E

Quarterly Reporting Template

API:

Month	Country	Purchaser	Name of API	Quantity (kg)	Total Value (USD)

Formulations:

Month	Country	Product	Customer/ Reseller Name	Strength	Formulation (IR Tablet/ scored / Dispersible)	Pack Size	Quantity (number of packs)	Total Value USD (FOB)*

* Please mention FOB (Free on Board) price basis country of origin
Note: this format is to be filled and sent to Licensor on a quarterly basis, 10 Business days from end of each calendar quarter.

Exhibit F

Developing & Filing Reporting Template

API:

Development Timelines	Start date (mm/yy)	End Date (mm/yy)
API Name (e.g. Glicepvir API)		
01. Investigation and route selection		
02. R&D Batch API		
03. Lab scale batch API		
04. RM Procurement		
05. API Trial Batch		
06. API Validation Batches		
07. API Stability loading		
08. API Stability Study		
09. DMF Compilation		
10. DMF Filing USFDA		
11. DMF Filing WHO-PQ		

Formulations:

Development Timelines	Start date (mm/yy)	End Date (mm/yy)
Product Name (e.g. glicepvir/pibrentasvir; other combinations)		
01. Development set-up		
02. Trial Batch		
03. Pilot BE		
04. Exhibit batches		
05. Pivotal BE		
06. Stability loading in different packs		
07. Stability data 6 months		
08. Dossier Compilation		
09. DF Dossier Filing USFDA		
10. DF Dossier Filing WHO		
11. DF Dossier Filing Rest of the World		



Country Filing Report

Country Name	Product Name
	Please fill in below the quarter and year in which you expect to file the product in respective country (e.g. Q1-19)

