

## AMENDED AND RESTATED LICENSE AGREEMENT

This AMENDED AND RESTATED LICENSE AGREEMENT (the “**Agreement**”) is made as of [redacted], 2017 (the “**Amended and Restated Effective Date**”) by and between **Gilead Sciences Ireland UC**, an Irish unlimited liability company having its principal place of business at IDA Business & Technology Park, Carigtohill, Co. Cork, Ireland (“**Gilead**”), and [Name of Licensee], a [type of company], and having a registered office at [address of Licensee] (“**Licensee**”). Gilead and Licensee may each be referred to herein as a “**Party**” or collectively as the “**Parties**.”

### RECITALS

WHEREAS, Gilead wishes to facilitate access to its proprietary compounds sofosbuvir, ledipasvir, velpatasvir and voxilaprevir to treat patients with Hepatitis C Virus (“**HCV**”) in low income countries, as identified in this Agreement, via certain non-exclusive licenses to Licensee with respect to the manufacture and sale of such proprietary compounds and products incorporating such proprietary compounds; and

WHEREAS, Licensee wishes to obtain such non-exclusive licenses to facilitate patient access to Products in the Territory, all as more fully described in this Agreement below; and

WHEREAS, to accomplish this goal, Gilead and Licensee entered into that certain License Agreement, effective [effective date of Original License Agreement] (the “**Original Effective Date**”), as amended (the “**Original License Agreement**”), under which certain non-exclusive licenses were granted to Licensee with respect to the manufacture and sale of sofosbuvir, ledipasvir, and velpatasvir, and products incorporating the foregoing; and

WHEREAS Gilead and Licensee now wish to amend and restate the terms of the Original License Agreement.

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 to amend and restate the terms of the Original License Agreement as follows:

### 1. Definitions

1.1 “**Affiliate**” means, with respect to a Party to this Agreement, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to applicable law of the country of incorporation or domicile), as applicable.

1.2 “**API**” means, individually and collectively, the following active pharmaceutical ingredients: (i) sofosbuvir (“**Sof**”), (ii) ledipasvir (“**LDV**”), (iii) velpatasvir (“**Vel**”), and (iv) voxilaprevir (“**Vox**”), the structures of each such compounds are disclosed in the Patents.

1.3 “**API Net Sales**” means, with respect to a given calendar quarter, the total amount received by Licensee from Ex-India LPSs as consideration for its supply of API to such Ex-India LPSs, less the following deductions calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP): (i) freight, insurance, packing, shipping charges, in each case as actually incurred and, to the extent applicable, included as a specific line item on a bill or invoice to such Ex-India LPSs; (ii) custom duty of imported components, VAT/Indian excise tax, sales tax, or other governmental charges upon or measured by the production, sale transportation, delivery or use of goods, in each case, to the extent applicable, included as a specific line item on a bill or an invoice to such Ex-India LPSs; and (iii) trade, quantity and cash discounts allowed and taken, refunds, chargebacks and any other allowances given (as determined in accordance with GAAP) and taken which effectively reduce the gross amounts billed or invoiced; in each of (i) through (iii) to the extent consistently applied across all supply of active pharmaceutical ingredients by Licensee.

1.4 “**Authorized Third Party**” means, individually and collectively, Licensed API Suppliers, Gilead API Suppliers, Licensed Product Suppliers, Limited Sublicensees, Product CMOs, Gilead Distributors, and Licensee Distributors.

1.5 “**Confidential Information**” shall have the meaning set forth in Section 11.1.

1.6 “**Combination Products**” means, individually and collectively, Sof/LDV Products, Sof/Vel Products, and Sof /Vel/Vox Products.

1.7 “**Ex-India LPS**” means a third party that is located in a country in the Territory other than India, and that has entered into a written agreement directly with Gilead pursuant to which Gilead grants such third party a license to manufacture and sell Product only in specified country(ies) in the Territory. As of the Amended and Restated Effective Date, only the entities set forth on Appendix 4 are Ex-India LPSs.

1.8 “**FDA**” means the United States Food and Drug Administration, and any successor agency thereto.

1.9 “**Field**” means with respect to a particular Product any use that is consistent with the label approved by the FDA or applicable foreign regulatory authority in the country of sale for the use of such Product.

1.10 “**Gilead API Supplier**” means such contract manufacturing organization designated by Gilead that the Parties may agree to include as part of this definition by written amendment to this Agreement.

1.11 “**Gilead Distributor**” means any third party distributor that is operating under an agreement with Gilead for the distribution and sale of Gilead’s branded product in one or more countries within the Territory.

1.12 “**Gilead Mark**” shall have the meaning set forth in Section 2.5(b).

1.13 “**Improvements**” shall have the meaning set forth in Section 2.2.

1.14 “**India LPS**” means an entity (other than Licensee) located in India that is licensed by Gilead to make, use, sell, have sold, offer for sale and export Product in the Field in the Territory.

1.15 “**LDV Product**” means a formulated and finished pharmaceutical product containing LDV as its sole active pharmaceutical ingredient.

1.16 “**Licensed API**” means API that is either (a) made by Licensee pursuant to the license grant set forth in Section 2.1(a)(i); or (b) acquired by Licensee from a Gilead API Supplier or from a Licensed API Supplier on the terms and conditions set forth in Section 3.2.

1.17 “**Licensed API Supplier**” means an entity (other than Licensee) that is located in India and licensed by Gilead to manufacture and sell API to third parties in the Field in the Territory.

1.18 “**Licensed Know-How**” means (a) the know-how actually transferred to Licensee pursuant to the terms of Section 5.5 (either prior to or following the Amended and Restated Effective Date) and (b) any other improvements or modifications to such transferred know-how (x) that are (i) specific to API and (ii) developed and controlled by Gilead during the term of this Agreement, and (y) specifically excluding any such improvements and modifications, methods and other know-how claimed in any patent or patent application.

1.19 “**Licensed Product Supplier**” means, individually and collectively, India LPSs and Ex-India LPSs.

1.20 “**Licensed Technology**” means the Patents and the Licensed Know-How.

1.21 “**Licensee Distributor**” means a third party wholesaler or distributor that is not a Gilead Distributor and that is operating under an agreement with Licensee or a Limited Sublicensee for the distribution and sale of Product in the Territory.

1.22 “**Limited Sublicensee**” means those third parties, or Affiliates of Licensee, in each case which are located in the Territory, and to which Licensee has granted a sublicense under its rights set forth in the Agreement to manufacture Product in a particular country in the Territory for sale in such country in the Territory, all in accordance with the terms set forth in Section 3.4.

1.23 “**Minimum Quality Standards**” shall have the meaning set forth in Section 6.2(a).

1.24 “**NCE Exclusivity**” means the five years of marketing exclusivity granted by FDA pursuant to its authority under 21 U.S.C. §§ 355(c)(3)(E)(ii) and 355(j)(5)(F)(ii), or similar regulatory exclusivity granted by the appropriate regulatory authority having jurisdiction over the Products.

1.25 “**Net Sales**” means, with respect to a given calendar quarter, the total amount invoiced by Licensee and Limited Sublicensees for sales of Product in the Territory to third parties, less the following deductions calculated in accordance with U.S. Generally Accepted Accounting Principles (GAAP): (a) freight, insurance, packing, shipping charges, in each case as actually incurred and included as a specific line item on a bill or invoice to such third party; (b) custom duty of imported components, VAT/Indian excise tax, sales tax, or other governmental charges upon or measured by the production, sale transportation, delivery or use of goods, in each case included as a specific line item on a bill or an invoice to such third party; (c) trade, quantity and cash discounts allowed and taken, refunds, chargebacks and any other allowances given (as determined in accordance with GAAP) and taken which effectively reduce the gross amounts billed or invoiced; in each of (a) through (c) to the extent consistently applied across all products of Licensee. Net Sales on Combination Products shall be calculated based on the portion of product Net Sales attributable to Licensed API, as set forth in Section 4.3(d).

1.26 “**Other Combination Product**” means a formulated and finished pharmaceutical product containing one or more API(s) in combination with any other active pharmaceutical ingredient(s), including any co-formulation, co-packaged product, bundled product, or other type of combination product, but excluding Combination Products.

1.27 “**Patents**” means (a) the patents and patent applications set forth in Appendix 2 hereto and (b) any other patents or patent applications (and resulting patents therefrom) that are in the Territory and (i) owned and controlled by Gilead and its Affiliates during the term of this Agreement and (ii) necessary for Licensee to practice the licenses granted in Article 2 hereof, including to the extent falling within clause (b) of this definition patents and patent applications claiming improvements or modifications to the manufacture of API, in each of (a) and (b) solely to the extent the claims in such patents and patent applications cover the manufacture, use or sale of API.

1.28 “**Product**” means, individually and collectively, Sole API Product, Combination Product, and Other Combination Product.

1.29 “**Product CMO**” means those contract manufacturing organization(s) (including an Affiliate manufacturing organization(s)) (i) which are located in a particular country in the Territory and (ii) which are engaged by Licensee to manufacture (on behalf of Licensee) Product in such country for Licensee’s sale within such country.

1.30 “**Product Patent**” shall have the meaning set forth in Section 4.3(b).

1.31 “**Quarterly Report**” shall have the meaning set forth in Section 4.4.

1.32 “**Royalty Term**” shall have the meaning set forth in Section 4.10.

1.33 “**Sof Product**” means a formulated and finished pharmaceutical product containing Sof as its sole active pharmaceutical ingredient.

1.34 “**Sof/LDV Product**” means a formulated and finished pharmaceutical product containing Sof and LDV as its sole active pharmaceutical ingredients, whether as a co-formulation, co-packaged product, bundled product, or other type of combination product.

1.35 “**Sof/Vel Product**” means a formulated and finished pharmaceutical product containing Sof and Vel as its sole active pharmaceutical ingredients, whether as a co-formulation, co-packaged product, bundled product, or other type of combination product.

1.36 “**Sof/Vel/Vox Product**” means a formulated and finished pharmaceutical product containing Sof, Vel and Vox as its sole active pharmaceutical ingredients, whether as a co-formulation, co-packaged product, bundled product, or other type of combination product.

1.37 “**Sole API Product**” means, individually and collectively, Sof Products, LDV Products, Vel Products, and Vox Products.

1.38 “**Territory**” means the countries set forth on Appendix 1.

1.39 “**Third Party Reseller**” means, individually and collectively, Licensee Distributors and Gilead Distributors.

1.40 “**Vel Product**” means a formulated and finished pharmaceutical product containing Vel as its sole active pharmaceutical ingredient.

1.41 “**Vox Product**” means a formulated and finished pharmaceutical product containing Vox as its sole active pharmaceutical ingredient.

## 2. License Grants

### 2.1 Licenses.

(a) API License. Subject to the terms and conditions of this Agreement (including but not limited to the terms of this Article 2), Gilead hereby grants to Licensee a non-exclusive, non-sublicensable, non-transferable license under the Licensed Technology to:

(i) make API only in India;

(ii) sell or otherwise supply Licensed API only in the Territory and solely to Product CMOs and Limited Sublicensees for use solely for purposes set forth in this Agreement; and

(iii) sell or otherwise supply Licensed API only in the Territory and solely to Licensed Product Suppliers (including sublicensees and contract manufacturers of Licensed Product Suppliers) for use solely for purposes set forth in the Licensed Product Supplier’s license from Gilead.

(b) Product License. Subject to the terms and conditions of this Agreement, Gilead hereby grants to Licensee a royalty-bearing, non-exclusive, non-sublicensable (other than as provided in Section 2.3 below), non-transferable license under the Licensed Technology solely to:

(i) make Product on its own from Licensed API in the Territory; and

(ii) sell, have sold, offer for sale such Product made from Licensed API in the Territory for the Field.

(c) Restrictions on License Scope. The licenses granted in this Section 2.1 do not include, expressly or by implication, a license under any Gilead intellectual property right to manufacture, use, sell or distribute any product containing any active pharmaceutical ingredients owned or controlled by Gilead other than Sof, LDV, Vel, and Vox. The licenses granted under this Section 2.1 shall not extend to any active pharmaceutical ingredient owned or controlled by Gilead other than Sof, LDV, Vel, and Vox.

2.2 License Grant to Gilead. Licensee hereby grants to Gilead a nonexclusive, royalty-free, worldwide, sublicensable license to all improvements, methods (including manufacturing processes), modifications and other know-how, including any chemistry improvements or modifications, developed by or on behalf of Licensee and relating to API or a Product (“**Improvements**”), subject to the restrictions on further transfer of Licensee’s technology by Gilead as set forth in Section 5.3. Licensee shall, as between Gilead and Licensee, own all such Improvements and shall, as between Licensee and Gilead, have the sole right, but not the obligation, to pursue intellectual property protection with respect to such Improvements.

2.3 Right to Grant Sublicenses. Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant sublicenses through a single tier (i.e. no Limited Sublicensee will have any further right to grant sublicenses) to Limited Sublicensees to (i) manufacture Product incorporating Licensed API in a particular country in the Territory, and (ii) sell such Product in such country (and only such country).

#### 2.4 Licensee’s Right to Sell.

(a) API Sales. Licensee agrees that it will not sell or offer to sell API to any entity other than to Limited Sublicensees, Product CMOs, and Licensed Product Suppliers located in the Territory, in each case in accordance with this Agreement.

(b) Product Sales. Licensee agrees that it will not sell, offer for sale, or assist third parties (including Affiliates) in selling Product in any country outside of the Territory or for any use outside the Field. Licensee agrees that it will prohibit Third Party Resellers and Licensed Product Suppliers from selling Product (i) to any other wholesaler or distributor, (ii) outside the Territory, or (iii) for any purpose outside the Field.

(c) Limitations on Product Combinations. Licensee will be allowed to manufacture and sell Other Combination Products containing one or more Licensed API in combination with other active pharmaceutical ingredients in the Territory, provided in each case (i) Licensee has the legal right to manufacture and sell such other active pharmaceutical ingredients in the applicable country in the Territory, and (ii) such manufacture and sale is in accordance with the terms and conditions of this Agreement.

#### 2.5 License Limitations.

(a) Gilead Retained Rights. Licensee hereby acknowledges that Gilead retains all right, title and interest in API and Products except as explicitly provided in this Agreement, and

that Gilead may license or otherwise convey to third parties rights with respect to API and Products as it wishes without obligation or other accounting to Licensee.

(b) Gilead Marks. The licenses granted hereunder do not include any license or other right to use any Gilead trade dress, trademark, trade name, logo or service mark (each, a “**Gilead Mark**”) or any word, logo or any expression that is similar to or alludes to any Gilead Mark, except as provided in Section 6.5.

(c) No Other Licenses.

(i) Except as expressly set forth in this Agreement, Licensee agrees that it shall not use any contract manufacturers without obtaining Gilead’s prior written consent, or grant any sublicenses hereunder to any other person, company or entity, including third parties and Affiliates.

(ii) Except as expressly set forth in this Agreement, Gilead does not grant any license under any of its intellectual property rights (including, without limitation, patents or rights to any proprietary compounds or drug substances other than API) to Licensee.

### **3. Sourcing of API; Third Party Arrangements**

3.1 Licensed API. Licensee agrees that it shall not make or use any API, other than Licensed API, for the manufacture of any Product for sale in the Territory.

3.2 Licensed API Suppliers; Gilead API Suppliers. In addition to the terms and conditions set forth in Section 3.6, the terms and conditions set forth in this Section 3.2 shall apply to Licensee’s engagements with Licensed API Suppliers and Gilead API Suppliers, as applicable, under this Agreement.

(a) Termination of Right to Use API Acquired From a Licensed API Supplier to Make Product. Licensee’s right to use API acquired from a Licensed API Supplier to make Product hereunder shall remain in effect solely for so long as such Licensed API Supplier was, at the time of Licensee’s acquisition of such API, compliant with the terms and conditions of its license agreement with Gilead, and provided such license agreement with Gilead was effective at the time of Licensee’s acquisition of such API.

(b) Gilead Assistance. Upon Gilead’s receipt from Licensee of a written notice describing its intention to obtain Licensed API from a Gilead API Supplier, Gilead shall use commercially reasonable efforts to assist Licensee in procuring supply of API from such Gilead API Supplier. Gilead shall not be obligated to assist Licensee in procuring any supply of API from a Licensed API Supplier.

(c) Agreement with Gilead API Supplier. Gilead shall be a party to all agreements that provide for the supply of API to Licensee from a Gilead API Supplier. All such agreements shall include and be subject to the following conditions:

(i) Licensee shall not obtain API from the Gilead API Supplier until Gilead has received confirmation in writing from the Gilead API Supplier of its ability to

continue to supply Gilead with Gilead's forecasted requirements of API, as reflected in Gilead's then-current twelve (12) month forecast for API provided to the Gilead API Supplier.

(ii) The Gilead API Supplier shall be permitted to supply API to Licensee only to the extent that any such supply does not (A) adversely affect its ability to meet Gilead's forecasted requirements or (B) adversely affect the Gilead API Supplier's ability to supply Gilead's requirements, whether or not such requirements are consistent with Gilead's twelve (12) month forecast. Gilead shall have the right to terminate any agreement between Licensee and its Gilead API Suppliers if the supply of API from such Gilead API Supplier to Licensee adversely affects Gilead's supply requirements as set forth in this Section 3.2(c)(ii).

(d) No Other Arrangements. Licensee agrees that it shall not enter into any agreements, nor amend any existing agreements, for the supply of intermediates or API on terms that are inconsistent with this Agreement without Gilead's prior written approval.

3.3 Licensed Product Suppliers. In addition to the terms and conditions set forth in Section 3.6, the terms and conditions set forth in this Section 3.3 shall apply to Licensee's engagement with Licensed Product Suppliers under this Agreement.

(a) Termination of Right to Sell API to the Licensed Product Suppliers. Licensee's right to sell API to a Licensed Product Supplier hereunder shall remain in effect solely for so long as such Licensed Product Supplier remains compliant with the terms and conditions of its license agreement with Gilead, and provided such license agreement with Gilead has not expired or been terminated. Gilead shall promptly inform Licensee in the event any agreement with any Licensed Product Suppliers terminate.

(b) Payments. No royalties will be owed on Licensee's sale of API to an India LPS, provided such India LPS has executed an agreement with Gilead requiring such India LPS to pay Gilead royalties on finished Product containing such API.

(c) Audits. Gilead has the right to audit, on no less than thirty (30) days' advance notice to Licensee such records of Licensee to the extent necessary to verify its compliance with this Section 3.3.

3.4 Limited Sublicensees; Product CMOs. In addition to the terms and conditions set forth in Section 3.6, the terms and conditions set forth in this Section 3.4 shall apply to Licensee's engagement with Limited Sublicensees and Product CMOs, as applicable, under this Agreement.

(a) Additional Information. With respect to each Limited Sublicensee and Product CMO, Licensee shall include the following information in the notice delivered to Gilead pursuant to Section 3.6(a) for such Limited Sublicensee or Product CMO: (i) the name of such Limited Sublicensee or Product CMO and (ii) each country in the Territory where such Limited Sublicensee or Product CMO will manufacture Product on behalf of Licensee.

(b) Liability. Licensee agrees that (i) the Limited Sublicensee(s) and Product CMO(s) shall be subject to the same terms and conditions set forth in the Agreement, including



terms and conditions pertaining to the manufacture of Product and (ii) Licensee shall remain responsible for Limited Sublicensees and Product CMOs compliance with the terms and conditions of this Agreement. If any act or omission of a Limited Sublicensee or Product CMO would constitute a breach of this Agreement, then Licensee shall be responsible for such act or omission as if such act or omission were performed by Licensee. Without limiting the foregoing, Licensee shall indemnify Gilead in respect of all liability, costs, damages and expenses arising out of or in connection with any such act or omission by a Limited Sublicensee or Product CMO which is suffered by Gilead or any of its Affiliates.

(c) Territory Limitations. Notwithstanding anything to the contrary set forth in the Agreement, the Parties acknowledge and agree that Licensee's and each Limited Sublicensee's rights to commercialize Product manufactured by a Product CMO or such Limited Sublicensee shall be limited to the country in the Territory in which such Product CMO or Limited Sublicensee manufactures such Product.

(d) Additional Terms. Without limiting Section 3.6, Licensee covenants and agrees that with respect to (i) API imported into a country in the Territory as set forth hereunder and (ii) Product manufactured from such API, Licensee shall require under its written agreements with Product CMOs and Limited Sublicensee(s) that each such Product CMO or Limited Sublicensee will not: (A) divert or knowingly allow the diversion of such API outside of the country in the Territory in which such Product CMO or Limited Sublicensee manufactures such Product, (B) divert or knowingly allow the diversion of such Product outside the country in the Territory in which such Product CMO or Limited Sublicensee manufactures such Product, or (C) assist or support, directly or indirectly, any third party in the conduct of the activities described in clauses (A) or (B) of this Section 3.4(d).

(e) Payments. Licensee will not be required to pay royalties to Gilead for the provision of Licensed API to a Limited Sublicensee or Product CMO, *provided however*, that any subsequent sale or transfer of Product incorporating such API shall be royalty-bearing in accordance with the terms and conditions set forth in this Agreement, including without limitation Article 4.

(f) Audits. Licensee will procure from each Limited Sublicensee the right for Gilead to audit such Limited Sublicensee in accordance with the terms of Section 4.7. In the event Licensee is unable to secure such right from any Limited Sublicensee, upon the request of Gilead, Licensee shall perform an audit of such Limited Sublicensee in the scope set forth in Section 4.7.

(g) Limitations on Number of Limited Sublicensees and CMOs. Notwithstanding anything to the contrary in this Section 3.4, Licensee will have the right to appoint no more than one (1) Limited Sublicensee or CMO (but for clarity not both a Limited Sublicensee and CMO) in each country within the Territory.

3.5 Gilead Distributors. In addition to the terms and conditions set forth in Section 3.6, the terms and conditions set forth in this Section 3.5 shall apply to Licensee's engagement of Gilead Distributors and Licensee Distributors, as applicable, under this Agreement.

(a) Gilead Distributors. Licensee may elect to sell Product in the Territory to a Gilead Distributor for the Field, provided that, Licensee shall only sell to such Gilead Distributor those Products that are bioequivalent to the branded products Gilead has granted such Gilead Distributor the right to sell in such country of the applicable Territory. Licensee shall only allow such Gilead Distributor to sell such Product within the country(ies) of the applicable Territory for which such Gilead Distributor has the right to sell branded Gilead product, and may not allow such Gilead Distributor to sell or offer for sale such Product outside the applicable Territory, and may not import such Product into any country outside the applicable Territory. Gilead will provide Licensee with a list, which may be updated by Gilead from time to time, of the identity of the Gilead Distributors and their licensed territories.

(b) Audits. Gilead has the right to audit, on no less than thirty (30) days' advance notice to Licensee such records of Licensee to the extent necessary to verify its compliance with this Section 3.5.

### 3.6 All Authorized Third Parties.

(a) Agreement; Notice. With respect to each Authorized Third Party engaged by Licensee under this Agreement, Licensee shall enter into a written agreement with such Authorized Third Party that is consistent with the terms and conditions of this Agreement prior to engagement of such Authorized Third Party under this Agreement, and Licensee shall notify Gilead of such agreement in writing within thirty (30) days thereafter. In the event of a conflict between this Agreement and any agreement between Licensee and such third party, the terms of this Agreement shall control.

(b) Gilead's Right to Review; Third Party Beneficiary. Upon Gilead's request, Licensee shall provide Gilead with a written copy of Licensee's agreement(s) with an Authorized Third Party and/or Licensee shall certify to Gilead in writing that such agreement(s) is/are consistent with the terms and conditions of this Agreement. Gilead shall 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, Gilead, Gilead shall have the right to require Licensee to amend such agreement with such Authorized Third Party to be consistent with the terms and conditions of this Agreement. If Licensee fails to enter into such amendment within a period of thirty (30) days following the date that Gilead makes such requirement, Gilead will have the right to immediately terminate Licensee's right under this Agreement to engage such Authorized Third Party. Further upon Gilead's request, Licensee shall name Gilead as a third party beneficiary in any such agreement, in which case Licensee shall consent and hereby does consent to Gilead's enforcement of such agreement to the extent relating to the obligations that Licensee is required hereunder to impose on such Authorized Third Party.

(c) Termination of Agreements. If any act or omission of an Authorized Third Party would constitute a breach of this Agreement by Licensee if such act or omission had been made by Licensee, at Gilead's sole discretion, Gilead may terminate Licensee's right to engage such Authorized Third Party, and/or require Licensee to terminate such engagement, in which case Licensee shall, immediately terminate its agreement(s) with such Authorized Third Party.

#### **4. Consideration/Payment Terms/Audit**

4.1 Licensed API Royalty. As consideration for the licenses granted in Section 2.1(a), Licensee shall pay Gilead the following royalties on API Net Sales of Licensed API:

(a) 3% of API Net Sales of Licensed API sold to an Ex-India LPS (or sublicensee or contract manufacturers of an Ex-India LPS) before first anniversary of the Amended and Restated Effective Date.

(b) 10% of API Net Sales of Licensed API sold to an Ex-India LPS (or sublicensee or contract manufacturers of an Ex-India LPS) on or after the first anniversary of the Amended and Restated Effective Date.

4.2 Product Royalty. As consideration for the licenses granted in Section 2.1(b), Licensee shall pay Gilead the following royalties on Net Sales of Product in the Territory for the duration of the Royalty Term:

(a) Sole API Product:

(i) 12% of Net Sales of Sof Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of Sof Product in all other countries within the Territory;

(ii) 12% of Net Sales of LDV Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of LDV Product in all other countries within the Territory;

(iii) 12% of Net Sales of Vel Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of Vel Product in all other countries within the Territory;

(iv) 12% of Net Sales of Vox Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of Vox Product in all other countries within the Territory;

(b) Combination Products:

(i) 12% of Net Sales of Sof/LDV Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of Sof/LDV Product in all other countries within the Territory;

(ii) 12% of Net Sales of Sof/Vel Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of Sof/Vel Product in all other countries within the Territory;

(iii) 12% of Net Sales of Sof/Vel/Vox Product in Malaysia, Thailand and Ukraine, and 7% of Net Sales of Sof/Vel/Vox Product in all other countries within the Territory;

(c) Other Combination Products: 12% of the portion of Net Sales of Other Combination Products in Malaysia, Thailand and Ukraine attributable to the API component(s) of such Other Combination Products, as determined in accordance with Section 4.3(d); and 7% of the portion of Net Sales of Other Combination Products in all other countries within the Territory

attributable to the API component(s) of such Other Combination Products, as determined in accordance with Section 4.3(d).

For clarity, Licensee shall pay Gilead royalties on sale of Product by its Limited Sublicensee(s). Royalties on sales of Product to Gilead Distributors will be based on Licensee's invoice price to such Gilead Distributor.

#### 4.3 Royalty Reduction.

(a) WHO Pre-Qualification. Following receipt of WHO pre-qualification approval for a Product, the royalty rate for such Product (or in the case of an Other Combination Product, the royalty rate attributable to the API component(s) of such other Other Combination Product) set forth in Section 4.2 shall be reduced to 9% for sales in Malaysia, Thailand and Ukraine, and to 4% for sales in all other countries within the Territory.

(b) Product Patent. On a Product by Product and country by country basis, if there is no Product Patent (as defined below) owned or controlled by Gilead (or its Affiliates) in India or the country in which such Product is manufactured and/or sold, and if there is no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals)) in India or the country in which such Product is manufactured and/or sold, then Gilead agrees to negotiate in good faith a reduction on the royalty due with respect to such Product under Section 4.2 of this Agreement on a country by country basis. As used in this Agreement, "**Product Patent**" shall mean any patent or patent application claiming any Product or any API contained in such Product, including any patent or patent application claiming the composition of matter for such Product or API, or their formulation, or any patent or patent application claiming the method of use or method of manufacture with respect to such Product or such API.

(c) Compulsory License. If any country within the Territory issues a valid, bona fide compulsory license pursuant to (1) the requirements promulgated under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) or (2) valid laws within such country ("**Compulsory License**") for any Product, then for the duration of such Compulsory License the royalty payable by Licensee on Net Sales for such Product in such country shall be reduced to the royalty rate paid to Gilead by such country for such Product under such Compulsory License.

(d) Adjustment for Other Combination Products. Solely for the purpose of calculating Net Sales of Other Combination Products, if Licensee sells Product in the form of an Other Combination Product containing any Licensed API and one or more other active pharmaceutical ingredients in a particular country, Net Sales of such Other Combination Product in such country for the purpose of determining the royalty due to Gilead pursuant to Section 4.1 will be calculated by multiplying actual Net Sales of such Other Combination Product in such country by the fraction  $A/(A+B)$ , where A is the invoice price of such Product if sold separately in such country, and B is the total invoice price of the other active pharmaceutical ingredient(s) in the combination if sold separately in such country. If, on a country-by-country basis, such other active pharmaceutical ingredient or ingredients in the Other Combination Product are not sold separately

in such country, but the Product component of the Other Combination Product is sold separately in such country, Net Sales for the purpose of determining royalties due to Gilead for the Other Combination Product will be calculated by multiplying actual Net Sales of such Other Combination Product by the fraction  $A/C$ , where A is the invoice price of such Product component if sold separately, and C is the invoice price of the Other Combination Product. If, on a country-by-country basis, such Product component is not sold separately in such country, Net Sales for the purposes of determining royalties due to Gilead for the Other Combination Product will be  $D/(D+E)$ , where D is the fair market value of the portion of the Other Combination Products that contains the Product, and E is the fair market value of the portion of the Other Combination Products containing the other active pharmaceutical ingredient(s) included in such Other Combination Product, as such fair market values are determined by mutual agreement of the Parties, which shall not be unreasonably withheld.

4.4 Reports. Within sixty (60) days after the end of each calendar quarter, Licensee shall provide Gilead with a detailed report (the “**Quarterly Report**”) that includes at least the information set forth in this Section 4.4 with respect to such calendar quarter.

(a) Product and API Information. In each Quarterly Report, Licensee shall include the following information:

- (i) the quantity of each API and each Product manufactured by Licensee;
  - (ii) the quantity of each API and each Product in Licensee’s stock;
  - (iii) the quantity of each Product Licensee provided to each Third Party Reseller (on a Third Party Reseller by Third Party Reseller basis);
  - (iv) the quantity of each API provided to each Licensed Product Supplier (on a Licensed Product Supplier by Licensed Product Supplier basis), Limited Sublicensee (on a Limited Sublicensee by Limited Sublicensee basis), and Product CMO (on a Product CMO by Product CMO basis);
  - (v) the quantity of each Product manufactured by each Product CMO;
- and
- (vi) the quantity of each API and each Product that Licensee intends to manufacture over the course of the following 12-month period, on a month by month basis.

(b) Payment Information. In each Quarterly Report, Licensee shall include the following information:

- (i) with respect to each API sold to an Ex-India LPS: (A) the financial structure by which Licensee is being compensated for its supply of API to Ex-India LPS (e.g. whether by direct payment for API or as a royalty on sales of Product by such Ex-India LPS) and, as applicable, the total invoiced sales of API or other compensation received as consideration for the supply of API, API Net Sales, the deductions used to

determine API Net Sales, quantity of API sold or otherwise supplied, and (B) total API Net Sales and total royalties owed on such API Net Sales for the calendar quarter;

(ii) with respect to each Product sold, on a country by county basis, and Product by Product basis, total invoiced sales, Net Sales, the deductions used to determine Net Sales, and number of units sold;

(iii) with respect to each Other Combination Product sold, the adjustments made pursuant to Section 4.3(d);

(iv) total royalties owed for the calendar quarter, the countries to which each Product has been sent and in what quantities;

(v) Net Sales by each Third-Party Reseller, if any; and

(vi) with respect to each Product sold by each Third Party Reseller, total invoiced sales, Net Sales, the deductions used to determine Net Sales, and number of Units sold.

(c) Regulatory Information. In each Quarterly Report, Licensee shall include, on a Product-by-Product basis:

(i) the countries within the Territory in which regulatory approval or authorization has been obtained for Product; and

(ii) a description of activities performed by Licensee, its designee or, to its knowledge any other third party, with respect to the filing, obtaining or maintaining of regulatory approvals or authorizations within the Territory for such Product.

(d) No Objection Certificates. In each Quarterly Report, Licensee shall provide Gilead with the following information: (i) any Central Drugs Standard Control Organization (CDSCO) No Objection Certificates (NOC) obtained by the Licensee for Product, including the quantity of Product exported, the final destination of the Product and the recipient of the Product; and (ii) any Central Drugs Standard Control Organization (CDSCO) No Objection Certificates (NOC) obtained by third parties for Product for which Licensee provided assistance, including the quantity of Product exported, the final destination of the Product and the recipient of the Product.

(e) Certifications; Payments. Together with each Quarterly Report, Licensee shall include a written certification of the accuracy of the contents of the Quarterly Report, signed by an appropriate Licensee senior officer. Licensee shall provide Quarterly Reports to Gilead at the address set forth in Section 12.4.

4.5 Payment Terms; Conversion. Licensee shall make all payments to Gilead in US Dollars within sixty (60) days following the end of each calendar quarter. With regard to sales in currencies other than US Dollars, conversion from local currency into US Dollars shall be in accordance with Licensee's normal and customary procedures, as reported in its audited financial statements. Licensee shall pay royalties to Gilead by wire transfer to the bank account indicated by Gilead.

4.6 Records. Licensee shall keep complete and accurate records of API and Product produced and sold in sufficient detail to enable Licensee to determine the amount of royalties due, the Parties to whom Product or API was sold, and the countries in which sales occurred.

4.7 Audit. Gilead has the right to engage an independent public accountant to perform, on no less than thirty (30) days' advance notice to Licensee, an audit, conducted in accordance with generally accepted auditing standards, of such books and records of Licensee that are deemed necessary by such public accountant to report amounts of API and Product produced, gross sales, Net Sales and API Net Sales for the periods requested and accrued royalties. Gilead will bear the full cost of any such audit unless such audit discloses a difference of more than five percent (5%) from the amount of royalties due. In such case, Licensee shall promptly pay Gilead any underpayment and shall bear the full cost of such audit.

4.8 Interest. Any amount payable hereunder by Licensee, which is not paid when due in accordance this Article 4, shall bear a pro rata monthly interest rate of one percent (1%) subject to any necessary approvals that may be required.

#### 4.9 Taxes

(a) Withholding Taxes. Licensee shall promptly pay the withholding tax for and on behalf of Gilead to the proper governmental authority and shall promptly furnish Gilead with the tax-withholding certificate furnished by the Licensee. Licensee shall be entitled to deduct the withholding tax actually paid from such payment due Gilead. Each Party agrees to assist the other Party in claiming exemption from such withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

(b) Other Taxes. Except as provided in this Section 4.9 all taxes or duties in connection with payments made by Licensee shall be borne by Licensee.

4.10 Royalty Term. Royalty payments shall be paid to Gilead by Licensee on country-by-country basis starting on the date of the first commercial sale of a Product in a country and continuing until the last to occur of the following: (a) the date of expiration of the last-to-expire Patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of API or Product in such country; and (b) the date of expiration of the last-to-expire Patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of API or Product in India, and (c) the date of expiration of the last-to-expire Patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of Product in the country in which the Product was made (if not India) (the "**Royalty Term**"). Notwithstanding the foregoing, the Royalty Term for any Product will not extend beyond the date on which all Product Patents covering such Product (or the API contained therein) in the United States expire.

## 5. **Intellectual Property**

5.1 Maintenance of Patents. Gilead shall not be obligated to maintain or enforce the Patents.

5.2 Cooperation. If either Party becomes aware of a suspected infringement of any Patent, or the occurrence of any prohibited activity described in 7.2(a)(i)-(v), such Party will notify the other Party promptly, and following such notification, the Parties agree to discuss the scope of such infringement. Gilead will have the sole right, but not the obligation, to bring an infringement or such other action at its own expense, in its own name, and entirely under its own direction and control. Licensee will reasonably assist Gilead in such actions or proceedings if so requested, and will lend its name to such actions or proceedings if required by law in order for Gilead to bring such an action.

5.3 Reporting of Improvements. Licensee shall provide Gilead with an annual report, in writing and in reasonable detail that sets forth any Improvements, including any patent application claiming Improvements. Licensee shall transfer to Gilead, upon request by Gilead and at Gilead's expense, any know-how owned or controlled by Licensee relating to such Improvements. Any failure to report any such Improvements to Gilead in accordance with the terms of this Agreement shall constitute a breach of this Agreement and shall provide Gilead with the right to terminate this Agreement pursuant to Section 10.2. Gilead shall not transfer any Improvements obtained from Licensee to any third party, provided, however, that Gilead may transfer Improvements to Gilead's own Affiliates and suppliers, provided such Affiliates and suppliers utilize such Improvements solely for the benefit of Gilead.

#### 5.4 Trademarks

(a) Any Product offered for sale or sold under this Agreement shall have a trade dress, including a distinct color, shape and trade name different from and not likely to be confused with, any product sold by or on behalf of Gilead. Licensee's non-performance of the obligations set forth in this Section 5.4(a) shall constitute a material breach of Licensee's material obligations under this Agreement.

(b) Licensee shall provide to Gilead, prior to any regulatory submissions for any Product, or selling or offering for sale any Product, samples of the Product and any packaging, labeling information or marketing materials (including, but not limited to, advertisement and promotional materials) to be used with the Product. Gilead shall have the right to review and approve the trademark and trade dress for such Product and its packaging to determine if such Product or its packaging is likely to be confused with Gilead's trade dress and trademarks, consistent with the requirements set forth in Section 5.4(a). If Gilead reasonably objects to the trade dress or other aspects of the Product or product packaging based on the requirements set forth in Section 5.4(a), the Parties shall discuss in good faith Gilead's concerns and Licensee agrees to make such modifications to the Product or packaging as are necessary to address Gilead's concerns.

(c) Without limiting the requirement with respect to Licensee's use of a trade dress distinct from any Gilead trade dress as described in this Section 5.4 above, Licensee further agrees that, Licensee (whether itself, or through a Limited Sublicensee or a Third Party Reseller) shall have the right to commercialize each Product, under a combined maximum of five (5) separate trademarks or trade names for each such Product. By way of example only, Licensee shall have the right to commercialize all formulations of Sof/LDV Product (whether itself, or through a Limited Sublicensee or a Third Party Reseller) under no more than five (5) different



trademarks or trade names; similarly Licensee shall have the right to commercialize all formulations of Sof/daclatasvir (whether itself, or through a Limited Sublicensee or a Third Party Reseller) under no more than five (5) different trademarks or trade names (to the extent Licensee has the legal right to manufacture and sell such Combination Product pursuant to the terms of the Agreement).

5.5 Technology Transfer. Licensee acknowledges that as of the Amended and Restated Effective Date Gilead has made the one-time technology transfers available to Licensee of know-how owned or controlled by Gilead relating to the manufacture of Sof, LDV, Vel, Sof Product, LDV Product, Vel Product, Sof/Vel Product, and Sof/LDV Product, in each case as described in Appendix 3 hereto. Licensee further acknowledges that the foregoing technology transfers are sufficient to enable Licensee to manufacture Sof, LDV, Vel, Sof Product, LDV Product, Vel Product, Sof/Vel Product, and Sof/LDV Product, as applicable, at commercial-scale quantities. Additionally, during the term of this Agreement:

(a) within ninety (90) days following Gilead's receipt of marketing approval from the FDA for a Sof/Vel/Vox Product, Gilead will make a one-time technology transfer available to Licensee of know-how owned or controlled by Gilead relating to the manufacture of such Sof/Vel/Vox Product to the extent and in the manner specified in Appendix 3 hereto, and

(b) within ninety (90) days following Gilead's receipt of marketing approval from the FDA for a Vox Product, Gilead will make a one-time technology transfer available to Licensee of know-how owned or controlled by Gilead relating to the manufacture of such Vox Product, to the extent and in the manner specified in Appendix 3 hereto.

With respect to each of the foregoing technology transfers, Licensee shall notify Gilead of its desire to receive such technology transfer within the time period therefor, and following receipt of such notice Gilead will promptly make the applicable technology transfer. If Licensee does not notify Gilead of its desire to receive a particular technology transfer within the time period therefor, then Gilead will be under no obligation to make such technology transfer. The know-how transferred to Licensee pursuant to the terms of this Section 5.5 shall be sufficient to enable Licensee to manufacture Vox, Vox Product and Sof/Vel/Vox Product, as applicable, at commercial-scale quantities. Gilead shall have no further obligation to transfer any other know-how under this Agreement.

## **6. Manufacturing and Commercialization of Product**

### **6.1 Commercialization of Product in the Territory.**

(a) Anti-Diversion Programs. Licensee shall provide Gilead with written notice 6 months prior to its anticipated first sale of Product in each country within the Territory. Following Gilead's receipt of such notice, the Parties shall discuss in good faith programs that Licensee may implement to minimize diversion of Product outside of such country, including by using commercially reasonable efforts in ensuring Product is sold direct to patients within such country, as may be determined by the Parties. On a country by country basis, if requested by Gilead at any time either prior to Licensee's sale of any Product in such country or at any time thereafter, the Parties shall discuss and agree upon a written anti-diversion plan that Licensee shall

implement to ensure Product is not diverted out of such country (for each such country, the “**Anti-Diversion Plan**”). Gilead shall have the right to prohibit Licensee’s sale of Product to any country (the “**Subject Country**”) within Territory if it reasonably believes that material quantities of Product are being sold, transferred or otherwise diverted from such Subject Country outside the Territory by providing written notice thereof to Licensee (each such notice, a “**Diversion Notice**”). Except as may be necessary for patients within any Subject Country who have previously initiated their treatment with Product to complete such treatment, upon Licensee’s receipt of a Diversion Notice, Licensee shall immediately cease all sales of Product in, and imports of Product to, the Subject Country(ies) that is covered by such Diversion Notice until such time that Gilead and Licensee have developed an Anti-Diversion Plan for such Subject Country(ies). Licensee shall not enter into any contractual arrangements or commitments that would prevent it from fulfilling its obligations under this Section 6.1(a).

(b) Promotion. The Parties hereto agree that an important purpose of this Agreement is to increase patient access to the Products within the Territory. Except as otherwise provided in this Agreement (including Section 5.4 and 6.1(a)), Licensee shall have the sole discretion to manage its own commercial strategy to promote and sell the Product in the Territory, *provided, however*, that Licensee shall not engage in activities that are inconsistent with the first sentence of this Section 6.1(b). By means of example and without limitation, Licensee agrees that Licensee shall not accept patient orders that Licensee does not have the capacity to fill, and shall not obtain API or Product without having the means, either directly or through the use of permitted third parties, to manufacture Product using such API and/or distribute such Product within the Territory.

## 6.2 Manufacturing Requirements

(a) Minimum Quality Standards. Licensee agrees that it shall manufacture API and Product in a manner consistent with (i) the applicable Indian manufacturing standards, including manufacturing standards promulgated by the Drug Controller General of India (DCGI), World Health Organization (“**WHO**”) pre-qualification standards, standards of the European Medicines Agency (“**EMA**”), or United States Food and Drug Administration (“**FDA**”) tentative approval standards (“**Minimum Quality Standards**”); and (ii) on a country-by-country basis, any applicable national, regional or local standards as may be required by the specific country where Product is sold. In addition, Licensee and its Limited Sublicensees shall meet the Minimum Quality Standards with respect to a particular Product prior to Licensee’s and its Limited Sublicensees’ sale of such Product to any country within the Territory.

(b) Audit Right. Licensee hereby agrees to allow Gilead reasonable access to Licensee’s books and records, facilities and employees solely for the purpose and to the extent required for Gilead to audit Licensee’s compliance with the requirements of this Section 6.2. Gilead agrees to provide at least thirty (30) days prior notice of the proposed audit, and agrees that such audits shall not be conducted more than once a year unless circumstances outside the ordinary course of business warrant such an audit (such as an investigation or other government action).

(c) Remedy for Failure. If Licensee fails at any time to meet the Minimum Quality Standards with respect to the manufacture of API or Product, Gilead may elect, in its sole discretion and notwithstanding Section 10.2 or 10.3 hereof, to suspend the licenses granted

hereunder until such time Gilead has determined that Licensee has corrected any such failure to Gilead's reasonable satisfaction. During any such suspension, Gilead and Licensee shall coordinate with each other to provide for the supply of API or Product, as appropriate, to ensure that end-user patient requirements are not disrupted as a result of such suspension.

(d) Dose Requirements. All Product used or sold by Licensee shall consist of single dose concentrations of Sof, LDV, Vel, and Vox that are the same as the dose concentration for such agent that has been approved by (i) the FDA or (ii) by (y) DCGI and (z) the appropriate regulatory authority having jurisdiction over such Product in the country of sale. Licensee agrees that it shall manufacture or sell Products only as approved by the FDA for the Field or as approved for use in the Field by the appropriate regulatory authority having jurisdiction over such Product in the country of sale.

6.3 Regulatory Filings and Inspections. Except as provided otherwise herein, Licensee shall be responsible for obtaining and maintaining all applicable regulatory or other approvals or authorizations to carry out its activities in the Territory as set forth in this Agreement. Gilead may, in its discretion, elect to file for regulatory or other approval or authorization to make and sell API and Product anywhere in the Territory. Upon either Party's request, the other Party shall provide non-proprietary data that the other Party believes is reasonably necessary to obtain any such approvals, authorizations, permits or licenses. Licensee shall obtain, have and maintain, and require its Limited Sublicensees and Product CMOs to obtain, have, and maintain, all required registrations for its manufacturing facilities. Licensee shall allow, and require its Limited Sublicensees and Product CMOs to allow, appropriate regulatory authorities to inspect such facilities to the extent required by applicable law, rule or regulation. Gilead agrees to provide Licensee with NCE Exclusivity, or other regulatory exclusivity, waivers as may be required by the applicable regulatory authorities in order to manufacture or sell Product that contains only API in the Territory, provided such manufacture and sale by Licensee is compliant with the terms and conditions of this Agreement. Licensee agrees not to pursue or obtain regulatory exclusivity on any Product in any country within the Territory.

6.4 Marketing Materials. Any marketing materials (including, but not limited to, advertisement and promotional materials) used by Licensee, Limited Sublicensee, and its Third Party Resellers shall not contain any misstatements of fact, shall be fully compliant with the applicable laws, rules and regulations, and shall be distinct from, and not cause any confusion with, any marketing materials or Products used or sold by Gilead. Any statements made in such marketing materials regarding Gilead, including without limitation statements made in reference to Licensee's collaboration with Gilead, shall require Gilead's prior written approval.

6.5 Product Labeling. Licensee shall expressly state on the labeling of all Products sold or offered for sale under this Agreement that the Product "is manufactured under a license from Gilead Sciences Ireland UC."

6.6 Safety Reporting.

(a) Licensee is responsible for all single and periodic reporting to all applicable regulatory authorities for the Products manufactured by or on behalf of Licensee under the Agreement.

(b) Licensee is responsible for all pharmacovigilance activities with respect to such Products, including but not limited to all associated signal detection, risk management and product labelling requirements.

(c) In the event Licensee receives an individual case safety report associated with any Gilead proprietary product, Licensee agrees to forward such reports to Gilead at E-Mail: [SafetyFC@gilead.com](mailto:SafetyFC@gilead.com) Fax: +1-650-522-5477.

(d) Licensee will forward details of any confirmed safety signals or emerging safety issues relating to Products manufactured by or on behalf of Licensee under this Agreement and any supporting documentation to the risk management contact at Gilead: [Neda.Shokrai@gilead.com](mailto:Neda.Shokrai@gilead.com).

## **7. Representations, Warranties and Covenants**

### **7.1 Ability to Perform.** Gilead and Licensee each represent and warrant that

(a) they are duly organized, validly existing and in good standing under the laws of the jurisdiction of their incorporation and have 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.

### **7.2 Diversion of Product and Technology.**

(a) Licensee covenants and agrees that Licensee and its Affiliates, Limited Sublicensees, and Product CMOs shall not, and shall require its Third Party Resellers and Licensed Product Suppliers not to: (i) divert or knowingly allow the diversion of API to any third party other than Limited Sublicensees, Product CMOs, and Licensed Product Suppliers (including sublicensees and contract manufacturers of Licensed Product Suppliers), (ii) divert or knowingly allow the diversion of Product outside the Territory, (iii) divert or knowingly allow the diversion of Licensed Technology to any third party, except as expressly permitted under this Agreement, or (iv) take any action that Gilead determines in good faith to be in furtherance of the activities described in clauses (i) – (iii), or (v) assist or support, directly or indirectly, any third party in the conduct of the activities described in clauses (i) - (iv) of this Section 7.2. The Parties agree that it shall not be a breach of Section 2.4(a) or this Section 7.2 for Licensee or its Affiliate to file marketing approval applications for any Product in a country outside of the Territory, or for Licensee or its Affiliate to provide developmental quantities of API or Product in support of such marketing approval applications or a third party's application for marketing approval, in each case, as required by applicable regulatory authorities in such country, it being understood that this provision shall not be construed as expressly or implicitly granting Licensee any right or license

under any Gilead intellectual property right beyond the licenses granted in Section 2.1 of this Agreement or otherwise providing any authorization by Gilead to do so, and does not constitute a waiver of any rights of Gilead under law that it may have to contest the filing or granting of such marketing approval applications.

(b) **Damages.** In the event (i) any Product is diverted (x) by Licensee or its Affiliates, Limited Sublicensees, or Product CMOs, or (y) by another party with the assistance of the Licensee or its Affiliates, Limited Sublicensees, or Product CMOs, in each case to any country outside the Territory in any manner described in Section 7.2(a), and (ii) a patent covering such Product has been granted in such country or in the country(ies) outside the Territory in which such Product is manufactured (collectively the circumstance described by clause (i) and (ii), a “**Diversio**n Event”), then in addition to any other remedies Gilead may be entitled to at law or in equity, Gilead shall be entitled to injunctive relief and to receive lost profits associated with the Diversion Event, which such lost profits will be determined by taking into consideration the following factors: (1) the quantity of Product that is the subject of such Diversion Event; (2) the average profit Gilead receives from its sale of such Product in the country(ies) outside the Territory into which such Product was sold or otherwise transferred; and (3) any erosion in Gilead’s market share in such country(ies) outside the Territory as a result of such Diversion Event.

7.3 Access Promotion. Licensee covenants and agrees that it shall not engage in activities that are contrary to the goal of promoting patient access to Product to satisfy unmet medical needs within the Territory.

#### 7.4 Compliance

(a) General. Licensee covenants and agrees that it shall perform all activities under this Agreement in accordance with all applicable laws, rules, and regulations, including, without limitation, with respect to privacy, data protection, 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 API and/or Product and any other Licensee activities contemplated under this Agreement.

(b) FCPA and UK Bribery Act. Licensee covenants and agrees that neither the Licensee, nor any of its Affiliates, nor any of their respective directors, officers, employees or agents (all of the foregoing, including affiliates collectively, “**Licensee Representatives**”) has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended (such act, including the rules and regulations thereunder, the “**FCPA**”), the U.K. Bribery Act of 2010 (“**Bribery Act**”), or any other applicable anti-bribery or anticorruption laws, rules or regulations (collectively with the FCPA and the Bribery Act, the “**Anticorruption Laws**”). Licensee covenants and agrees that Licensee and Licensee Representatives have conducted and will conduct their businesses in compliance with the Anticorruption Laws. Licensee covenants and agrees that it shall provide to Gilead on the Amended and Restated Effective Date and within thirty (30) days after the beginning of each calendar year thereafter, certification in writing by Licensee of Licensee’s compliance with the Anticorruption Laws.

(c) 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 any applicable law, rule or regulation, provided, however, that both Licensee and Gilead are in agreement regarding (i) the requirements of such law, rule or regulation, and (ii) the affect that such law, rule or regulation has on such action or obligation required under this Agreement.

7.5 Patent Infringement. Licensee covenants and agrees that it shall not infringe the Patents outside the scope of the licenses granted to it pursuant to Article 2.

7.6 EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, GILEAD DOES NOT GIVE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT IN THE TERRITORY. Gilead also does not give any warranty, express or implied, with regard to the safety or efficacy of API or the Product.

## **8. Liability and Indemnity**

8.1 Licensee Indemnity. Licensee shall indemnify, hold harmless and defend Gilead, and its Affiliates, licensors, directors, officers, employees and agents (together the “**Gilead 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 a Gilead Indemnatee becomes legally obligated to pay because of any 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 API or Product (including, without limitation, its manufacture, use or sale of API or Product). The indemnification obligations of Licensee stated in this Section 8.1 shall apply only in the event that Gilead provides Licensee with prompt written notice of such claims, grants Licensee the right to control the defense or negotiation of settlement (using counsel reasonably approved by Gilead), and makes available all reasonable assistance in defending the claims. Licensee shall not agree to any final settlement or compromise with respect to any such claim that adversely affects Gilead without obtaining Gilead’s consent.

8.2 Product Liability. Licensee shall be solely responsible in respect of any product liability or any other statutory liability under any regulation, in respect of API or the Product.

8.3 Gilead Liability. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT, IN NO EVENT SHALL GILEAD 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 API OR PRODUCT, 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.

## 9. Insurance

Within thirty (30) days prior to the first commercial launch by or on behalf of Licensee of a Product, and each year thereafter for so long as this Agreement is in effect, Licensee shall provide to Gilead certificates of insurance by insurers acceptable to Gilead evidencing comprehensive general liability coverage, including products liability, with a combined limit of no less than one million dollars (\$1,000,000.00) for bodily injury, including personal injury, and property damage. Such liability coverage may be in the form of a global policy. Licensee shall not cancel any such policy without at least sixty (60) days prior written notice to Gilead, and agrees that such policy shall be maintained (or have an extended reporting period) of at least two (2) years after the termination of this Agreement.

## 10. Term and Termination

10.1 Term. This Agreement shall enter into force upon the Amended and Restated Effective Date and, unless earlier terminated as provided herein, shall continue until the expiration of the Royalty Term. Upon expiration of the Royalty Term (but not the earlier termination of this Agreement), and with respect to a particular Product in a particular country in the Territory, subject to the terms and conditions herein with respect to such Product and such country, the licenses granted in Article 2 to Licensee shall become a perpetual, irrevocable, fully paid-up, royalty free license under the Licensed Know-How to develop, make, have made, use, sell, have sold, offer for sale, import and distribute such Product in the Field in such country.

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 thirty (30) days after such written notice is provided to cure such breach. If such breach is not cured within the thirty day period, this Agreement shall effectively terminate.

### 10.3 Gilead Right to Terminate

(a) Gilead shall have the right to terminate this Agreement and/or the licenses granted pursuant to Article 2 (whether or not such event constitutes a right of termination pursuant to Section 10.2), immediately if in the reasonable opinion of Gilead, control (through ownership or otherwise) of Licensee changes.

(b) Gilead shall have the right to terminate this Agreement and/or the licenses granted pursuant to Section 2.1 (whether or not such event constitutes a right of termination pursuant to Section 10.2), if:

(i) Gilead determines in good faith that a material quantity of API has been diverted outside of the Territory or to third parties other than as expressly permitted in this Agreement, or Product made and/or sold by or on behalf of Licensee has been diverted to countries

outside the Territory, whether or not by any fault or action or inaction of Licensee or any of the prohibited activities described in Section 7.2(a)(i)-(v) has occurred;

(ii) Gilead determines in good faith that, due to material deficiencies in Licensee's compliance, or repeated failure to comply, with the Minimum Quality Standards, Licensee is unable to reliably and consistently manufacture API or Product in accordance with the Minimum Quality Standards; or

(iii) Gilead determines in good faith that Licensee has obtained material quantities of API from sources outside the Territory, or in ways that are inconsistent with the terms and conditions of Section 3.2.

Gilead shall give Licensee written notice of any such event and provide Licensee with a period of thirty (30) days after such notice to demonstrate that the conditions giving rise to Gilead's determination no longer exist to Gilead's reasonable satisfaction. If Licensee is unable to do so, this Agreement shall be terminated effective upon the thirtieth (30<sup>th</sup>) day following such notice.

(c) (i) For clarity, and notwithstanding anything to the contrary in this Agreement, with respect to a particular Product, and on a Product-by-Product and country-by-country basis, if there is no Product Patent owned or controlled by Gilead (or its Affiliates) in India, the country in which such Product is manufactured (if not India), and a particular country outside of the Territory, and if there is no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals)) in India, the country in which such Product is manufactured (if not India), and such country outside of the Territory, it shall not be deemed to be a breach of this Agreement for Licensee to supply such Product in such country and Licensee shall not be obligated to pay Gilead any royalty therefor; provided that Licensee obtained applicable regulatory approval in such country.

(ii) Similarly, on an API-by-API and Product-by-Product basis, it shall not be deemed to be a breach of the Agreement for Licensee: (x) to manufacture API in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such API in such country, and there is no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country; (y) to sell such API referred to in clause (x) of this Section 10.3(c)(ii) in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such API in such country, and there is no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country; or (z) to manufacture and/or sell Product incorporating such API referred to in clause (x) of this Section 10.3(c)(ii) in any country where there is no Product Patent owned or controlled by Gilead (or its Affiliates) covering such Product (or the API contained therein) in such country, and there is no reasonable possibility of obtaining such a Product Patent within a reasonable period of time (for example, through pending patent applications, the filing of patent applications, or by legal action (including appeals) in such country.



(d) For further clarity, and notwithstanding anything to the contrary in this Agreement, it shall not be deemed to be a breach of the Agreement for Licensee to supply an API or Product outside the Territory into a country where: (i) the government of such country has issued a Compulsory License relating to such API or Product allowing for the importation of such API or Product into such country, provided that Licensee's supply of Product or API 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/or (ii) the Government of India has issued a Compulsory License allowing for the export of an API or Product from India and into such country, provided that: (Y)(1) there are no Product Patents owned or controlled by Gilead (or its Affiliates) issued in such country or (2) a Compulsory License has also been issued by the relevant authorities of such country; and (Z) Licensee's supply of Product or API into such country is solely within the scope and geographic range of the Compulsory License issued by the Government of India, and only for the duration that such Compulsory License is in effect.

10.4 Licensee Right to Terminate. Licensee will have the right to terminate this Agreement for its convenience on an API-by-API basis upon thirty (30) days prior written notice to Gilead, which such notice may be given at any time following the fifth anniversary of the Original Effective Date. Any written notice given under this Section 10.4 shall expressly identify the API(s) for which Licensee desires to terminate its license from Gilead (each, a “**Terminated API**”). In the event of any such termination, with respect to any such Terminated API, the following terms shall apply as of the effective date of termination for such API (the “**API Termination Date**”).

(a) All licenses granted by Gilead under this Agreement with respect to such Terminated API, and any other rights granted by Gilead with respect to such Terminated API, including without limitation Gilead's obligation to make a technology transfer available with respect to such API pursuant to Section 5.5 (to the extent such technology transfer has not already occurred), shall terminate and all Sections of this Agreement shall be interpreted to exclude such Terminated API therefrom.

(b) Without limiting the foregoing clause (a) of this Section 10.4, the licenses granted by Gilead under the Licensed Technology related to such Terminated API or any Product incorporating such Terminated API to make, use, sell, offer for sale, export or import such Terminated API and/or any Product containing such Terminated API shall terminate.

(c) Termination of any license with respect to any API under this Section 10.4 shall not relieve Licensee of any obligation accruing on or prior to the API Termination Date therefor, including the obligation to pay royalties pursuant to Article 4 on Net Sales of any Product sold prior to the API Termination Date. Upon termination of all API licensed to Licensee under this Agreement, this Agreement shall be deemed terminated in its entirety pursuant to Section 10.4. Nothing set forth in this Section 10.4 shall be deemed a waiver by Gilead to enforce any Patent or any other intellectual property right owned or controlled by Gilead against Licensee for any activities Licensee may undertake with respect to any Terminated API or Product incorporating such Terminated API after any such API Termination Date.

10.5 Insolvency. In the event that Licensee becomes insolvent, makes an assignment to the benefit of creditors, or has a petition in bankruptcy filed for or against it, Gilead shall have the right to treat such event as a material breach.

10.6 Waiver. The waiver by either 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.

10.7 Survival. On a Product-by-Product and API-by-API basis, Sections 1, 2.2 (with respect to Improvements developed prior to the effective date of expiration or termination), 2.4(a), 2.4(b), 2.5(c)(ii), 4.5 (with respect to API and Product manufactured and/or sold prior to the effective date of expiration or termination), 4.6 (for a period of 3 years following the effective date of expiration or termination), 4.7 (for a period of 3 years following the effective date of expiration or termination), 5.2 (solely with respect to the obligations set forth in the last sentence of Section 5.2), 5.3 (for a period of 1 year following the effective date of expiration or termination of the Agreement, and solely with respect to Improvements developed prior to the effective date of expiration or termination), 7.2(b) (with respect to Products sold prior to expiration or termination) 7.6, 8, 9, 10.1, 10.4(c), 10.6, 10.7, 11 and 12 shall survive (a) termination or expiry of this Agreement or (b) in the event that Licensee terminates its license with respect to API pursuant to Section 10.4, the API Termination Date with respect to such Terminated API. Except as otherwise provided in this Section 10.7, all rights and obligations of the Parties under this Agreement shall terminate upon the expiration or termination of this Agreement.

## 11. Confidentiality and Publications

11.1 Confidential Information. All information of proprietary nature, including technology and know-how (“**Confidential Information**”), disclosed by one Party (the “**Disclosing Party**”) to the other Party (the “**Receiving Party**”) hereunder shall (a) be used solely and exclusively by the Receiving Party in a manner consistent with the licenses and rights granted hereunder; (b) be maintained in confidence by the Receiving Party; and (c) not be disclosed to any third party or used for any purpose except to exercise its rights and perform its obligations under this Agreement. The foregoing confidentiality obligations shall not apply if the Receiving Party can demonstrate by competent written evidence that such information: (i) 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; (ii) is in the public domain other than as a result of any breach of this Agreement by the Receiving Party; (iii) is subsequently disclosed to the Receiving Party on a non-confidential basis by a third party who may lawfully do so; or (iv) 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 thirty (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 (1) 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 confidential obligations under this Agreement shall survive this Agreement for a period of five (5) years.

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 Use of Name. Except as provided for under Section 11.2, neither Party shall use the other Party's name, logo or trademarks for any purpose including without limitation publicity or advertising, except with the prior written consent of the other Party.

## **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. Gilead and Licensee hereby expressly agree that this Agreement amends and restate in its entirety the Original License Agreement as of the Amended and Restated Effective Date and the terms of the Original License Agreement shall apply with respect to the period of time preceding the Amended and Restated Effective Date.

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

### **12.4 Notices**

(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 (ii) three days after mailing by registered or certified mail, postage paid:

In the case of Gilead:

Gilead Sciences Ireland UC  
IDA Business & Technology Park  
Carigtohill, Co. Cork, Ireland

Attention: General Manager

With a copy to:

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404  
U.S.A.  
Attention: General Counsel  
Facsimile: (650) 522-5537

In the case of Licensee:

[address]

(b) Either Party may change its address for communications by a notice in writing to the other Party in accordance with this Section 12.4.

12.5 Governing Law. This Agreement is made in accordance with and shall be governed and construed under the laws of England, without regard to its choice of law principles.

#### 12.6 Arbitration

(a) All disputes arising out of or in connection with the present Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators.

(b) Each Party shall nominate one arbitrator. Should the claimant fail to appoint an arbitrator in the Request for Arbitration within thirty (30) days of being requested to do so, or if the respondent should fail to appoint an arbitrator in its Answer to the Request for Arbitration within thirty (30) days of being requested to do so, the other Party shall request the ICC Court to make such appointment.

(c) The arbitrators nominated by the Parties shall, within thirty (30) days from the appointment of the arbitrator nominated in the Answer to the Request for Arbitration, and after consultation with the Parties, agree and appoint a third arbitrator, who will act as a chairman of the Arbitral Tribunal. Should such procedure not result in an appointment within the thirty (30) day time limit, either Party shall be free to request the ICC Court to appoint the third arbitrator.

(d) London, England shall be the seat of the arbitration.

(e) The language of the arbitration shall be English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with an English translation.

(f) This arbitration agreement does not preclude either Party seeking conservatory or interim measures from any court of competent jurisdiction including, without limitation, the courts having jurisdiction by reason of either Party's domicile. Conservatory or

interim measures sought by either Party in any one or more jurisdictions shall not preclude the Arbitral Tribunal granting conservatory or interim measures. Conservatory or interim measures sought by either Party before the Arbitral Tribunal shall not preclude any court of competent jurisdiction granting conservatory or interim measures.

(g) In the event that any issue shall arise which is not clearly provided for in this arbitration agreement the matter shall be resolved in accordance with the ICC Arbitration Rules.

12.7 Assignment. Gilead is entitled to transfer and assign this Agreement and the rights and obligations under this Agreement on notice to Licensee. Licensee is not entitled to transfer or assign this Agreement or the rights and obligations under this Agreement.

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

*[signatures appear on following page]*

IN WITNESS WHEREOF, the Parties hereto have executed this License Agreement effective as of the Amended and Restated Effective Date.

**Gilead Sciences Ireland UC**

By: \_\_\_\_\_  
Name:  
Title:  
Date:

**[Name of Licensee]**

By: \_\_\_\_\_  
Name:  
Title:  
Date:

## Appendix 1 Territory

1. Afghanistan	41. India	82. Somalia
2. Algeria	42. Indonesia	83. South Africa
3. Angola	43. Kenya	84. South Sudan
4. Antigua and Barbuda	44. Kiribati	85. Sri Lanka
5. Bangladesh	45. Kyrgyzstan	86. St. Vincent and the Grenadines
6. Belarus	46. Lao, People's Dem. Rep.	87. Sudan
7. Benin	47. Lesotho	88. Surinam
8. Bhutan	48. Liberia	89. Swaziland
9. Bolivia	49. Libya	90. Tajikistan
10. Botswana	50. Madagascar	91. Tanzania, U. Rep. of
11. Burkina Faso	51. Malawi	92. Thailand
12. Burundi	52. Malaysia	93. Timor-Leste
13. Cambodia	53. Maldives	94. Togo
14. Cameroon	54. Mali	95. Tonga
15. Cape Verde	55. Marshall Islands	96. Tunisia
16. Central African Republic	56. Mauritania	97. Turkmenistan
17. Chad	57. Mauritius	98. Tuvalu
18. Comoros	58. Micronesia	99. Uganda
19. Congo, Rep	59. Mongolia	100. Ukraine
20. Congo, Dem. Rep. of the	60. Morocco	101. Uzbekistan
21. Cook Islands	61. Mozambique	102. Vanuatu
22. Côte d'Ivoire	62. Myanmar	103. Vietnam
23. Cuba	63. Namibia	104. Zambia
24. Djibouti	64. Nauru	105. Zimbabwe
25. Dominica	65. Nepal	
26. Egypt	66. Nicaragua	
27. El Salvador	67. Niger	
28. Eritrea	68. Nigeria	
29. Ethiopia	69. North Korea	
30. Equatorial Guinea	70. Pakistan	
31. Fiji	71. Palau	
32. Gabon	72. Papua NewGuinea	
33. Gambia	73. Paraguay	
34. Ghana	74. Philippines	
35. Guatemala	75. Rwanda	
36. Guinea	76. Samoa	
37. Guinea-Bissau	77. São Tomé and Príncipe	
38. Guyana	78. Senegal	
39. Haiti	79. Seychelles	
40. Honduras	80. Sierra Leone	
	81. Solomon Islands	

## Appendix 2 Patents

For purposes of this Appendix 2, references to “PCT,” “OAPI,” “EAPO,” “ARIPO,” “GCC” and other regions or areas shall not be construed or interpreted to grant rights to Licensee in any country other than those countries expressly included within the licenses granted to Licensee in Section 2.1 of this Agreement.

### Sofosbuvir

Country	Status	AppNumber	FilDate	PatNumber	IssDate
<b>(PH3000) MODIFIED FLUORINATED NUCLEOSIDE ANALOGUES</b>					
India	Pending	2079/DELNP/2011	04/21/2004		
India	Granted	6087/DELNP/2005	04/21/2004	273003	05/09/2016
Indonesia	Pending	W-00201101421	04/21/2004		
Indonesia	Granted	000503201	04/21/2004	P0028288	05/19/2011
Malaysia	Granted	041584	04/21/2004	138477	06/30/2009
Philippines	Granted	1-2005-502136	04/21/2004	1-2005-502136	09/30/2009
South Africa	Granted	2005/09521	04/21/2004	2005-09521	10/25/2006
Thailand	Pending	0401001521	04/29/2004		
<b>(PH3010) 2-DEOXY-2-FLUORO-2-METHYL-D-RIBONOLACTONE DERIVATIVES AND PROCESS FOR PREPARATION OF THE SAME</b>					
India	Granted	605/KOLNP/2007	07/21/2005	252108	04/25/2012
India	Granted	1301/KOLNP/2011	07/21/2005	280338	02/17/2017
South Africa	Granted	2007/00634	07/21/2005	2007/00634	05/27/2009
<b>(PH3020) PREPARATION OF 2-FLUORO-2-C-ALKYL- AND OTHER OPTIONALLY SUBSTITUTED RIBOFURANOSYL PYRIMIDINES AND PURINES AND THEIR DERIVATIVES</b>					
India	Granted	1283/KOLNP/2007	09/13/2005	253415	07/18/2012
South Africa	Granted	2007/03005	09/13/2005	2007/03005	12/30/2009
<b>(PH3080) NUCLEOSIDE PHOSPHORAMIDATE PRODRUGS</b>					
Congo, Democratic Republic of	Pending		03/26/2008		
Ethiopia	Pending	ET/PI/2017/238	03/26/2008		
Fiji	Allowed	1237	03/26/2008		
Gambia	Granted	GM/P/3/2016	03/26/2008	2203462	09/30/2016
Guyana	Granted	1665	03/26/2008	1665	12/28/2016
India	Pending	3658/KOLNP/2009	03/26/2008		
Kiribati	Granted	14/2017	03/26/2008	14/2017	05/22/2017
Malaysia	Pending	PI2013700238	03/26/2008		
Malaysia	Pending	PI2013700240	03/26/2008		
Malaysia	Granted	PI20094079	03/26/2008	MY-147409-A	11/30/2012
Nauru	Pending		03/26/2008		
Nepal	Pending	12	03/26/2008		
Philippines	Granted	1-2009-501847	03/26/2008	1/2009/501847	10/11/2016
Seychelles	Granted	2203462	03/26/2008	2203462	02/06/2017
Solomon Islands	Granted	J37/384	03/26/2008	J37/384	10/27/2016
South Africa	Granted	2009/06647	03/26/2008	2009/06647	06/26/2013
South Africa	Granted	2012/00310	03/26/2008	2012/00310	05/29/2013
Thailand	Published	0801001634	03/26/2008		
Tuvalu	Pending		03/26/2008		
Tuvalu	Granted				
<b>(PH4050) NUCLEOSIDE PHOSPHORAMIDATES</b>					
African Intellectual Property Organization (OAPI)	Granted	1201200367	03/31/2011	16103	10/31/2013
African Regional	Granted	AP/P/2012/006543	03/31/2011	AP3515	01/29/2016



Industrial Property Organization						
Egypt	Pending	1955/2011	05/20/2010			
Egypt	Pending	1659/2012	03/31/2011			
El Salvador	Pending	2012004314	03/31/2011			
Eurasian Patent Organization	Granted	201290993	03/31/2011	026341		03/31/2017
Eurasian Patent Organization	Granted	201171417	05/20/2010	026731		05/31/2017
Eurasian Patent Organization	Allowed	201592101	05/20/2010			
Eurasian Patent Organization	Allowed	201370186	05/20/2010			
India	Published	4972/KOLNP/2011	05/20/2010			
India	Published	9149/CHENP/2012	03/31/2011			
Indonesia	Pending	W00201204454	03/31/2011			
Malaysia	Pending	PI 2016701103	05/20/2010			
Malaysia	Allowed	PI2011005625	05/20/2010			
Pakistan	Pending	748/2012	03/31/2011			
Pakistan	Pending	233/2011	03/31/2011			
Philippines	Granted	1-2011-502433	05/20/2010	1-2011-502433		01/14/2016
Philippines	Published	1-2014-502684	05/20/2010			
Philippines	Pending	1-2015-502237	05/20/2010			
South Africa	Granted	2012/07799	03/31/2011	2012/07799		03/26/2014
South Africa	Granted	2011/08749	05/20/2010	2011/08749		05/29/2013
South Africa	Granted	2014/00249	03/31/2011	2014/00249		08/31/2016
South Africa	Granted	2013/01620	05/20/2010	2013/01620		10/30/2013
Thailand	Published	1201005189	03/31/2011			
Thailand	Pending	1001000775	05/20/2010			
Ukraine	Pending	201311603	03/31/2011			
Ukraine	Pending	a201212444	03/31/2011			
Vietnam	Pending	1-2012-03236	03/31/2011			
<b>(PH50X3) COMPOSITIONS AND METHODS FOR TREATING HEPATITIS C VIRUS</b>						
African Intellectual Property Organization (OAPI)	Granted	1201400229	11/27/2012	17352		01/29/2016
African Regional Industrial Property Organization	Allowed	AP/P/2014/007699	11/27/2012			
Bolivia	Published	SP-0434-2012	11/28/2012			
Egypt	Pending	PCT864/2014	11/27/2012			
El Salvador	Published	2014004722	11/27/2012			
Eurasian Patent Organization	Granted	201490903	11/27/2012	027296		07/31/2017
India	Published	4542/DELNP/2014	11/27/2012			
Indonesia	Granted	P00201403478	11/27/2012	IDP000046094		05/29/2017
Malaysia	Pending	PI2014001520	11/27/2012			
Pakistan	Pending	803/2012	11/28/2012			
Paraguay	Published	56476/2012	11/28/2012			
Philippines	Granted	1-2014-501133	11/27/2012	1-2014-501133		03/03/2016
South Africa	Allowed	2014/04061	11/27/2012	2014/04061		09/28/2016
Thailand	Published	1401002830	11/27/2012			
Ukraine	Granted	a201405757	11/27/2012	114097		04/25/2017
Vietnam	Granted	1-2014-01861	11/27/2012	16616		02/21/2017

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CountryName	ApplicationStatus	AppNumber	FilDate	PatNumber	IssDate
<b>(792) ANTIVIRAL COMPOUNDS</b>					
African Intellectual Property Organization (OAPI)	Granted	1201100414	05/12/2010	15651	09/28/2012
African Regional Industrial Property Organization	Pending	AP/P/2016/008993	05/12/2010		
African Regional Industrial Property Organization	Granted	AP/P/2011/005987	05/12/2010	AP3622	03/31/2016
Belarus	Granted	201190259	05/12/2010	021974	10/30/2015
Belarus	Granted	201490854	05/12/2010	026536	04/28/2017
Bolivia	Published	SP-00128-2010	05/12/2010		
Bolivia	Pending	SP-0128-2010-F1	05/13/2009		
Congo, Democratic Republic of	Pending		05/12/2010		
Ethiopia	Pending	ET/PI/17/243	05/12/2010		
Eurasian Patent Organization	Granted	201590073	05/12/2010	027493	07/31/2017
Eurasian Patent Organization	Granted	201190259	05/12/2010	021974	10/30/2015
Eurasian Patent Organization	Granted	201490854	05/12/2010	026536	04/28/2017
Eurasian Patent Organization	Pending	201790515	05/12/2010		
Fiji	Pending		05/12/2010		
Gambia	Granted	GM/P/4/2017	05/12/2010	GM/P/4/2017	04/05/2017
Guyana	Pending		05/12/2010		
India	Published	4931/DELNP/2014	05/12/2010		
India	Pending	9313/DELNP/2011	05/12/2010		
India	Published	4889/DELNP/2014	05/12/2010		
Indonesia	Granted	W00-2011-04295	05/12/2010	IPD000039409	08/28/2015
Indonesia	Pending	P00201502494	05/12/2010		
Kiribati	Granted	16/2017	05/12/2010	16/2017	06/23/2017
Kyrgyz Republic	Granted	201490854	05/12/2010	026536	04/28/2017
Kyrgyz Republic	Granted	201190259	05/12/2010	021974	10/30/2015
Nauru	Pending	2430014	05/12/2010		
Nepal	Pending	41	05/12/2010		
Pakistan	Pending	248/2016	05/12/2010		
Pakistan	Pending	415/2010	05/12/2010		
Paraguay	Published	18498/2010	05/12/2010		
Seychelles	Granted	2430014	05/12/2010	2430014	05/04/2017
South Africa	Granted	2011/08436	05/12/2010	2011/08436	01/30/2013
Tajikistan	Granted	201490854	05/12/2010	026536	04/28/2017
Tajikistan	Granted	201190259	05/12/2010	021974	10/30/2015
Thailand	Published	1101003118	05/12/2010		
Turkmenistan	Granted	201190259	05/12/2010	021974	10/30/2015
Turkmenistan	Granted	201490854	05/12/2010	026536	04/28/2017
Tuvalu	Granted		05/12/2010	TVP2430014	05/16/2017
Ukraine	Granted	a201113524	05/12/2010	108610	05/25/2015
Ukraine	Granted	201113524	08/28/2016		10/10/2016
Ukraine	Pending	a201413049	05/12/2010		
Vietnam	Granted	1-2011-03386	05/12/2010	17117	06/27/2017
<b>(851) METHODS FOR TREATING HCV</b>					

African Intellectual Property Organization (OAPI)	Pending	1201400117	09/14/2012		
African Regional Industrial Property Organization	Pending	AP/P/2014/007575	09/14/2012		
Belarus	Granted	201490588	09/14/2012	0026667	05/31/2017
Egypt	Pending	PCT392/2014	09/14/2012		
El Salvador	Published	2014004680	09/14/2012		
Eurasian Patent Organization	Granted	201490588	09/14/2012	0026667	05/31/2017
India	Pending	2956/DELNP/2014	09/14/2012		
Indonesia	Published	P00201402133	09/14/2012		
Kyrgyz Republic	Granted	201490588	09/14/2012	0026667	05/31/2017
Morocco	Pending	36906	09/14/2012		
Philippines	Published	1-2014-500557	09/14/2012		
South Africa	Allowed	2014/02534	09/14/2012		
Tajikistan	Granted	201490588	09/14/2012	0026667	05/31/2017
Thailand	Pending	1401001362	09/14/2012		
Turkmenistan	Granted	201490588	09/14/2012	0026667	05/31/2017
Ukraine	Pending	a201403617	09/14/2012		
Vietnam	Pending	1-2014-01180	09/14/2012		
<b>(898) SYNTHESIS OF ANTIVIRAL COMPOUND</b>					
India	Published	2496/MUMNP/2014	06/04/2013		
<b>(PH5040) COMBINATION FORMULATION OF TWO ANTIVIRAL COMPOUNDS</b>					
African Intellectual Property Organization (OAPI)	Granted	1201500300	01/30/2014	17450	03/31/2016
African Regional Industrial Property Organization	Pending	AP/P/2015/008630	01/30/2014		
Egypt	Pending	PCT790/2014	01/30/2014		
El Salvador	Published	E-5026-2015	01/30/2014		
Eurasian Patent Organization	Allowed	201490806	01/30/2014		
India	Pending	3953/DELNP/2014	01/30/2014		
Indonesia	Pending	P00201504713	01/30/2014		
Malaysia	Pending	PI2015001926	01/30/2014		
Pakistan	Pending	0054/2014	01/30/2014		
Paraguay	Pending	03356/2014	01/31/2014		
Philippines	Published	1-2015-501710	01/30/2014		
South Africa	Pending	2015/05718	01/30/2014		
Thailand	Pending	1501004314	01/30/2014		
Ukraine	Pending	a201508402	01/30/2014		
Vietnam	Pending	1-2015-02805	01/30/2014		

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CountryName	ApplicationStatus	AppNumber	FilDate	PatNumber	IssDate
<b>(852) ANTIVIRAL COMPOUNDS</b>					
Bolivia	Pending	SP-0347-2011	11/16/2011		
Bolivia	Published	SP-0347-2011-F1	11/16/2011		
Pakistan	Pending	289/2016	11/17/2010		
Pakistan	Pending	815/2011	11/16/2011		
Paraguay	Published	49489/2011	11/16/2011		
<b>(887) CONDENSED IMIDAZOLYLIMIDAZOLES AS ANTIVIRAL COMPOUNDS</b>					

African Intellectual Property Organization (OAPI)	Granted	1201300262	11/16/2012	17167	08/31/2015
African Regional Industrial Property Organization	Pending	AP/P/2013/006877	11/16/2012		
Belarus	Granted	201390576	11/16/2012	023644	06/30/2016
Congo, Democratic Republic of	Pending		11/16/2012		
Egypt	Pending	PCT833/2013	11/16/2012		
El Salvador	Pending	2015004891	11/16/2012		
El Salvador	Granted	2013004461	11/16/2012	00069	05/14/2015
Ethiopia	Pending	ET/PI/17/244	11/16/2012		
Eurasian Patent Organization	Published	201591244	11/16/2012		
Eurasian Patent Organization	Granted	201390576	11/16/2012	023644	06/30/2016
Fiji	Pending		11/16/2012		
Gambia	Granted	GM/P/3/2017	11/16/2012	GM/P/3/2017	04/05/2017
Guyana	Pending	1676	11/16/2012		
India	Pending	4351/DELNP/2013	11/16/2012		
Indonesia	Pending	W00201302050	11/16/2012		
Kiribati	Granted	15/2017	11/16/2012	15/2017	06/23/2017
Kyrgyz Republic	Granted	201390576	11/16/2012	023644	06/30/2016
Malaysia	Pending	PI2014001415	11/16/2012		
Morocco	Granted	36000	11/16/2012	34727	12/03/2013
Nauru	Pending	2635588	11/16/2012		
Nepal	Pending	40	11/16/2012		
Philippines	Pending	1-2015-502839	11/16/2012		
Philippines	Granted	1/2013/500976	11/16/2012	1/2013/500976	09/15/2016
Seychelles	Granted	2635588	11/16/2012	2635588	05/04/2017
South Africa	Allowed	2013/04829	11/16/2012		
South Africa	Pending	2014/06307	11/16/2012		
Tajikistan	Granted	201390576	11/16/2012	023644	06/30/2016
Thailand	Published	1301002526	11/16/2012		
Turkmenistan	Granted	201390576	11/16/2012	023644	06/30/2016
Tuvalu	Granted	TVP200	11/16/2012	TVP200	05/19/2017
Ukraine	Granted	201306068	11/16/2012	110354	12/25/2015
Ukraine	Pending	a201507807	11/16/2012		
Vietnam	Granted	1-2013-01721	11/16/2012	17119	06/27/2017
Vietnam	Pending	1-2017-00502	11/16/2012		
<b>(PH1046) PROCESSES FOR PREPARING ANTIVIRAL COMPOUNDS</b>					
Eurasian Patent Organization	Published	201692219	06/08/2015		
India	Published	201627041076	06/08/2015		
<b>(PH5090) COMBINATION FORMULATION OF TWO ANTIVIRAL COMPOUNDS</b>					
Bolivia	Published	SP-00026-2014	01/31/2014		
Eurasian Patent Organization	Published	201690473/26	01/30/2014		
India	Published	201627008488	01/30/2014		
Pakistan	Pending	0055/2014	01/30/2014		
Paraguay	Pending	03357/2014	01/31/2014		
<b>(PH6040) SOLID FORMS OF AN ANTIVIRAL COMPOUND</b>					
Eurasian Patent Organization	Published	201692220	06/08/2015		
India	Pending	201627039572	06/08/2015		

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CountryName	ApplicationStatus	AppNumber	FilDate	PatNumber	IssDate
<b>(1063) SYNTHESIS OF A MACROCYCLIC HCV NS3 INHIBITING TRIPEPTIDE</b>					
Eurasian Patent Organization	Published	201691031	12/18/2014		
India	Published	201627021364	12/18/2014		
<b>(913) INHIBITORS OF HEPATITUS C VIRUS</b>					
African Intellectual Property Organization (OAPI)	Granted	1201400575	07/02/2013	17196	08/31/2015
African Regional Industrial Property Organization	Granted	AP/P/2014/008166	07/02/2013	AP3903	11/17/2016
Bolivia	Published	SP-00204-2013	07/03/2013		
Congo, Democratic Republic of	Pending		07/02/2013		
Egypt	Pending	2100/2014PCT	07/02/2013		
El Salvador	Published	2015004886	07/02/2013		
Ethiopia	Pending	ET/PI/2017/250	07/02/2013		
Eurasian Patent Organization	Published	201790661	07/02/2013		
Eurasian Patent Organization	Granted	201492214	07/02/2013	027390	07/31/2017
Fiji	Pending	2870160	07/02/2013		
Gambia	Granted	GM/P/2/2017	07/02/2013	GM/P/2/2017	09/28/2016
Guyana	Pending	1680	07/02/2013		
India	Published	2598/MUMNP/2014	07/02/2013		
Indonesia	Pending	P00201408047	12/19/2014		
Kiribati	Granted		07/02/2013	19/17	08/11/2017
Malaysia	Pending	PI2014003617	07/02/2013		
Morocco	Pending	37659	12/16/2014		
Nauru	Pending	2870160	07/02/2013		
Nepal	Pending	52	07/02/2013		
Pakistan	Pending	442/2013	07/02/2013		
Paraguay	Pending	29361/2013	07/02/2013		
Philippines	Granted	1-2014-502862	07/02/2013	1-2014-502862	03/07/2017
Philippines	Pending	1-2016-502040	07/02/2013		
Solomon Islands	Granted	J37/397	07/02/2013	J37/397	06/06/2017
South Africa	Pending	2015/07933	07/02/2013		
South Africa	Pending	2014/09219	07/02/2013		
Thailand	Published	1401007673	07/02/2013		
Ukraine	Pending	a201413651	07/02/2013		
Vietnam	Pending	1-2014-04304	07/02/2013		

### **Appendix 3**

#### **Terms for Technology Transfer**

A. Licensee acknowledges that, as of the Amended and Restated Effective Date, Gilead has made the following information available to Licensee in accordance with Section 5.5 to fully enable Licensee to manufacture Sof, LDV, and Vel API, as well as Sof Product, LDV Product, Vel Product, Sof/LDV Product, Sof/Vel Product, and, as applicable, at commercial-scale quantities and in compliance with Gilead's required quality specifications:

1. Manufacturing process descriptions, specifications and methods;
2. Stability data;
3. Analytical method validation; and
4. Discussion of impurities.

B. Gilead will make the following information available to Licensee in accordance with Section 5.5 to fully enable Licensee to manufacture Vox API, Vox Product and Sof/Vel/Vox Product, as applicable, at commercial-scale quantities and in compliance with Gilead's required quality specifications:

1. Manufacturing process descriptions, specifications and methods;
2. Stability data;
3. Analytical method validation; and
4. Discussion of impurities.

**Appendix 4**  
**Ex-India LPSs**

<b>Name</b>	<b>Country of Registration</b>	<b>Address</b>
Ferozsons Laboratories Limited	Pakistan	5 km, Sundar Raiwind Road Raiwind, Lahore Pakistan
Magic Pharma	Egypt	5, 14 <sup>th</sup> May Street Elsayadla Buildings, 7 <sup>th</sup> Floor Semouha, Sedi Gaver Precinct, Alexandria Egyot
Pharmed Healthcare	Egypt	7, Mostafa Refaat Street Heliopolis, Sheraton El Nozha, Cairo Egypt