AMENDMENT AND RESTATEMENT AGREEMENT
in relation to the Licence Agreement dated 23 July 2022

THIS AMENDMENT AND RESTATEMENT AGREEMENT (the "**Amendment**") is entered into on the date of last signature hereto (the "**Amendment Effective Date**") by and between:

> **VIIV HEALTHCARE COMPANY** ("**ViiV**"), a company incorporated under the laws of Delaware and having its registered office at Corporation Service Company, Suite 400, Wilmington, Delaware, 19808; and
>
> **THE MEDICINES PATENT POOL FOUNDATION** (the "**MPPF**"), a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva,

each a "**Party**" and collectively referred to as the "**Parties**".

RECITALS

WHEREAS ViiV and MPPF entered into a licence agreement dated 23 July 2022 (the "**Agreement**") to enable broad access in resource-limited countries to cabotegravir for pre-exposure prophylaxis to reduce the risk of HIV-1 infection in persons weighing at least 35kg at risk of acquiring HIV-1;

WHEREAS ViiV and MPPF wish to amend and restate the Agreement, including the form of Sublicence as set out at Schedule 2 thereto, to (i) enable broad access in resource-limited countries to cabotegravir (for use in combination with rilpivirine) for the treatment of HIV-1 infection in persons weighing at least 35 kg and (ii) allow Sublicensees to make Licensed Product available in the Private Market within Royalty Countries (as each of those terms are defined in the Agreement);

NOW THEREFORE, based on the foregoing premises and mutual covenants and obligations contained herein and other good and valuable consideration, the receipt, adequacy, and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

AGREEMENT

1. **Definitions.** All capitalised terms not otherwise defined herein shall have the meaning assigned to them in the Restated Agreement.

2. **Amendment.** The Agreement is, with effect from the Amendment Effective Date, amended to take the form set out in Annexure 1 to this Amendment, which restates the Agreement as amended by this Amendment ("**Restated Agreement**").

3. **General.**

   3.1. Amendments. No provision of this Amendment may be modified or amended except expressly in writing signed by all parties.

   3.2. Governing law and dispute resolution. The provisions of Clause 29 of the Restated Agreement are hereby incorporated into this Amendment as if set out herein.

3.3. Counterparts. This Amendment may be executed in any number of counterparts, each of which will be considered an original, and together will constitute one agreement, and any part of this Amendment may be executed using an electronic signature and an electronic record (e.g., a photographic, scanned or facsimile copy of a signature) of the Agreement will have the same effect as an original hard copy.

IN WITNESS WHEREOF the Parties have executed this Amendment by their duly authorised representatives.

By and on behalf of
VIIV HEALTHCARE COMPANY

Signature Courtney M. Callihan

Name Courtney Callihan

Title Treasurer

Date 08-Jul-2025

By and on behalf of
MEDICINES PATENT POOL FOUNDATION

Signature Charles Gore

Electronically signed by: Charles Gore
Reason: I am signing for the reasons as stated in the document.
Date: Jul 8. 2025 21:28 GMT+2

Name Charles Gore

Title Executive Director

Date 08-Jul-2025

ANNEXURE 1

Restated Agreement

Licence Agreement

between

ViiV Healthcare Company
as ViiV

and

The Medicines Patent Pool Foundation
as the MPPF

THIS LICENCE AGREEMENT (this "**Agreement**") is entered into as of 23 July 2022 (the "**Effective Date**") and is amended and restated on the date of last signature hereto (the "**Amendment Effective Date**"):

BETWEEN:

(1) **VIIV HEALTHCARE COMPANY** ("**ViiV**"), a company incorporated under the laws of Delaware and having its registered office at Corporation Service Company, Suite 400, Wilmington, Delaware, 19808; and

(2) **THE MEDICINES PATENT POOL FOUNDATION** (the "**MPPF**"), a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva,

each a "**Party**" and collectively referred to as the "**Parties**".

BACKGROUND:

(A) The intent of this Agreement is to enable broad access in resource-limited countries to cabotegravir for pre-exposure prophylaxis to reduce the risk of HIV-1 infection in persons (weighing at least 35kg) at risk of acquiring HIV-1 and to cabotegravir (for use in combination with rilpivirine) for the treatment of HIV-1 infection in adults and adolescents (weighing at least 35 kg).

(B) ViiV is a pharmaceutical company focused on the needs of people living with and affected by HIV.

(C) The MPPF is a non-profit organisation with a mission to improve the health of people by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property to medicines.

(D) ViiV or its Affiliates own or have a licence to use, with the right to license or sublicense (as applicable), certain patents and patent applications relating to the compounds known as cabotegravir.

(E) The MPPF wishes to obtain a licence from ViiV of the patents and patent applications relating to cabotegravir solely to enable it to grant sublicences to such patents and patent applications to agreed third parties.

(F) As at the Effective Date, ViiV has granted the MPPF the right to sublicense certain patents and patent applications which relate to the compound known as cabotegravir for pre-exposure prophylaxis to reduce the risk of HIV-1 infection. As at the Amendment Effective Date, ViiV further grants the MPPF the right to sublicense certain patents and patent applications to cabotegravir to enable its use in combination with rilpivirine for the treatment of HIV-1 infections.

(G) ViiV is willing to grant such a licence provided that such sublicences are in the form of the Sublicence (as defined below).

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1. **Definitions and interpretation**

1.1 Capitalised terms not defined in this Agreement have the meaning given to such terms in the form of Sublicence as included at Schedule 2 to this Agreement.

1.2 "**Licensee Selection Process**" means the process set out in Clause 4.

1.3 "**Sublicence**" means a licence agreement in the form set out in Schedule 2 hereto.

1.4 "**Successful Applicant**" has the meaning given to such term in Clause 4.3.

1.5 "**Sublicensee**" means a Successful Applicant that has entered into a Sublicence.

1.6 "**Third Party**" means any party other than a Party to this Agreement.

1.7 Clause and Schedule headings shall not affect the interpretation of this Agreement.

1.8 The Schedules form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Schedules.

1.9 References to Clauses and Schedules are to the Clauses and Schedules of this Agreement, unless otherwise stated.

1.10 References to the provisions of a Sublicence are to those provisions in the form of Sublicence as included at Schedule 2 to this Agreement or to any equivalent provision in any Sublicence entered into with any Sublicensee.

1.11 Unless the context otherwise requires, words in the singular include the plural and, in the plural, include the singular.

1.12 Unless the context otherwise requires, a reference to one gender shall include a reference to the other gender.

1.13 A reference to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time, and shall include any subordinate legislation made from time to time under that statute or statutory provision.

1.14 Any words following the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.15 A "person" includes a natural person, corporate or unincorporated body (whether or not having separate legal personality) and that person's legal and personal representatives, successors and permitted assigns.

2. Governance

2.1 As soon as reasonably practicable and in any event within thirty (30) days after the Effective Date, the Parties will establish a steering committee (the "**Steering Committee**"). The Steering Committee shall be responsible for: (i) reviewing the performance of the Parties' respective obligations under this Agreement; (ii) reviewing the performance of the Sublicensee and the MPPF's respective obligations under each Sublicence; (iii) facilitating communication between the Parties; (iv) considering whether any amendments or extensions are required to this Agreement or any Sublicence (subject always to Clause 18 and 26).

2.2 The Steering Committee shall be composed of four (4) persons ("**Members**"), two (2) Members from each Party, each with appropriate seniority and operational expertise. Each Party may replace any of its Members, either on an ad hoc or permanent basis. A Party that replaces a Member shall notify the other Party prior to the next scheduled meeting of the Steering Committee. The quorum for a meeting of the Steering Committee shall be one (1) Member of each Party, or the relevant Member's replacement. Both Parties may invite a reasonable number of additional experts and/or advisors and/or observers to attend a part or the whole of each Steering Committee meeting, if and as the need arises, with prior notification to the Steering Committee and subject to obligations of confidentiality no less onerous than those in Clause 13.

2.3 The venue for the Steering Committee meetings shall be agreed by the Steering Committee and such meetings shall be held on a quarterly basis, either in person or by tele-/video-conference, or as frequently as the Members may agree shall be reasonably necessary. Each Party shall bear responsibility for all travel and other related costs for its Members and representatives to attend and/or participate in Steering Committee meetings.

2.4 A Member from the MPPF shall: chair each Steering Committee meeting; prepare and distribute in advance of each meeting a draft agenda; and record and circulate draft minutes of each meeting within five (5) Business Days of the meeting. Any comments on the draft minutes must be provided to the relevant drafting MPPF Member in writing within fourteen (14) days after receipt. The Members shall act in good faith to attempt to resolve any disputes over the content of the Steering Committee minutes as quickly as possible. If, however the Parties cannot agree on the content of the Steering Committee minutes it shall be noted in the minutes that the Parties did not agree on the content of the minutes and each Party's view shall be recorded.

2.5 The Members of the Steering Committee shall act in good faith and cooperate with one another and seek agreement with respect to issues to be decided by the Steering Committee. All decisions are to be made by unanimous consensus of Members in attendance and voting, with the MPPF Members collectively having one vote and the ViiV Members collectively having one vote. If the Steering Committee is unable to decide a matter by consensus within ten (10) Business Days of the matter first being discussed at a Steering Committee meeting following inclusion on a draft agenda distributed to the Steering Committee Members, the issue shall be resolved pursuant to Clause 29.

3. **Grant of Licence**

3.1 Subject to the terms and conditions of this Agreement ViiV hereby grants to the MPPF a non-exclusive, non-transferable licence under the Patent Rights to enter into Sublicences with Successful Applicants. For the avoidance of doubt, no rights are granted, including any intellectual property rights, to rilpivirine.

3.2 No rights are hereby granted for any other purpose and the MPPF agrees that it will not use or exploit the Patent Rights itself or grant sublicences: (i) to entities other than Successful Applicants; and/or (ii) other than in the form of the Sublicence.

3.3 The number of Sublicences granted pursuant to Clause 3.1 shall be limited to three (3), subject to the following:

(A) if at any time during the Term, the MPPF considers that public health demand for Licensed Product is not met by the volume of Licensed Product sold or otherwise supplied pursuant to the then existing Sublicences (other than due to temporary interruptions to existing supply), in respect of either the pre-exposure prophylaxis indication or the treatment indication (or both), the MPPF shall notify ViiV of the same, sharing appropriate supporting evidence. If ViiV determines, acting reasonably, that the evidence demonstrates a public health need for additional Licensed Product in the Territory, it shall grant the MPPF the right to enter into additional Sublicence(s) under Clause 3.1, the number of which shall be determined by ViiV based on the evidence shared by the MPPF; and

(B) if at any time during the Term, any Sublicence is terminated pursuant to Clause 21 of such Sublicence, MPPF shall have the right to grant additional Sublicence(s) under Clause 3.1 to bring the number of Sublicenses back up to 3 (or such other number of Sublicenses as agreed by ViiV pursuant to Clause 3.3(A)).

4. **Licensee Selection Process**

4.1 The MPPF will coordinate the Licensee Selection Process and the subsequent execution of a Sublicence between the MPPF and each Successful Applicant.

4.2 Promptly after the Effective Date (and in any event within ninety (90) days of the Effective Date), or pursuant to Clause 4.5 below, the MPPF will identify and notify ViiV of up to a maximum of three (3) Third Parties, each of which has:

(A) demonstrated possession of, or demonstrated readiness to acquire, adequate infrastructure (operating under current Good Manufacturing Practice), technical capability, capacity, and willingness to (i) develop Licensed Compound and Licensed Product, and (ii) manufacture Licensed Product in a manner consistent with WHO pre-qualification standards or the standards of any regulatory authority which was a member or observer of the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**"), or associated with an ICH member through a legally-binding, mutual recognition agreement, in each case as before 23 October 2015;

(B) demonstrated possession of adequate infrastructure to enable it to distribute and supply Licensed Product to the majority of the Territory;

(C) provided a current EcoVadis report, or if the Third Party has no current report, has committed to obtaining such EcoVadis report as quickly as possible; and

(D) in place a quick and efficient batch trace procedure following the GS1 Global Traceability or comparable standard, so as to enable the identification and location of Licensed Compound

and Licensed Products from individual batches with minimal delay and the ability to implement upon request,

collectively the "**Selection Criteria**". At the same time, the MPPF shall provide documentary evidence, to ViiV's satisfaction, that each proposed Third Party meets such Selection Criteria.

4.3 Within fifteen (15) Business Days of receipt by ViiV of satisfactory documentary evidence that such proposed Third Party meet the Selection Criteria, ViiV shall inform the MPPF in writing whether it agrees or disagrees that the Third Party proposed by the MPPF meet the Selection Criteria. In the event ViiV considers that the proposed Third Party has not satisfied the Selection Criteria, ViiV shall provide its reasons. In the event ViiV considers that the Third Party has satisfied the Selection Criteria, ViiV shall as soon as reasonably practicable undertake and complete any additional due diligence on such Third Party as it, in its sole discretion, considers necessary, and inform the MPPF of the outcome of such due diligence. MPPF shall facilitate compliance by the Third Party with the due diligence process. A Third Party who has satisfied the Selection Criteria and who has successfully passed ViiV's due diligence process shall be referred to in this Agreement as a "**Successful Applicant**".

4.4 Following ViiV's written confirmation that a Third Party proposed by the MPPF is a Successful Applicant pursuant to Clause 4.3, the MPPF shall promptly (and in any event within one (1) Calendar Month of the Effective Date) execute a Sublicence with such Successful Applicant.

4.5 If at any time during the Term, the MPPF has the right to grant additional Sublicences pursuant to Clauses 3.3(A) and/or 3.3(B), MPPF shall re-initiate the Licensee Selection Process in order to identify qualified sublicensee(s) up to the maximum number of permitted Sublicensees.

5. **Assistance with Product Development and Regulatory Approvals**

Data Package

5.1 In the event the MPPF receives (pursuant to Clause 5 of a Sublicence) a written request for ViiV to provide a data package to expedite development and filing for Regulatory Approval in the Territory, the MPPF shall promptly forward such request to ViiV. Upon receipt of the request, ViiV shall consider the request and, if ViiV in its sole discretion considers it feasible to do so, ViiV shall assemble and make available to each Sublicensee a single discrete data package, which (i) content shall be determined by ViiV in its sole discretion, and (ii) provision shall be conditional on such Sublicensee entering into a separate non-disclosure agreement with ViiV regarding the data package.

ViiV Products

5.2 ViiV commits to sell to each Sublicensee that has executed a Sublicence prior to the Amendment Effective Date, at a discounted price to be determined by ViiV at its sole discretion, and subject to terms to be agreed between ViiV and such Sublicensee, up to 1000 tablets of oral cabotegravir (30mg tablets) and up to 1000 vials of extended-release injectable suspension of cabotegravir (600mg/3mL vials), solely for use in (a) *in vitro* research related to the Sublicensee's Licenced Product development and (b) bioequivalence studies required to obtain Regulatory Approval. In the event the MPPF receives (pursuant to Clause 5 of a Sublicence) a written request for ViiV to sell ViiV Product to a Licensee, the MPPF shall promptly forward such request to ViiV. The MPP shall ensure that as part of any request, a Sublicensee provides details of its (a) development plan and associated milestones and (b) bioequivalence study plans. ViiV shall work directly with the relevant Sublicensee to agree the terms of such sale.

Exclusivity waivers

5.3 Subject to compliance by a Sublicensee with the terms of the Sublicence, ViiV shall provide such Sublicensee:

(A) with new chemical entity exclusivity or other regulatory exclusivity waivers to the extent required by the applicable regulatory authorities to enable such Sublicensee to apply for Regulatory Approval; and

(B) such consents which it has the legal capacity to give as are necessary to enable such Sublicensee to perform its obligations under Clauses 4.2 and 4.3 of the Sublicence.

5.4 If a request for a Selective Waiver Letter is made to the MPPF by a Sublicensee in accordance with

Clause 6 of the Sublicence:

(A) the MPPF shall notify ViiV and provide ViiV with the information required by ViiV to prepare the requested Selective Waiver Letter; and

(B) provided that the Sublicensee has complied with all the requirements of Clause 6 of the Sublicence (including in relation to the inclusion of a Paragraph III Certification), ViiV will complete the Selective Waiver Letter (including by printing such Selective Waiver Letter onto its official letterhead and arranging for the Selective Waiver Letter to be signed by a suitably authorised employee of ViiV or its Affiliate) and submit the Selective Waiver Letter to the FDA within thirty (30) days of receiving all the information required to prepare the requested Selective Waiver Letter, from the MPPF.

5.5 ViiV shall retain sole discretion as to the form and content of the Selective Waiver Letter, provided that the form and content of such Selective Waiver Letter is consistent with the terms of Clause 6 of the Sublicence.

5.6 ViiV shall remain entitled at any time to revoke a Selective Waiver Letter and/or any consent or waiver contained therein if the relevant Licensee fails to comply with any of the terms of the Sublicence (including any of the requirements of Clause 6 of the Sublicence) and/or if the relevant Sublicensee submits a Paragraph IV Certification in relation to any Relevant ANDA or Relevant NDA.

5.7 ViiV shall provide a copy of each Selective Waiver Letter as submitted by it to the FDA to the MPPF within ten (10) Business Days of its submission to the FDA.

5.8 The provisions of Clauses 5.4 to 5.7 (inclusive) are without prejudice to the provisions of Clause 5.3.

Clinical Research Activities

5.9 The MPPF shall (a) promptly forward to ViiV any notice of Clinical Research Activity received pursuant to Clause 4.8 of the Sublicence, (b) provide ViiV with regular updates of any meetings with the Licensee regarding any Clinical Research Activity and (c) ensure that Licensees complies with ViiV's reasonable requests in relation to the design and conduct of such Clinical Research Activities.

6. **Reporting**

Annual reporting

6.1 As soon as practicable and in any event by no later than 15 November in each Calendar Year of the Term and provided that the MPPF receives the relevant information from the appropriate Third Parties, the MPPF shall provide to ViiV a written forecast (in a form that is satisfactory to ViiV) of the amount of Licensed Product it expects the Sublicensee(s) to sell in the following Calendar Year, broken down in respect of each country in the Territory and each Licensed Product.

6.2 By no later than 28 February in each Calendar Year of the Term, the MPPF shall deliver a written report (in a form that is satisfactory to ViiV) setting out, (i) on a country-by-country, Sublicensee-by-Sublicensee and Licensed Product-by-Licensed Product basis the total amount of Licensed Product sold by each Sublicensee in each country in the Territory in the previous Calendar Year; (ii) on a country-by-country and Licensed Product-by-Licensed Product basis the total amount of Licensed Product which was forecast to be sold in that Calendar Year pursuant to the relevant forecast in Clause 6.1; and (iii) the difference between the amounts in (i) and (ii) above.

Quarterly reporting

6.3 Within twenty (20) Business Days after the end of each Agreement Quarter, the MPPF shall deliver written report(s) to ViiV consolidating the contents of all reports provided to the MPPF by each Sublicensee under Clause 8 of the Sublicence and setting out:

(A) on a country-by-country, Sublicensee-by-Sublicensee and Licensed Product-by-Licensed Product basis:

(i) all Development Activities and Regulatory Approval activities and estimated timelines for Stringent Regulatory Authority, WHO-Listed Authority and/or WHO Prequalification Programme submissions and national regulatory submissions;

(ii) the total amount of Licensed Products sold and/or supplied for the immediately preceding Agreement Quarter;

(iii) the total aggregate amount of Licensed Products sold and/or supplied in that Calendar Year up to and including the immediately preceding Agreement Quarter; and

(iv) the calculations for any royalty due to ViiV in respect of each Sublicence for the immediately preceding Agreement Quarter; and

(B) on a country-by-country and Licensed Product-by-Licensed Product basis, the estimated total number of persons on a Licensed Product in the Calendar Year up to and including the immediately preceding Agreement Quarter; and

(C) for each sale or supply of Licenced Product made pursuant to an Approved Royalty Country Procurement, the outcome of MPPF's verification under Clause 8.1(B), summarising the steps taken by the MPPF in reaching such outcome.

Such report(s) shall further include a written certification by an officer of the MPPF confirming that the MPPF has reviewed the contents of all reports provided to the MPPF by each Sublicensee in the preparation of this report and that, in the MPPF's reasonable opinion: (i) each Sublicensee's sales comply with the terms of the Sublicence and (ii) each Sublicensee's royalty calculations for the relevant period are correct.

Pharmacovigilance reporting

6.4 By no later than twenty (20) Business Days after the end of the Agreement Quarters ending 30 June and 31 December, the MPPF shall deliver a written report to ViiV (in a form to be provided by ViiV) consolidating the contents of every pharmacovigilance report provided to the MPPF by each Sublicensee under Clause 13.2.4 of the Sublicence.

6.5 By no later than five (5) Business Days following receipt by the MPPF of a clinical trial report under Clause 13.2.5 of a Sublicence, the MPPF shall forward such report to ViiV.

7. **Approval Requests**

The Parties acknowledge and agree that pursuant to the terms of the Sublicence, each Sublicensee is required to seek the MPPF's approval in respect of certain actions. The MPPF shall, using reasonable skill and care, promptly review:

7.1 **Royalty Country Public Procurement** – under Clause 3.7 of the Sublicence, any request by a Sublicensee for an Approved Royalty Country Public Procurement. The MPPF shall determine based on the evidence provided by the Sublicensee, whether the proposed sale or supply is (i) to a Public Market and (ii) of a volume of Licensed Product that is commensurate with the demand for Licensed Product(s) in such Public Market for the applicable Usage Period, as such demand is reasonably estimated by the MPPF. The MPPF shall only approve (or allow its approval to be deemed to be granted) for proposed sales or supplies that are to a Public Market and of a volume of Licensed Product(s) that is commensurate with demand;

7.2 **Affiliates and Local Distributors** – under Clauses 3.3 and 3.4 of the Sublicence, any request by a Sublicensee for an Approved Affiliate or an Approved Local Distributor (respectively). The MPPF shall, on the basis of the documentation provided by the Sublicensee:

(A) assess:

(i) in the case of a request for approval of an Affiliate, whether the proposed entity is an Affiliate of the Sublicensee; and

(ii) in the case of requests for approval of a Local Distributor, whether for the Licensed Product to be lawfully sold or otherwise supplied in such country the Regulatory Approval must be held in the name of a legal entity registered in the relevant country of the Territory and if so, whether the proposed Local Distributor fulfils the MPPF's reasonable due diligence requirements; and

(B) inform the Sublicensee whether it approves the Affiliate as an Approved Affiliate or the Local Distributor as an Approved Local Distributor (providing its grounds for refusal in the event it

does not approve the request).

The MPPF shall keep an up to date written record of all Approved Affiliates and Approved Local Distributors, and make such record available to ViiV through the MPPF's online trade dress portal or in any other manner agreed between the Parties; and

7.3 **Trade Dress and Trade Marks** –under Clause 7 of the Sublicence**,** any request by a Sublicensee for written approval to use a Trade Mark or Trade Dress in relation to a Licensed Product. The MPPF shall promptly assess whether the proposed Trade Mark and/or Trade Dress for use in relation to Licensed Product complies with the Trade Dress Guidance. If the MPPF determines that such Trade Mark and/or Trade Dress does not comply with the Trade Dress Guidance, it shall promptly inform the Sublicensee of the same, with a written statement of why the request is not being approved. If the MPPF determines that such Trade Mark and/or Trade Dress complies with the Trade Dress Guidance, it shall inform ViiV of the same, and the Parties agree that ViiV shall, within thirty (30) days of receipt of such notification, review the Sublicensee's request and shall, on behalf of the MPPF and at ViiV's sole discretion, provide (through the MPPF's online trade dress portal or in any other manner agreed between the Parties) a written approval or a written statement of why the request is not being approved. ViiV shall provide the MPPF with the Trade Dress Guidance and shall keep it up to date by including information such as specific tablet shapes, tablet/vial/packaging colours to be avoided, and any additional new and/or future ViiV trade dress as soon as practicable after ViiV considers such information no longer to be confidential. The Trade Dress Guidance does not limit in any way ViiV's right to refuse to provide approval under this Clause, and the basis of ViiV's refusal to provide approval under this Clause is not limited to breaches of Clause 7.2 of the Sublicence.

8. **Sublicence Compliance**

8.1 **Monitoring** – The MPPF shall, using all reasonable care, diligence and skill, actively monitor each Sublicensee's compliance with the terms of its Sublicence, including:

(A) **Reporting** – procuring that all Sublicensees provide the reports referred to in Clauses 8 and 13 of the Sublicence in a timely manner and in accordance with the terms of those Clauses and any Reporting Guidance (where applicable). If, notwithstanding the MPPF's efforts, a Sublicensee does not provide such reports:

(i) in the case of reports under Clause 8 of the Sublicence, within five (5) Business Days after the ten (10) Business Day period provided under the terms of the Sublicence; or

(ii) in the case of the report under Clause 13 of the Sublicence, (a) within five (5) Business Days after the required ten (10) Business Day period provided under Clause 13.2.4 of the Sublicence and (b) promptly in the case of clinical trial reports (provided under Clause 13.2.5 of the Sublicence) at the conclusion of the relevant clinical research),

the MPPF shall inform ViiV of the same and provide details of its efforts to date to procure such reports;

(B) **Approved Royalty Country Public Procurement** – verifying that every sale or supply of Licensed Product for use in the Public Market of a Royalty Country was made in accordance with an Approved Royalty Country Public Procurement and report the outcome of such verification to ViiV (summarising the steps taken by the MPPF in reaching such outcome) in the relevant quarterly report under Clause 6.3;

(C) **Non-diversion** – verifying that:

(i) all sales and/or supplies of Licensed Product by each Sublicensee were made in compliance with Clause 10 of the Sublicence; and

(ii) the volume of Licensed Product sold and/or supplied by Sublicensee(s) for use in any Permitted Market for any period of time is commensurate with the demand for Licenced Product(s) in such Permitted Market for such period of time, as reasonably estimated by the MPPF. If the volume of Licenced Product sold and/or supplied by Sublicensee(s) for use in a Permitted Market exceeds such demand, the MPPF shall take reasonable steps to determine whether any Sublicensee has breached the terms of its Sublicence;

(D) **Royalty calculations** - verifying the accuracy of any royalty calculation included in or

accompanying each sales report provided by the Sublicensee pursuant to Clause 9 of the Sublicence. If an error is identified by the MPPF in respect of such a royalty calculation, the MPPF shall promptly take all steps necessary to ensure that such error is rectified and that the correct amount of royalties payable under the Sublicence is remitted to ViiV;

(E) **Royalty payment** – where applicable, ensuring the timely quarterly (i) delivery of invoices issued by ViiV in respect of royalties owed to ViiV pursuant to (and in accordance with) Clause 9 of the Sublicence to each Sublicensee and (ii) payment of such royalties (together with any interest due) to ViiV (or to such other person as ViiV has nominated). ViiV shall use reasonable endeavours to issue all invoices in a timely manner to ensure compliance by the MPPF with the timelines under Clause 9 of the Sublicence;

(F) **Pharmacovigilance –** monitor the activities and duties of each Sublicensee as regards pharmacovigilance obligations under Clause 13 of the Sublicence, and (b) otherwise procuring compliance by each Sublicensee with such Clause 13 of the Sublicence. ViiV will communicate to MPP any significant safety issue that may (i) impact the benefit/risk ratio of the Product, (ii) require urgent communication by Licensees to health care professionals regarding Licensed Product or (iii) require the restriction of the use of the Product in a certain population. The MPPF shall promptly forward any such communications to each Licensee; and

(G) **Audit rights** – fully exercising the audit right set out in Clause 19 of the Sublicence at the MPPF's own cost as soon as the MPPF has reasonable cause to believe an audit is necessary (including grounds for suspecting non-compliance with the Sublicence).

8.2 **Management of breaches** – If the MPPF becomes aware of any act or omission of a Sublicensee which may in the MPPF's reasonable opinion constitutes a breach of the Sublicence, then the MPPF shall:

(A) share with ViiV as soon as reasonably practical details of the suspected breach and the MPPF's proposed course of action; and

(B) keep ViiV up to date of the management of such breach including any mitigation plan agreed with the Sublicensee.

8.3 **Unconditional obligations** – The MPPF's obligations under this Clause 8 constitute direct, primary and unconditional obligations of the MPPF and shall not require ViiV to first take any steps against any Sublicensee or any other person.

9. **Liability and Indemnity**

9.1 The MPPF shall be held jointly and severally liable with each Sublicensee for any breach of a Sublicence by such Sublicensee.

9.2 The MPPF undertakes to indemnify, defend and hold harmless ViiV, its Affiliates and each of their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") in respect of any and all losses, claims, liabilities, costs, awards, fines, penalties, damages and expenses (including, legal costs and other professional expenses) of any nature whatsoever and whether or not reasonably foreseeable or avoidable ("**Losses**") arising out of, or in connection with any claim by a Third Party relating to:

(A) any breach by the MPPF of any provisions of this Agreement;

(B) any negligence or wilful misconduct by or on behalf of the MPPF; and/or

(C) any breach of a Sublicence by the MPPF or any Sublicensee,

except to the extent arising or resulting from ViiV's negligence or wilful misconduct.

9.3 If ViiV exercises its rights under Clause 9.2, ViiV shall: (i) provide the MPPF with prompt written notice of such Third Party claims; and (ii) grant the MPPF the right to control the defence or negotiation of settlement of such Third Party claims (except to the extent such claims relate to the validity or enforcement of Patent Rights); and (iii) make available all reasonable assistance which is reasonably requested by the MPPF in defending any claims (at the MPPF's cost).

9.4 ViiV will not be liable to the MPPF for any Losses incurred by the MPPF as a result of: (i) the MPPF's exercise of the rights granted to it under this Agreement; or (ii) a Sublicensee's exercise of the rights granted to it under a Sublicence, in both cases including any Losses in relation to any infringement of the intellectual property rights of any Third Party.

9.5 EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES REGARDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF INTELLECTUAL PROPERTY OR OTHER THIRD PARTY RIGHTS, VALIDITY OR ENFORCEABILITY OF INTELLECTUAL PROPERTY RIGHTS, THE GRANT OF ANY PENDING PATENT APPLICATIONS, OR RELEVANCE OF THE PATENT RIGHTS TO THE COMPOUND OR PRODUCT, ARE MADE OR GIVEN BY OR ON BEHALF OF VIIV AND, EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. IN PARTICULAR NO REPRESENTATION OR WARRANTY IS MADE IN RESPECT OF THE ACCURACY OF ANY DETAILS PROVIDED IN RESPECT OF THE PATENT RIGHTS INCLUDING THOSE SET OUT IN APPENDIX C OF THE SUBLICENCE. Notwithstanding the foregoing, nothing in this Agreement shall limit or exclude the liability of either Party for death or personal injury resulting from negligence or fraud or fraudulent misrepresentation or other matters, the exclusion of liability for which is not allowable under Applicable Law.

10. Records and Audit Rights

10.1 During the Term and for a period of three (3) years thereafter, the MPPF shall keep, complete, accurate and systematic records of all transactions under or in connection with this Agreement. The MPPF must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

10.2 During the Term of this Agreement and for a period of three (3) years thereafter, ViiV shall have the right to, upon reasonable advance written notice to the MPPF, and during normal business hours at a mutually agreed upon time (such agreement not to be unreasonably withheld or delayed), and through the engagement of an independent, internationally recognized accounting firm (at ViiV's expense and subject to confidentiality restrictions consistent with Clause 13), review and inspect records maintained by the MPPF in respect of its performance of this Agreement and the Sublicences and its compliance with Applicable Law for the sole purpose of determining the MPPF's compliance with this Agreement, the Sublicences and Applicable Law. The scope of any such review may at ViiV's discretion include the review of relevant internal procedures, training records, financial books and records and any other documents reasonably necessary to assess compliance by the MPPF with any of the terms of this Agreement or the Sublicence(s). The MPPF will cooperate fully with any audit and provide all reasonable assistance to ViiV and its representatives or contractors for completion of such audit. To the extent that any material deficiencies are identified as the result of such inspection, the MPPF shall take all reasonable corrective measures to remedy any such material deficiencies.

11. Intellectual Property

11.1 Other than as set out under Clause 3.1, this Agreement confers no intellectual property rights whatsoever on the MPPF.

11.2 ViiV agrees only to exercise the rights granted to it under Clause 14.2 of the Sublicence in accordance with the licence granted therein.

11.3 ViiV shall have the exclusive right, but shall be under no obligation whatsoever, to maintain, prosecute, renew, defend or enforce any of the Patent Rights. For the avoidance of doubt, the MPPF shall have no rights whatsoever to maintain, prosecute, renew, defend or enforce any of the Patent Rights and nor shall it purport to grant any such rights to any Sublicensee or Third Party.

12. Compliance With Applicable Law and Ethical Business Practices

The MPPF shall perform all activities under or in connection with this Agreement in compliance with all Applicable Law and the provisions of Schedule 1.

13. Confidentiality

13.1 Each Party shall hold Confidential Information disclosed to it under or in connection with this Agreement in strict confidence and shall not use such Confidential Information for any other purpose than the performance of this Agreement.

13.2 The Party that releases, exchanges, or discloses Confidential Information (the "**Disclosing Party**") shall use reasonable efforts to mark such Confidential Information as "Confidential". In the event that Confidential Information is disclosed and not so marked, the receiving Party agrees to treat such information as confidential to the extent that a reasonable person would consider such information to be confidential given the content and circumstances of the disclosure.

13.3 A receiving Party shall not disclose any Confidential Information received from the Disclosing Party and/or any of its Affiliates under or in connection with this Agreement, or otherwise developed by any Party in the performance of activities in furtherance of this Agreement, except to such of its, and its Affiliates' officers, employees, agents, representatives, advisors, consultants and Sublicensees to whom disclosure is necessary to exercise the Party's rights or perform the Party's obligations under this Agreement, and who are bound by confidentiality and non-use obligations (i) no less onerous than those contained in this Clause 13 and (ii) enforceable by the Disclosing Party.

13.4 The obligations in Clauses 13.1, 13.2 and 13.3 shall not apply to the following as established by reasonable, written proof:

(A) information which at the time of disclosure is in the public domain;

(B) information which, after its disclosure, becomes part of the public domain by publication or otherwise, except by breach of this Agreement;

(C) information that a Party can demonstrate was lawfully possessed by it prior to disclosure under or in connection with this Agreement;

(D) information that a Party receives from a Third Party which is not legally prohibited from disclosing such information;

(E) information a Party is required by law to disclose, provided that the other Party is promptly notified of any such requirement; or

(F) information which is independently developed by the receiving Party or its Affiliates who had no knowledge of the Disclosing Party's Confidential Information.

13.5 If a receiving Party becomes obligated by law to disclose Confidential Information received under or in connection with this Agreement, or any portion thereof, to any Third Party, governmental authority or court, that Party shall immediately notify the Disclosing Party thereof of each such requirement and identify the Confidential Information to be disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and, to the extent necessary, waive the receiving Party's compliance with the confidentiality obligations of this Agreement.

13.6 The Parties acknowledge that disclosure of any Confidential Information in breach of this Agreement could give rise to irreparable injury to the non-breaching Party or its Affiliates and that such injury will not be adequately compensated by damages. Accordingly, the non-breaching Party and its Affiliates shall be entitled to the remedies of specific performance and injunctive relief or other equitable relief for any threatened or actual breach of this Clause 13. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.

13.7 All Confidential Information shall remain the property of the Disclosing Party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party , based on the insolvency or bankruptcy of such Party (or based on any other analogous or similar status of that Party under foreign laws), the bankrupt or insolvent Party shall promptly notify the court or other tribunal:

(A) that Confidential Information remains the property of the Disclosing Party; and

(B) of the confidentiality obligations under this Agreement.

In addition, the bankrupt or insolvent Party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of such Confidential Information and to ensure that the court,

other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

13.8 For the avoidance of doubt, ViiV shall treat any information relating to a Sublicensee disclosed to it by the MPPF under Clauses 6 as Confidential Information provided that ViiV shall be entitled to disclose information about the quantities of Licensed Products sold or supplied by Sublicensees on an aggregate basis provided such disclosure does not reveal any Confidential Information of any Sublicensee.

13.9 The obligations under this Clause 13 shall remain in full force and effect for the duration of this Agreement plus five (5) years.

14. Publicity and external communications

14.1 Each Party shall seek the other Party's written approval of any initial press release or public announcement concerning the grant, scope or terms of this Agreement ("**Initial Announcement**") prior to such press release, or any other publication regarding this Agreement, being made. Following the Initial Announcement, neither Party shall be required to seek the other Party's consent to respond to reactive statements to the Initial Announcement, provided such statements are accurate and not misleading.

14.2 The MPPF shall not refer to ViiV and/or its Affiliates, or ViiV's and/or its Affiliate(s)' Trade Marks in any external communications without prior approval from ViiV, except where such reference is to the ViiV company name and is limited to a factual statement that ViiV is the licensor of the Patent Rights under this Agreement. For the avoidance of doubt, the MPPF shall in no circumstances refer to any brand name of ViiV and/or its Affiliates in any communication without ViiV's prior written approval.

14.3 Subject to Clauses 13, 14.1 and 14.2, neither Party shall be required to obtain the other Party's prior consent for any external communication relating to this Agreement.

14.4 The MPPF shall provide ViiV the opportunity to review and comment on the methodology behind any external communication regarding the MPPF's analysis of the economic and public health impact of this Agreement at least five (5) Business Days prior to publication of any such communication. For the avoidance of doubt, the MPPF shall not be required to provide ViiV the opportunity to review any subsequent communications made by MPPF regarding its analysis of the economic and public health impact of this Agreement that are based on methodology already reviewed by ViiV, however the MPPF will use reasonable endeavours to provide copies of any such communications to ViiV at least five (5) Business Days prior to publication, where practicable.

14.5 Each Party shall ensure that any of its external communication relating to this Agreement is accurate and not misleading.

14.6 Each Party acknowledges that it is solely responsible and liable for its external communications relating to this Agreement, including compliance with any Applicable Law.

14.7 The MPPF shall promptly submit to ViiV for review any Materials submitted to the MPPF by a Sublicensee under Clause 12.4 of the Sublicence. ViiV shall within fifteen (15) Business Days of receipt of the Materials provide its comments to the MPPF and MPPF shall share such comments with such Sublicensee. The MPPF shall ensure that the Licensee takes into consideration any reasonable comment of ViiV on the Materials.

14.8 The MPPF shall promptly inform ViiV any Sublicensee's proposal under Clause 12.5 of the Sublicence to engage with any guideline bodies or external experts in relation to the development of Licenced Product, and shall at ViiV's request, (a) meet with ViiV to discuss such engagement and (b) ensure that the Sublicensee complies with any reasonable request of ViiV regarding the engagement.

15. Term and termination

15.1 **Term.** Unless terminated earlier in accordance with the terms of this Agreement, this Agreement shall come into force on the Effective Date and shall remain in effect on a country-by-country basis until the expiration, lapse or invalidation of the last remaining Patent Right in the Territory and, where the country of manufacture of a Sublicensee's Licenced Compound or Licensed Product is outside the Territory, in such country of manufacture (the "**Term**").

15.2 **Mutual termination rights.** In addition to any other rights to terminate at law or as expressly provided

in this Agreement, either Party may terminate this Agreement immediately (or on such date that it set out in the notice of termination) upon written notice to the other Party:

(A) **Insolvency** – if the other Party is affected by an insolvency or adjudication of bankruptcy, the filing of a voluntary petition in bankruptcy, the making of an assignment for the benefit of creditors, any substantial part of a Party's assets coming under the jurisdiction of a receiver, administrator, liquidator, trustee or similar officer in an insolvency proceeding authorised by law or if proceedings are instituted against the other Party for winding up or reorganisation or other relief under any insolvency law. For the purposes of this Clause, "**insolvency**" means either the Party's liabilities exceed its assets, each fairly stated; or the Party's inability to pay its business obligations in the regular course of business;

(B) **Material breach** – if the other Party commits a material breach of any provision of this Agreement that is not capable of being remedied, or if capable of being remedied, fails to remedy such material breach within thirty (30) days following receipt of a written notice specifying the nature of the breach. For the avoidance of doubt, breaches of the following Clauses are, without limitation, deemed a material breach of the Agreement: Clauses 3 (Grant of Licence), 4 (Licensee Selection Process), 7 (Approval Requests), 12 (Compliance With Applicable Law and Ethical Business Practices), 13 (Confidentiality), and 18 (Exercise of rights by the MPPF under a Sublicence);

(C) **Repeated breach** – if the other Party repeatedly (meaning more than once) breaches any of the terms of this Agreement (whether or not those such breaches are material breaches); or

(D) **Force Majeure** - in accordance with Clause 17.

15.3 **ViiV's termination rights.** ViiV may terminate this Agreement, in whole or in part, immediately (or on such date that it set out in the notice of termination) upon written notice to the MPPF if:

(A) Infringement of Third Party intellectual property – ViiV receives a Third Party claim that a Sublicensee's use of any Patent Rights under a Sublicence infringes the intellectual property rights of a Third Party, unless all Sublicensees confirm in writing to ViiV that they will indemnify any and all Indemnified Person (as defined in Clause 9.2) against any and all Losses (as defined in Clause 9.2) in connection with the Sublicensees continued use of the Patent Rights pursuant to their Sublicences; or

(B) Ownership or control of the MPPF – the legal or beneficial ownership or control of the MPPF changes in such a manner as ViiV shall in its sole discretion consider significant. For the avoidance of doubt, MPPF securing new or different funders or donors shall not constitute a change of control of the MPPF under this Clause.

16. **Consequences of expiry or termination**

16.1 **Duties.**

(A) Upon termination or expiry of this Agreement:

(i) all rights and licences granted hereunder (including those in Clause 3.1) shall immediately terminate; and

(ii) each Party shall promptly return or (at the other Party's election) destroy and irretrievably erase all embodiments of the other Party's Confidential Information which are in its power, possession, custody or control; provided, that (i) ViiV may retain copies of such of the MPPF's Confidential Information as may be required to be able to have the benefit of any continuing licences under Clause 16.1(B)(ii); and (ii) each Party may retain one copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes or as (and to the extent) required by Applicable Law and shall continue to comply with the terms of Clause 13 in respect of the same.

(B) Upon termination of this Agreement, the MPPF shall procure that each Sublicence granted and in full force and effect at the time of termination of this Agreement shall either be:

(i) if there are grounds to terminate such Sublicence under Clause 21 of the Sublicence and upon request by ViiV, immediately terminated in accordance with its terms; or

(ii) if there are no grounds to terminate such Sublicence under Clause 21 of the Sublicence, or if such grounds exist ViiV does not request termination under Clause 16.1(B)(i) above, converted (by way of the MPPF, ViiV and the relevant Sublicensee entering into a novation agreement transferring the rights and obligations of the MPPF under the Sublicence to ViiV) into a licence between ViiV and the relevant Sublicensee under the same terms and conditions of the Sublicence.

Rights and remedies. Upon the termination of this Agreement, the MPPF shall have no claim for compensation for any loss of whatever nature arising as a result of such termination. To the extent (and only to the extent) that Applicable Law provides for compensation upon such an event, the MPPF hereby expressly agrees to waive this right (to the extent possible under the Applicable Law) or otherwise repay to ViiV any such compensation or indemnity.

16.2 **Survival.** Any provision of this Agreement which expressly survives expiry or termination of the Agreement or which, by its terms, requires performance after the termination or expiry of the Agreement, or has application to events that may occur after the termination or expiry of the Agreement, will survive such expiry or termination (including Clauses 9 (Liability and Indemnity), 10 (Records and Audit Rights), 13 (Confidentiality) and 29 (Governing Law and Dispute Resolution)).

17. **Force Majeure**

Neither Party will be liable to the other for its failure or delay in performing its obligations to the extent that such failure or delay is caused by a Force Majeure Event; provided the affected party promptly notifies the other party of the Force Majeure Event; gives the other Party details of the known or anticipated impact of the Force Majeure Event on the performance of their obligations under this Agreement; and takes commercially reasonable action to mitigate the effects of the Force Majeure Event. This Clause will not relieve a Party of any obligation to implement or comply with a business continuity plan. If any Force Majeure Event prevents the affected Party from carrying out its obligations for more than ninety (90) days, the other Party may terminate the Agreement by written notice to the affected Party. To the extent the affected Party is excused from performance of its obligations under this Clause, the other Party will be relieved of its corresponding obligations.

"**Force Majeure Event**" means any circumstances beyond the reasonable control of the affected Party including: flood, fire, earthquake or other acts of God; war, threat of or preparation for war, armed conflict, imposition of sanctions, embargo, breaking off of diplomatic relations or similar actions; terrorist attack, civil war, civil commotion or riots, epidemic (excluding HIV epidemics) or pandemic (excluding HIV pandemic); strikes, labour stoppages or slowdowns; and any law or government order, rule, regulation or direction, or any action taken by a government or public authority, including imposing an embargo, export or import restrictions.

18. **Exercise of rights by the MPPF under a Sublicence**

18.1 MPPF agrees that it will not, without express prior written consent from ViiV:

(A) approve any Trade Mark or Trade Dress in accordance with by Clause 7.4 of the Sublicence;

(B) make any request for differentiation as provided for by Clause 7.6 of the Sublicence;

(C) agree to payment of royalties in any other currency than USD, as provided for in Clause 9.10 of the Sublicence;

(D) consent to the supply of Licenced Product for use outside the Field, in accordance with Clause 10.1.2 of the Sublicence;

(E) exercise the rights granted in Clauses 31.2 and/or 31.3 of the Sublicence, to amend Appendices B or C or the Sublicence; or

(F) permit the sale of Licensed Compound or Licensed Product pursuant to Clause 22.1.4 of a Sublicence.

18.2 If the MPPF wishes to independently exercises its right to terminate a Sublicence, it shall prior to exercising such right, notify ViiV of the same in writing. Upon receipt of such notice, ViiV shall inform the MPPF whether it wishes, instead of the Sublicence being terminated, for the Sublicence to be novated to ViiV, in which case the MPPF shall procure that the Sublicence is converted (by way of the

MPPF, ViiV and the relevant Sublicensee entering into a novation agreement transferring the rights and obligations of the MPPF under the Sublicence to ViiV) into a licence between ViiV and the relevant Sublicensee under the same terms and conditions of the Sublicence.

19. **Third Party Rights**

19.1 **ViiV's third party rights under a Sublicence** – The MPPF agrees to exercise the rights of ViiV as granted under Clause 24 of any Sublicence as and to the extent requested in writing by ViiV. For the avoidance of doubt, this shall not affect or prejudice ViiV's ability to exercise its rights directly under any Sublicence. Upon ViiV's request, the MPPF shall provide all reasonable assistance to ViiV in any dispute that might arise between ViiV and a Sublicensee.

19.2 **Third party rights under this Agreement** – No person or entity other than the Parties has the right to enforce any of the terms of this Agreement or has any Third Party beneficiary rights, except that ViiV and its Affiliates and any other Indemnified Person will be Third Party beneficiaries under this Agreement, and each will have the rights and benefits accorded to them under this Agreement and will subsequently be entitled to enforce any relevant terms as if they were named a party to this Agreement. Upon demand by ViiV, the MPPF will fulfil the Third Party beneficiary rights directly to such Third Party beneficiaries (without further conditions), even where Licensor is entitled to the fulfilment of the corresponding obligations. The rights of the parties to rescind, vary or terminate this Agreement are not subject to the consent of any person who is not a Party.

20. **Severability**

The parties intend each provision of this Agreement to be distinct and severable. If any provision of this Agreement is found to be unenforceable, the enforceability of the remaining provisions will not be affected.

21. **Entire Agreement**

This Agreement contains the entire agreement between the Parties in relation to its subject matter and supersedes all prior representations and understandings, whether oral or written.

22. **Notices**

22.1 Any notice given by a Party under this Agreement shall:

(A) be in writing and in English;

(B) be signed by, or on behalf of, the Party giving it; and

(C) and be sent to the relevant Party at the address set out in Clause 22.3.

22.2 Notices may be given, and are deemed received:

(A) by hand: on receipt of a signature at the time of delivery; or

(B) by pre-paid recorded delivery or registered post: on the third (3rd) Business Day after posting.

22.3 Notices shall be sent to:

(A) **The Medicines Patent Pool Foundation** for the attention of the General Counsel at:
Rue de Varembé 7
CH-1202 Geneva
Switzerland

(B) **ViiV Healthcare Company** for the attention of the Head of Legal North America at:
ViiV Healthcare,
410 Blackwell Street,
Durham, North Carolina, 27701,
United States of America

Copied to the Head of Government Affairs and Global Public Health, at ViiV Healthcare, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

22.4 Any change to the contact details of a Party as set out in Clause 22.1 shall be notified to the other Party

in accordance with Clause 22.1 and shall be effective:

(A) on the date specified in the notice as being the date of such change, provided such date is on or after the date the notice is deemed to be received; or

(B) if no date is so specified, three (3) Business Days after the notice is deemed to be received.

22.5 All references to time are to the local time at the place of deemed receipt.

22.6 The provisions of this Clause 22 shall not apply to notices given in legal proceedings or arbitration.

22.7 For the avoidance of doubt, and although a notice given under this Agreement is not valid if sent by e-mail, this Clause 22 is not intended to prohibit the use of e-mail for day-to-day operational communications between the Parties, including where this Agreement requires written approval by a Party.

22.8 The MPPF shall copy ViiV (at the address provided under Clause 22.3 above) on any notice sent to a Sublicensee under Clause 27 of the Sublicence. In the event the MPPF receives a notice under a Sublicence which has not been copied to ViiV (as required under such Sublicence), the MPPF will forward such notice to ViiV forthwith.

23. Assignment and Sub-Contracting

23.1 Neither this Agreement nor any interest arising out of or under this Agreement shall be assignable by the MPPF.

23.2 Neither Party shall be entitled to subcontract any of its rights or obligations under this Agreement provided however that:

(A) each Party shall have the right to engage professional agents, advisors and/or consultants in relation to performance of this Agreement, and

(B) ViiV shall have the right to fulfil any of its obligation under this Agreement through any of its Affiliates.

24. Further Assurance

The MPPF agrees that it shall provide such assistance as ViiV reasonably requires to enable ViiV to exercise its rights under this Agreement and any Sublicence.

25. Costs

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

26. Waiver and Amendments

26.1 The Parties may only amend or vary this Agreement or waive any rights or remedies under this Agreement in writing and signed by a duly authorised representatives of each of the Parties.

27. No Partnership or Agency

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties, nor constitute either Party as the agent of the other Party.

28. Execution in Counterparts

This Agreement may be executed in any number of counterparts, each of which will be considered an original, and together will constitute one agreement, and any part of this Agreement may be executed using an electronic signature and an electronic record (e.g. a photographic, scanned or facsimile copy of a signature) of the Agreement will have the same effect as an original hardcopy.

29. Governing Law and Dispute Resolution

29.1 This Agreement and any dispute or claim arising under or relating to this Agreement or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in

accordance with the laws of England and Wales.

29.2 The Parties wish to facilitate the resolution of any dispute arising out of or relating to this Agreement including but not limited to the breach, termination, interpretation or validity thereof (a "**Dispute**") in an expedient manner by mutual cooperation and agree to follow the procedures set forth in this Clause 29 to resolve any such Dispute.

29.3 ESCALATION – If a Dispute cannot be resolved between the Parties within thirty (30) days of written notice by one Party to another, such Dispute shall be referred in writing to the Parties' respective executive officers or their designees for attempted resolution by good faith negotiations which shall take place within thirty (30) days after such referral (or within such other time period as may be agreed by the Parties in writing).

29.4 MEDIATION – Any Dispute remaining unresolved thirty (30) days (or such other time period as may be agreed by the Parties in writing) after referral to the Parties' executive officers pursuant to Clause 29.3 shall first be submitted to mediation in accordance with the Rules of Mediation of the International Chamber of Commerce.

29.5 ARBITRATION – Any Party may refer any Dispute not resolved by mediation within forty-five (45) days (or within such other time period as may be agreed by the Parties in writing) after the appointment of the mediator, for resolution by final and binding arbitration conducted in accordance with the Rules of Arbitration of the International Chamber of Commerce (the "**ICC Rules**") provided that to the extent that the following provisions of this Clause conflict with the said ICC Rules the following provisions shall prevail:

(A) the arbitration shall be conducted by a sole arbitrator;

(B) the seat of the arbitration shall be London;

(C) the language of the arbitration shall be English;

(D) the decision of the arbitrator shall be final and binding on the Parties;

(E) judgment upon the arbitration award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party and its assets; and

(F) all documents and proceedings in any arbitration pursuant to this Clause 29.5 shall be confidential and all hearings shall be held in private, save to the extent necessary to enforce any award or to comply with any requirement of any lawful authorities. No public statement shall be made with regard to any arbitral proceedings save to the extent agreed between the Parties in writing.

29.6 INJUNCTIVE RELIEF – Notwithstanding the foregoing, nothing in this Clause 29 shall be construed as precluding a Party from bringing an action in court for interim injunctive relief or other interim equitable relief.

[Signature page follows]

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Agreement.

Signed for and on behalf of:
VIIV HEALTHCARE COMPANY

Courtney M. Callihan
_____

Signature

Name Courtney Callihan

Position Treasurer

Date 08-Jul-2025

Signed for and on behalf of:
THE MEDICINES PATENT POOL FOUNDATION

Charles Gore
_____

Electronically signed by: Charles Gore
Reason: I am signing for the reasons as stated in the document.
Date: Jul 8, 2025 21:28 GMT+2

Signature

Name Charles Gore

Position Executive Directofr

Date 08-Jul-2025

SCHEDULE 1: COMPLIANCE WITH LAWS AND ETHICAL BUSINESS PRACTICES

Anti-bribery and corruption

1. "**Government Official**" (where "government" means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means any officer or employee of a government or any department, agency or instrumentality of a government (including public enterprises, and entities owned or controlled by the state); any officer or employee of a public international organisation such as the World Bank or United Nations; any officer or employee of a political party, or any candidate for public office; any person defined as a government or public official under Applicable Laws (including anti-bribery and corruption laws) and not already covered by any of the above; or any person acting in an official capacity for or on behalf of any of the above. "Government Official" will include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting ViiV (and/or any ViiV Affiliate) business.

2. The MPPF will, and will take reasonable measures to ensure its subcontractors, agents or any other third parties subject to its control or determining influence will, comply with anti-corruption laws, and will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or ViiV (and/or any ViiV Affiliates) in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents and any other Third Parties, subject to its control or determining influence, from doing so. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which either Party is legally entitled.

3. ViiV shall be entitled to terminate this Agreement immediately on written notice to the MPPF, if the MPPF fails to perform its obligations in accordance with this Schedule. Notwithstanding any other provision in the Agreement, if ViiV terminates the Agreement due to the MPPF's breach of this Schedule, ViiV will not be obliged to make any payments, indemnify, or otherwise provide compensation to Licensee subsequent to the termination of the Agreement.

4. The MPPF shall inform ViiV in writing, if, during the course of this Agreement, it is convicted of or pleads guilty to a criminal offence involving fraud or corruption, or becomes the subject of any government investigation for such offences, or is listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs

5. The MPPF represents and warrants that except as disclosed to ViiV in writing prior to the commencement of this Agreement: (1) none of its senior management or significant donors (i.e. a donor contributing greater than 25% of the funding of the MPPF from time to time) have influence over ViiV's (and/or any ViiV Affiliate's) business; (2) no member of senior management team, members of the Board of Directors, or key individuals who will be responsible for the performance of this Agreement or any Sublicence, are currently or have been in the past two years a Government Official with actual or perceived influence which could affect ViiV business; (3) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed above having a public or private role which involves making decisions which could affect ViiV (and/or any ViiV Affiliate) business or providing services or products to, or on behalf of ViiV (and/or any ViiV Affiliate); (4) it does not have any other interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (5) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of ViiV in performance of this Agreement. The MPPF shall inform ViiV in writing at the earliest possible opportunity of any conflict of interest as described in this Schedule that arises during the performance of this Agreement

6. The MPPF, upon request by ViiV, will certify that adequate anti-bribery and anti-corruption training has been provided to relevant MPPF personnel.

7. The MPPF agrees that in the event that ViiV believes that there has been a possible violation of the terms of this Agreement, ViiV may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and their agencies, and to whomsoever ViiV determines in good faith has a legitimate need to know.

Labour Rights

8. The MPPF represents and warrants, to the best of its knowledge, that in connection with this Agreement, it: (i) respects the human rights of its staff and does not employ child labour, forced labour, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace; (ii) does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity); and (iii) that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates, and will not use any employees to perform the Agreement who are employed under a zero hour contract. The MPPF shall be respectful of its employees' right to freedom of association and the MPPF shall encourage compliance with these standards by any supplier that it uses in performing its obligations under this Agreement.

Pharmacovigilance

9. The responsibilities of the Parties for reporting of adverse drug experiences related to the Licensed Products to regulatory authorities in the Territory shall be performed in accordance with Applicable Law. The responsibilities of the Parties for safety related or Licensed Product related inquiries shall be performed in accordance with Applicable Law.

SCHEDULE 2: FORM OF SUBLICENCE

LICENCE AGREEMENT

THIS LICENCE AGREEMENT (this "**Agreement**") is entered into as of the date of last signature hereto (the "**Effective Date**"):

BETWEEN:

(1) **THE MEDICINES PATENT POOL FOUNDATION**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva (the "**Licensor**"); and

(2) **[*NAME OF LICENSEE*]**, a company incorporated under the laws of [*Licensee country of incorporation*] and having its registered office at [*Licensee address*] (the "**Licensee**"),

with the Licensor and the Licensee collectively referred to as the "**Parties**".

WITNESSETH THAT:

WHEREAS the intent of this Agreement is to enable broad access in resource-limited countries to cabotegravir for pre-exposure prophylaxis to reduce the risk of HIV-1 infection in persons (weighing at least 35kg) at risk of acquiring HIV-1, and to cabotegravir, for use in combination with rilpivirine, for the treatment of HIV-1 infection in persons (weighing at least 35 kg);

WHEREAS the Licensor has been granted by ViiV (as defined below) the right to sublicense certain patents and patent applications which relate to the compound known as cabotegravir on the terms and conditions set out in the Head Licence;

WHEREAS the Licensee wishes to obtain a sublicence of the licensed patents and patent applications from the Licensor and the Licensor is willing to grant to the Licensee such a licence in accordance with the terms and subject to the conditions of this Agreement;

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1 DEFINITIONS AND INTERPRETATION

1.1 "**Abuse**" means persistent or sporadic intentional excessive use of a medicinal product by a patient or clinical trial subject accompanied by harmful physical and/or psychological effects.

1.2 "**Adverse Event**" or "**AE**" means any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

1.3 "**Affiliate**" means, in relation to an entity, any entity that directly or indirectly controls, is controlled by, or under common control with that entity. In this context, "**control**" means ownership by one entity, directly or indirectly, of more than 50% of the voting shares of another entity; or the power of one entity to direct the management or policies of another entity. In relation to ViiV, Affiliate shall be limited to members of the ViiV Healthcare group of companies.

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

1.5 **"Applicable Law"** means all laws, statutes, rules, regulations, government orders and guidance, binding court orders, and industry guidance and standards.

1.6 "**Approved Affiliate**" shall have the meaning given in Clause 3.3.

1.7 **"Approved Local Distributor**" shall have the meaning given in Clause 3.4.

1.8 "**Approved Sublicensee**" shall have the meaning given in Clause 3.5.

1.9 "**Approved Royalty Country Public Procurement**" shall have the meaning given in Clause 3.7.

1.10 **"APRETUDE NDA"** means U.S. New Drug Application number 215499 for APRETUDE (cabotegravir) extended-release injectable suspension as approved by the FDA on 20 December 2021.

1.11 "**Business Day**" means a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.

1.12 **"Cabotegravir Licence"** means a licence between the Licensor and a Third Party granted pursuant to the Head Licence.

1.13 **"Cabotegravir Licensee"** means a Third Party licensee to a Cabotegravir Licence.

1.14 "**Calendar Month**" means a period from a specified day in one month to the day numerically corresponding to that day in the following month, less one.

1.15 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.16 "**Compound**" means the chemical compound set forth in Appendix A(1) known generically as cabotegravir and all pharmaceutically acceptable salts and esters thereof.

1.17 "**Combination Antiretroviral Therapy**" means a two-drug antiretroviral therapy consisting of the Compound used in combination with Rilpivirine.

1.18 "**Confidential Information**" means all information that would reasonably be regarded as, or is designated as, of a confidential or commercially sensitive nature by the person to which the information relates including any matter relating to, or arising in connection with, this Agreement or the business or affairs of any of the parties, ViiV, and/or any of their Affiliates.

1.19 "**Clinical Research Activity**" means any of the following: initiating, conducting, sponsoring, supporting, or providing Licensed Product for use in any clinical research relating to the Licensed Product.

1.20 "**Development Activity**" means any activity (clinical and non-clinical) by the Licensee to develop Licensed Compound and/or Licensed Product in order to obtain Regulatory Approval.

1.21 "**Effective Date**" means the date of this Agreement.

1.22 "**Field**" means the pre-exposure prophylaxis of persons at-risk of acquiring HIV-1 weighing at least 35 kg to reduce the risk of HIV-1 infection and/or the treatment of HIV-1 infection in persons living with HIV-1 weighing at least 35 kg using a Combination Antiretroviral Therapy..

1.23 "**First U.S. Application**" means, in respect of a Product, the first application by the Licensee to the FDA during the NCE Exclusivity Period for tentative approval of either an Abbreviated New Drug Application or a New Drug Application, in relation to the Product in accordance with the terms and conditions of this Agreement.

1.24 "**Good Manufacturing Practice**" means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. § 210 and 211 and in applicable U. S. and World Health Organization guidance and regulatory requirements for a pharmaceutical product, as amended from time to time;

1.25 "**Head Licence**" means the licence agreement entered into between ViiV and the Licensor which grants the Licensor the right to license the Patent Rights under this Agreement.

1.26 "**Human Safety Information**" or "**HSI**" shall mean information relating to human health and/or wellbeing following exposure to the product such as Adverse Event information, and including:

(i) any unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated);

(ii) failure to produce expected benefits (i.e. lack of efficacy);

(iii) off-label Use, Medication Errors or Misuse, including drug Overdose, whether accidental or intentional;
(iv) drug abuse or effects of drug withdrawal;
(v) Occupational Exposure;
(vi) Patients taking the Products whilst pregnant or breastfeeding;
(vii) paternal exposure to the Product before and during pregnancy;
(viii) transmission of an infectious agent via a medicinal product;
(ix) safety information received as part of a product quality complaint;
(x) drug interaction; and
(xi) unexpected therapeutic benefits (i.e. an unexpected improvement in a concurrent condition other than the one being treated)

1.27 "**Import Waiver**" means, in respect of a country in the Territory where, at the time of the intended sale or supply, the Licensed Product does not have Regulatory Approval, all export and import licences, authorisations, permits, consents or approvals necessary to supply, sell and/or offer for sale that Licensed Product in that country.

1.28 "**Improvement**" means any new or improved use, formulation, process, invention, development or finding related to the Compound and/or Product.

1.29 "**Improvement Patent Rights**" means any patents or patent applications which generically or specifically claim any Improvements, controlled by the Licensee, or to which the Licensee otherwise has the right to grant licences, now or in the future.

1.30 "**Licensed Compound**" means Compound, manufactured, and/or sold or otherwise supplied pursuant to this Agreement. For the avoidance of doubt, any Compound within the scope of a Patent Right shall be considered a Licensed Compound;

1.31 "**Licensed Product**" means Product registered, manufactured, and/or sold or otherwise supplied pursuant to this Agreement. ;

1.32 **"Listed Patent"** means US Patent Nos. 8,410,103, 10,927,129, 11,224,597, and 12,138,264 and any other patents listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book)* or its online database for the APRETUDE NDA and/or VOCABRIA NDA.

1.33 **"Medication Error"** means unintentional error on the prescribing, dispensing or administration of a Product while the medication is in the control of a healthcare professional, patient or consumer.

1.34 "**Misuse**" means a situation where the Product is intentionally and inappropriately used not in accordance with the authorised product information

1.35 **"NCE Exclusivity Period"** means in relation to each of the VOCABRIA NDA and the APRETUDE NDA, the applicable periods described in section 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) including any applicable extensions of paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the U.S Food, Drugs and Cosmetics Act.

1.36 "**Net Sales Value**" means gross sale price of the Licensee or its Affiliates (or any person acting on their behalf) to their customers multiplied by the number of units sold less value of the sales taxes, returned/rejected products, costs of clearing and forwarding, freight and insurance charges.

1.37 "**Occupational Exposure"** means exposure to a Product as a result of one's occupation.

1.38 "**Off-label Use**" means intentional use of a Product for a medical purpose not in accordance with the authorised product information.

1.39 "**Overdose**" means administration of a quantity of a Product given per administration or cumulatively which is above the maximum recommended dose according to the authorised product information. Clinical judgement should always be applied in determining whether any given administration constitutes an overdose.

1.40 **"Paragraph III Certification"** means a certification described in section 505(j)(2)(A)(vii)(III) and 505(b)(2)(A)(iii) of the U.S Food, Drugs and Cosmetics Act.

1.41 **"Paragraph IV Certification"** means a certification described in section 505(j)(2)(A)(vii)(IV) and 505(b)(2)(A)(iv) of the U.S Food, Drugs and Cosmetics Act.

1.42 "**Patent Rights**" means rights under any unexpired letters patent or any pending patent applications as set forth (each patent or patent application identified by its PCT application number and/or WIPO publication number where applicable) in Appendix C attached hereto, that are granted or pending, relating to the Compound and/or Licensed Product, including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, paediatric exclusivity, and the like of any such patents and patent applications, and international (e.g., WIPO), regional (e.g., EP or EA), and foreign national equivalents of the foregoing, in each case to the extent controlled by ViiV or any of its Affiliates.

1.43 "**PEPFAR**" means the United States President's Emergency Plan for AIDS Relief;

1.44 **"Permitted Market"** means the Private Markets and Public Markets in the Territory set out in Appendix B.

1.45 "**Pharmacovigilance**" means science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. In line with this general definition, underlying objectives of Pharmacovigilance in accordance with the applicable EU legislation for are: 1) preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure; and 2) promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public. Pharmacovigilance is therefore an activity contributing to the protection of patients and to public health.

1.46 "**Pregnancy Report**" means a report of pregnancy in a patient or trial subject to whom a Product or investigational Product has been administered.

1.47 "**Private Market**" means any entity in any country in the Territory that is not in the Public Market.

1.48 "**Product**" means:

(A) an oral pharmaceutical composition in a tablet form for use in the Field containing 30 mg of Compound as its sole active pharmaceutical ingredient; and/or

(B) a pharmaceutical composition containing the Compound in an extended-release injectable suspension form for use in the Field;

and which pharmaceutical form and composition:

(ii) corresponds with that of a pharmaceutical composition which has been approved by the FDA or EMA for use in the Field, and/or

(i) has been recommended by the WHO or the U.S. Department of Health and Human Services for use in the Field.

1.49 "**Public Market**" means:

(A) the following organisations to the extent that they are not for profit organisations:

(i) the government of any country in the Territory, including the ministries and agencies of such government, appointed procurement agencies acting on behalf of such government, and institutions and programs funded by such government such as state-run hospitals and prison services (referred to together as "**Government**");

(ii) non-government organisations ("**NGOs**") recognized by the applicable Government;

(iii) organisations of the United Nation working for or in a country of the Territory, including but not limited to UNDP and UNICEF;

(iv) Médecins Sans Frontieres, Save the Children, OXFAM and the International Committee of the Red Cross (ICRC); and

(v) the funding mechanisms (and programs funded by such mechanisms) Unitaid, PEPFAR, U.S. Agency for International Development, Children's Investment Fund Foundation or Global Fund, or procurement agencies acting on their behalf, to the extent that they support local implementation of public HIV prevention program(s) for people >35 kg at risk of HIV infection and/or for people >35 kg living with HIV in a country of the Territory; and

(B) Third Party distributors, solely to the extent that such Third Party distributors distribute the Licensed Product to or for one or more entities identified in (A) of this Clause 1.491.49.

1.50 "**Regulatory Approval**" means, in relation to each country of the Territory and each Licensed Product, a marketing authorisation from a Relevant Regulatory Authority for that Licensed Product for use in the Field in that country.

1.51 "**Relevant ANDA**" means an Abbreviated New Drug Application in the U.S. in relation to a Licensed Product submitted to the FDA by the Licensee under section 505(j) of the U.S Food, Drugs and Cosmetics Act during the NCE Exclusivity Period which is a First U.S. Application for that Licensed Product.

1.52 "**Relevant NDA**" means a New Drug Application in the U.S. in relation to a Licensed Product submitted to the FDA by the Licensee under section 505(b)(2) of the U.S Food, Drugs and Cosmetics Act during the NCE Exclusivity Period which is a First U.S. Application for that Licensed Product.

1.53 "**Relevant Regulatory Authority**" means (i) in relation to a particular country in the Territory, any applicable federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Licensed Product in that country, or (ii) WHO pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).

1.54 "**Reporting Guidance**" means guidance on reporting, elaborating the requirements in Clause 8 of this Agreement, issued by the Licensor to the Licensee, and as may be amended from time to time.

1.55 **"Rilpivirine"** means the chemical compound set forth in Appendix A(2) known generically as rilpivirine and all pharmaceutical acceptable salts and esters thereof.

1.56 "**Royalty Country**" means any country in Appendix B identified as a "Royalty Country".

1.57 "**Royalty-Free Country**" means any country in Appendix B not identified as a "Royalty Country".

1.58 "**Selection Process**" means the expression of interest and selection process run by the Licensor to select Licensee as a licensee under this Agreement.

1.59 **Selective Waiver Letter"** means a letter submitted by ViiV to the FDA pursuant to Clause 6 which authorizes the FDA to receive, review and tentatively approve a Relevant NDA or Relevant ANDA submitted by the Licensee during the NCE Exclusivity Period.

1.60 "**Serious Adverse Event (SAE)**" means an untoward medical occurrence that at any dose:
(i) results in death;
(ii) is life-threatening; that is, an event where the patient was at risk of death at the time of the event: it does not refer to an event which, hypothetically, might have caused death if it were more severe;
(iii) requires hospitalisation or prolongation of existing hospitalisation
(iv) results in persistent or significant disability/incapacity;
(v) is a congenital anomaly/birth defect;
(vi) involves transmission via a medicinal product of an infectious agent; or

(vii) is a medically important event, that is an AE that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the subject or require medical or surgical intervention to prevent one of the outcomes listed in 1.60 (i) – (vi). Examples of such events include intensive treatment (in an emergency room or at home) for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation, or the development of drug dependency or Abuse.

1.61 "**Stringent Regulatory Authority**" means a regulatory authority which was a member or observer of the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**"), or associated with an ICH member through a legally-binding, mutual recognition agreement, in each case as before 23 October 2015.

1.62 "**Territory**" means all those countries as are set out in Appendix B, as may be amended from time to time in accordance with Clause 31.

1.63 "**Third Party**" means any party other than a party to this Agreement.

1.64 "**Trade Dress**" means the get-up of a Licensed Product including tablet specification (including colour, embossing, size, shape), vial specification (including vial, stopper, vial label), packaging (including internal, intermediary, and external), and patient information leaflet.

1.65 "**Trade Dress Guidance**" means guidance on Trade Marks and Trade Dress, elaborating the requirements in Clause 7 of this Agreement, issued by the Licensor and ViiV, as amended from time to time.

1.66 "**Trade Mark**" means a trade mark, service mark, symbol, logo or device in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

1.67 "**Usage Period**" means, in relation to each proposed sale or supply, the calendar period within which the Licensed Product subject to such proposed sale or supply is intended to be used, in each instance as indicated by the relevant Permitted Market.

1.68 "**U.S.**" means United States of America, its territories and possessions including Puerto Rico

1.69 "**ViiV**" means ViiV Healthcare Company, party to the Head Licence.

1.70 "**ViiV Product**" means a Product manufactured by or on behalf of a ViiV Healthcare Group company.

1.71 **"VOCABRIA NDA"** means U.S. New Drug Application number 212887 for VOCABRIA (cabotegravir sodium) oral tablet as approved by the FDA on 21 January 2021

1.72 "**WHO**" means the World Health Organization.

1.73 "**WIPO Arbitration Rules**" means the arbitration rules adopted by the World Intellectual Property Organization from time to time.

1.74 "**WIPO Mediation Rules**" means the mediation rules adopted by the World Intellectual Property Organization from time to time.

1.75 Clause and Schedule headings shall not affect the interpretation of this Agreement.

1.76 The Appendices form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Appendices.

1.77 References to Clauses and Appendices are references to the Clauses and Appendices of this Agreement, unless otherwise stated.

1.78 Unless the context otherwise requires, words in the singular include the plural and, in the plural, include the singular.

1.79 Unless the context otherwise requires, a reference to one gender shall include a reference to the other genders.

1.80 A reference to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time, and shall include any subordinate legislation made from time to time under that statute or statutory provision.

1.81 Any words following the terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

1.82 A “person” includes a natural person, corporate or unincorporated body (whether or not having separate legal personality) and that person’s legal and personal representatives, successors and permitted assigns.

2 CONTRACT MANAGEMENT

2.1 Within thirty (30) days following the expiration of every ten (10) Business Day period referred to in Clause 8 of this Agreement, Licensee agrees to meet and confer with Licensor to review the operational elements of, and compliance with, this Agreement including but not limited to performance of the Licensee's obligations under this Agreement (“**Quarterly Meeting**”).

2.2 At each Quarterly Meeting, the Parties will review Licensee's Development Activities and regulatory activities and plans and sales of the Licensed Products.

2.3 Licensee shall promptly take corrective actions in relation to any identified non compliance of its obligations under this Agreement, as agreed during each Quarterly Meeting.

3 GRANT OF LICENCE

3.1 **Scope of licence**. Subject to the terms and conditions of this Agreement and to the extent to which the Licensor has the right to grant a licence in respect of the Patent Rights, the Licensor hereby grants to the Licensee a non-exclusive, royalty-bearing (in relation to Royalty Countries), non-sublicensable (other than to Approved Affiliates and Approved Local Distributors in accordance with Clauses 3.3 or 3.43.4 below), non-transferable licence of the Patent Rights, to the extent necessary, to:

3.1.1 obtain Regulatory Approval for Licensed Product;

3.1.2 manufacture, sell, or otherwise supply Licensed Product solely for use in the Field in the Permitted Market; and

3.1.3 sell or otherwise supply Licensed Compound to a Cabotegravir Licensee for use under a Cabotegravir Licence.

3.2 This Agreement does not grant any rights, including but not limited to intellectual property rights, in relation to Rilpivirine.

3.3 **Affiliates**. Upon Licensor’s prior written approval, such approval not to be unreasonably withheld, Licensee shall have the right, pursuant to the licence granted to it under Clause 3.1, to grant sublicences to any of its Affiliates, which the Licensee has demonstrated by means of appropriate supporting documents is an Affiliate of the Licensee. The Licensor shall respond to any requests for approval within thirty (30) days of receipt of appropriate supporting documents from the Licensee, with an approval or a written statement of why the request is not been approved. Any Affiliate of the Licensee approved by the Licensor pursuant to this Clause 3.3 shall be referred to in this Agreement as an “**Approved Affiliate**”.

3.4 **Local Distributors**. The Licensor acknowledges that in some countries of the Territory, for Licensed Product to be lawfully sold or otherwise supplied, Regulatory Approval must be held in the name of a local entity registered in such country (“**Local Distributor**”). Where Licenced Product can only be lawfully sold or otherwise supplied in a country of the Territory by a Local Distributor, and an Approved Affiliate of the Licensee cannot act as such Local Distributor pursuant to Clause 3.3, the Licensee may submit a written request to the Licensor to use a Third Party that is not an Affiliate as a Local Distributor in such country. Such request shall be supported by appropriate documentation on (a) the need to use a Local Distributor and (b) due

diligence on the Third Party. The Licensor, acting reasonably, shall consider the request and respond within thirty (30) days of receipt of all appropriate supporting documents from the Licensee, with an approval or a written statement of why the request is not being approved. Any Third Party approved in writing by the Licensor pursuant to this Clause 3.4 shall be referred to in this Agreement as an "**Approved Local Distributor**". The Licensee shall have the right, pursuant to the licence granted to it under Clause 3.1, to grant a sublicence to such Approved Local Distributor, solely to the extent necessary for such Approved Local Distributor to obtain Regulatory Approval and/or sell or otherwise supply the Licensed Product in the relevant country of the Territory.

3.5 **Approved Sublicensees**. Licensee shall ensure that any Approved Affiliate and/or Approved Local Distributor (each an "**Approved Sublicensee**" and together "**Approved Sublicensees**") complies with all the terms of this Agreement as if it was the Licensee under this Agreement, and Licensee shall be liable for the acts and omissions of such Approved Sublicensee as if such acts and/or omissions were the act and/or omissions of the Licensee. In the event an Approved Sublicensee fails to comply with any terms of this Agreement, the Licensor shall have the right to withdraw its approval of such Approved Sublicensee with immediate effect by providing written notice to the Licensee.

3.6 **Countries with no applicable Patent Rights or with Compulsory Licences**. Nothing in this Agreement shall be construed to prevent the Licensee from undertaking any activity anywhere in the world where such activity (i) is outside the scope of the Patent Rights or (ii) is permitted pursuant to a compulsory license of the Patent Rights.

3.7 **Royalty Country Public Procurements**. In any Royalty Country, the Licensee must obtain prior written approval from the Licensor for any sale or supply of Licensed Product by the Licensee in the Public Market, unless the Licensor has expressly indicated that approval is not granted. The Licensor shall approve or reject any such written requests within five (5) Business Days of receipt of the request and approval shall be deemed given if not issued by the end of the fifth Business Day following receipt of the request. Any such written request for approval shall include copies of the relevant Royalty Country procurement documentation regarding the proposed sale or supply. Any Royalty Country Public Market procurement approved by the Licensor pursuant to this Clause 3.73.7 shall be referred to in this Agreement as an "**Approved Royalty Country Public Procurement**".

3.8 **No other licences**. Other than the rights expressly granted under Clauses 3.1, 3.3 and 3.4, no intellectual property rights whatsoever are granted to the Licensee under this Agreement. The licence granted under this Agreement is subject to the intellectual property rights of any Third Party, and no licence is granted to perform any acts or omissions which infringe any rights of any Third Party.

3.9 **Existing voluntary licences**. This Agreement is without prejudice to any other rights and/or obligations that the Licensee may have pursuant to separate written agreement(s) with ViiV and/or the Licensor relating to the Patent Rights. Notwithstanding anything contained in this Agreement, activities of the Licensee performed in compliance with such other agreement(s) shall not constitute a breach of this Agreement.

4 DEVELOPMENT, REGISTRATION AND COMMERCIALISATION

4.1 **Control and responsibility.** As of the Effective Date and subject always to ViiV's retained interests to the Patent Rights (and those of its licensees), the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation (as applicable) of all Licensed Compound and all Licensed Product.

4.2 **Compliance**. The Licensee shall:

4.2.1 undertake all activities in connection with Licensed Compound and Licensed Product in accordance with all Applicable Law and good industry practice. The Licensee shall manufacture Licensed Compound and Licensed Product in a manner consistent with (i) Good Manufacturing Practice and (ii) WHO pre-qualification standards or the

standards of any Stringent Regulatory Authority or WHO-Listed Authority. Where such standards are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable; and

4.2.2 obtain from the relevant authorities in the Territory and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorisations relating to the importation, manufacture and sale of the Licensed Compound and Licensed Product (including but not limited to Import Waivers where applicable) which are necessary to enable the Licensed Compound and/or Licensed Product to be sold or otherwise supplied in the Territory in accordance with this Agreement.

4.3 **Timelines for Regulatory Approval.** The Licensee shall file, for Regulatory Approval (for both an oral Licensed Product and an extended-release Licensed Product) before at least one Relevant Regulatory Authority as soon as possible and in any event not later than 60 months from the Effective Date, in each case using the fastest approval route possible. Licensee shall also, upon Licensor's reasonable request, file for regulatory approval before the Relevant Regulatory Authority for any subsequent Licensed Product within a reasonable time.

4.4 **Regulatory exclusivity.** The Licensee agrees, where applicable and to the extent that it is able, to not seek, and to waive, regulatory exclusivity in the Territory in relation to any data relating to Licensed Product.

4.5 **Access.** The Licensee shall, acting in compliance with all Applicable Law, use its best endeavours to enable broad access to Licensed Product in the Permitted Market of a country of the Territory as soon as it has obtained Regulatory Approval for such Licensed Product in such country.

4.6 **Quality Audits**. The Licensee shall immediately notify the Licensor of any quality audits conducted by WHO, a Stringent Regulatory Authority or a WHO-Listed Authority that results in any major observations or actions in relation to Licensed Compound and/or Licensed Product or the manufacturing sites where Licensed Compound and/or Licensed Product is being manufactured or proposed to be manufactured.

4.7 **Supplies prior to Regulatory Approval**. Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or otherwise supply a Licensed Product in a country of the Territory prior to

4.7.1 Regulatory Approval in that country, unless the sale or supply is made pursuant to an Import Waiver; and

4.7.2 WHO prequalification or Stringent Regulatory Authority or WHO-Listed Authority approval, or through any provisional authorizations available through WHO or a Stringent Regulatory Authority or WHO-Listed Authority.

4.8 **Clinical Research Activities.** Prior to engaging in any Clinical Research Activity, the Licensee shall:

4.8.1 provide the Licensor with not less than one (1) month's written notice of its intention to carry out such Clinical Research Activity;

4.8.2 meet with the Licensor at such times and with such frequency as is reasonably requested by them to discuss the proposed activity; and

4.8.3 comply with the Licensor's reasonable requests in relation to the design and conduct of such Clinical Research Activity.

5 REFERENCE PRODUCT AND DATA PACKAGE

In the event that the Licensee:

(a) wishes to procure ViiV Product directly from ViiV for use in bioequivalence studies required to obtain Regulatory Approval; and/or

(b) would like ViiV to consider providing the Licensee with a data package to expedite filing for Regulatory Approval,

Licensee shall submit a written request for the same (which shall, for any request to procure ViiV Product, include the details of the Licensee's (a) development plan and associated milestones and (b) bioequivalence study plans) to the Licensor. Upon receipt of such request, the Licensor shall forward the request to ViiV for consideration under Clauses 5.1 and 5.2 of the Head Licence (as applicable), and keep Licensee informed of progress and outcome of the request.

6 SELECTIVE WAIVER LETTER

6.1 The Parties acknowledge that, in order for the Licensee to be able to supply a Licensed Product to applicable countries in the Territory under PEPFAR, it may be necessary for the Licensee to obtain tentative approval for that Licensed Product from the FDA under section 505(b)(2) or 505(j) of the U.S. Food, Drugs and Cosmetics Act (the "**Act**"). In the event that the Licensee wishes to obtain tentative approval from the FDA for a Licensed Product in circumstances where:

6.1.1 the purpose of obtaining such tentative approval from the FDA is solely to enable the Licensee to supply that Licensed Product to countries in the Territory under PEPFAR;

6.1.2 the FDA's tentative approval is sought in respect of a Relevant ANDA or Relevant NDA (as applicable);

6.1.3 the NCE Exclusivity Period has not expired; and

6.1.4 the Licensee has complied with, and continues to comply with this Agreement, including the requirements of this Clause 6,

the Licensee shall submit a written request to do so to the Licensor. The Licensor shall, following receipt of such written request, request pursuant to Clause 5 of the Head Licence that ViiV submits to the FDA a Selective Waiver Letter in respect of the Licensee's Relevant ANDA or Relevant NDA (as applicable). The Licensee shall provide to the Licensor such information in respect of its Relevant ANDA or Relevant NDA as the Licensor or ViiV may reasonably require in connection with the preparation of such a Selective Waiver Letter and/or in order to assess the Licensee's compliance with the requirements of this Clause 6.

6.2 The Licensee acknowledges Clauses 5.3 to 5.6 of the Head Licence.

6.3 The Licensor shall, on request, provide the Licensee with a copy of any Selective Waiver Letter in respect of the Licensee's Relevant ANDA or Relevant NDA following receipt by the Licensor of the same.

6.4 The Licensee undertakes, in respect of any Relevant ANDA or Relevant NDA for which a Selective Waiver Letter is requested, to:

6.4.1 identify the VOCABRIA NDA or the APRETUDE NDA (as applicable) as the "listed drug" (as that term is used and defined in section 505 of the Act and related regulations) in such Relevant ANDA or Relevant NDA; and

6.4.2 include with Relevant ANDA or Relevant NDA (as applicable) a Paragraph III Certification in respect of each Listed Patent; and

6.4.3 maintain that Paragraph III Certification until the expiration of the period described in sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Act, as extended by any applicable paediatric exclusivity describe in section 505A(c)(1)(A)(i)(I) of the Act; and

6.4.4 submit any Relevant ANDA or Relevant NDA (as applicable) within 90 days of the date of the Selective Waiver Letter.

6.5 Nothing in this Agreement or any Selective Waiver Letter issued pursuant to this Clause 6 shall:

6.5.1 be read, interpreted or otherwise considered to be a waiver of any other rights which extend to ViiV under section 505 of the Act, including (without limitation) the right to receive notice of any Paragraph IV Certification, to bring suit within forty-five (45) days

of receiving such a notice and, to prevent the approval of an application during the applicable periods set forth in sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Act, as extended by any applicable paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the Act (the Licensee acknowledges that nothing in this Agreement or any Selective Waiver Letter shall relieve the Licensee of any obligations in respect of a Paragraph IV Certification that may be imposed by the Act); or

6.5.2 authorise the Licensee to obtain final approval for a Relevant ANDA or Relevant NDA prior the expiration of the NCE Exclusivity Period and any other applicable periods set forth in sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Act, as extended by any applicable paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the Act; or

6.5.3 authorise the Licensee to do (or permit any Third Party to do) anything that infringes a Patent Right or Listed Patent.

6.6 The provisions of this Clause 6 apply solely in respect of a Relevant ANDA or Relevant NDA submitted by the Licensee for the purposes specified in Clause 6.1 and, for the avoidance of doubt and without limitation, the provisions of this Clause 6 do not apply in respect of:

6.6.1 any Abbreviated New Drug Application or New Drug Application submitted to the FDA:

(a) that is not, in respect of the Licensed Product concerned, a First U.S. Application; and/or

(b) in connection with which the Licensee submits a Paragraph IV Certification; or

6.6.2 any application for a marketing authorisation or equivalent licence in respect of any product (including any Licensed Product) in any country other than the U.S.

7 TRADE DRESS AND TRADE MARKS

7.1 **Ownership of Trade Marks.** Subject always to Clauses 7.2 and 7.4, the Licensee shall, at its expense, be responsible for the selection, registration and maintenance of all Trade Marks which it employs in connection with Licensed Product and shall own and control such Trade Marks. Nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensor, ViiV, or any of their Affiliates to use such Trade Marks for any purpose. Further, nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensee to use any Trade Marks owned by the Licensor, ViiV, and/or any of their Affiliates anywhere in the world for any purpose.

7.2 **Restrictions on Trade Marks**. The Licensee shall not use or seek to register (or, where it is possible to do so, apply to use or register) any Trade Mark in relation to Licensed Product, which incorporates or is identical or confusingly similar to any Trade Mark used by the Licensor, ViiV and/or any of their Affiliates anywhere in the world. If the Licensor, in its reasonable opinion, considers that the Licensee is in breach of this Clause 7.2, the Licensee shall immediately stop any such use and withdraw any such Trade Mark application and/or registration upon request by the Licensor. This Clause shall be without prejudice to any legal rights the Licensee may have in relation to the use of a Trade Mark which is identical or confusingly similar to any Trade Mark used by the Licensor, ViiV and/or any of their Affiliates anywhere in the world, where that use by the Licensee pre-dates the rights of the Licensor, ViiV and/or any of their Affiliates.

7.3 **Trade Dress**. The Licensee shall ensure that the Trade Dress of each Licensed Product is visually differentiated from that of products sold or supplied by ViiV and/or its Affiliates in a manner further elaborated under the Trade Dress Guidance.

7.4 **Approval.**

7.4.1 The Licensee shall seek the Licensor's written approval (such approval not to be unreasonably withheld or conditioned):

(a) to register (if applicable) and use a Trade Mark in relation to a Licenced Product, prior to such registration or such use, whichever is the earliest; and

(b) to use a Trade Dress in relation to a Licensed Product (including any Trade Dress in any promotional materials for the Licensed Product), prior to such use.

7.4.2 Licensee shall submit the request for approval via the Licensor's online trade dress portal or in any other manner specified by Licensor, providing all documentation necessary to consider the request (as further elaborated in the Trade Dress Guidance). Licensor shall use reasonable endeavours to ensure a response to any request for approval is provided within forty-five (45) days of receipt of all necessary documentation, with an approval or a written statement of why the request is not being approved. For the avoidance of doubt, the Trade Dress Guidance does not limit in any way the Licensor's right to refuse to provide approval under this Clause 7.4, and the basis of Licensor's refusal to provide approval under this Clause 7.4 shall not be limited to breaches of Clauses 7.2.

7.5 **Local requirements.** For the avoidance of doubt, any approval provided pursuant to Clause 7.4 is not to be interpreted as acquiescence by the Licensor and/or ViiV that any Trade Mark, Trade Dress and/or labelling complies with Applicable Law or any regulatory requirements, which remains the Licensee's sole responsibility.

7.6 **Additional request for differentiation.** Once Licensor has approved a Trade Mark and/or Trade Dress for a Licensed Product, the Licensee agrees only to sell and supply Licensed Product that conform to the Trade Mark and Trade Dress approved pursuant to this Clause 7. Without prejudice to the foregoing, the Licensee shall comply with such additional requirements for differentiation of the Trade Mark and/or Trade Dress of Licensed Product as Licensor may request, and Licensee agrees to use its reasonable endeavours to ensure timely registration of the variation with all such Relevant Regulatory Authorities as may be required, provided that the Licensee may continue to sell the Licensed Product(s) with original Trade Mark and/or in the original Trade Dress in the Permitted Market of a country until such time as the variation for the differentiated Trade Dress is approved for sale in that country.

7.7 **Acknowledgment.** The Licensee shall ensure that all elements of the Trade Dress (including external, intermediate and internal elements) relating to a Licensed Product, carry a clear statement in bold type that the Licensed Product has been produced under a licence from the Medicines Patent Pool and ViiV Healthcare, unless inclusion of such statement is prohibited by Applicable Law, national procurement policy or the relevant Regulatory Authority. Where inclusion of the statement is prohibited, the Licensee shall inform the Licensor of the prohibition and provide appropriate supporting evidence.

8 REPORTING OBLIGATIONS

8.1 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor written reports for such Agreement Quarter (prepared in accordance with any Reporting Guidance) on:

8.1.1 Development Activities and regulatory activities. Such report shall set out:

(a) a summary of all Development Activities, including a list of Licensed Product(s) in the Licensee's development pipeline and status of development of such Licensed Product(s), summary of work completed and in progress, current schedule of anticipated events and milestones, all bioequivalence data generated by or on behalf of Licensee related to Licensed Product;

(b) Regulatory Approval filing plan for each Licensed Product(s); and

(c) list of the countries in which applications for Regulatory Approval have been planned, filed and/or Regulatory Approvals have been obtained for such Licensed Product(s) as well as anticipated market introduction dates; and

8.1.2 all Licensed Products sold or otherwise supplied, setting out:

(d) the smallest unit, pack size, gross sales and Net Sales Value in US Dollars on a Licensed Product-by-Licensed Product, month-by-month, country-by-country and purchaser-by-purchaser basis;

(e) any royalty calculations regarding royalties due under Clause 9 for such sales and/or supplies; and

(f) where any Licensed Product was sold and/or supplied pursuant to an Approved Royalty Country Public Procurement, all relevant Public Market procurement documentation relating to such sale/supply.

8.2 For avoidance of doubt, the Licensor agree that information contained in any reports under this Clause 8 shall be treated as Confidential Information.

9 ROYALTIES

9.1 In consideration for the grant of the licence set out in Clause 3.1 in relation to the Royalty Countries, the Licensee agrees to pay to ViiV (or to such other person as ViiV may nominate in writing) the applicable royalty fee set out in Appendix B for all Licensed Product sold or otherwise supplied for use in such Royalty Countries subject to, and in accordance with, this Clause 9.

9.2 The Licensee shall pay the royalty fee due under this Clause 9 in relation to each Royalty Country quarterly, for as long as the Licensed Product falls within the scope of a Patent Right in such Royalty Country.

9.3 In the event that a transaction contemplated by this Clause 9 is not conducted on an arm's length basis, then for the purposes of calculating the royalty fee for such a transaction, the Net Sales Value shall be deemed to be what it would have been had the transaction been conducted on an arm's length basis (irrespective of the actual Net Sales Value for that transaction).

9.4 Licensee shall provide its calculation of the royalty fee payable pursuant to this Clause 9 (if any) for each Agreement Quarter in the relevant written report under Clause 8.1.2.

9.5 If upon examination of a royalty fee calculation provided by the Licensee, the Licensor (or its nominee) disagrees with such calculation, it shall promptly notify the Licensee of the same. The Parties shall endeavour to resolve any disagreement as quickly as possible, and in any event at the next scheduled Quarterly Meeting. If the Parties cannot reach consensus, the matter shall be resolved in accordance with Clause 34.

9.6 The Licensor shall supply the Licensee with an invoice from ViiV in US dollars each Agreement Quarter for any royalty fee payable for the Agreement Quarter immediately preceding such Agreement Quarter. Each invoice shall be issued as soon as reasonably practical following receipt by Licensor of the report under Clause 8.1.2 for the relevant Agreement Quarter, and in any event within thirty (30) Business Days of such receipt. The Licensee shall, on or before the thirtieth (30^{th}) calendar day following the date of each invoice issued by ViiV, pay to ViiV (or to such other person as ViiV may nominate in writing) the amount due under that invoice.

9.7 In the event of any delay in the Licensee paying to ViiV (or ViiV's nominee) any sum due under this Clause 9 on the relevant due date, the Licensee shall pay to ViiV (or ViiV's nominee) interest (calculated on a daily basis) on the overdue payment from the date such payment was overdue to the date of actual payment at the annual rate of 2% above the Bank of England base rate on the due date of payment (or on the next Business Day if the due date is not a Business Day), on a daily basis using a three hundred and sixty-five (365) day year and such annual rate, compounded monthly.

9.8 If an examination pursuant to Clause 19 reveals an underpayment by the Licensee, the Licensee shall promptly, and in any event on or before the thirtieth (30^{th}) calendar day following the date of an invoice issued by ViiV for such shortfall, pay to ViiV (or ViiV's nominee) the amount of such shortfall (including any interest payable pursuant to Clause 9.7) together with all costs incurred by ViiV and/or the Licensor in carrying out the examination.

9.9 Without prejudice to Clause 9.8, if at any point the Licensee becomes aware of it having made an underpayment, it shall promptly, and in any event within ten (10) days of it becoming so aware notify Licensor of the same, providing its calculations in accordance with Clause 9.4. The Licensee shall promptly, and in any event on or before the thirtieth (30^{th}) calendar day

following the date of an invoice issued by ViiV for such shortfall pay to ViiV (or ViiV's nominee) the amount of such shortfall (including any interest payable pursuant to Clause 9.7).

9.10 All amounts payable pursuant to this Agreement shall paid in US Dollars (or such other currency as may be agreed) and shall be made in full without any set-off or counterclaim, except for any withholding or deduction of, or in respect of, any tax, levy, impost, duty, charge or fee required by law. If any such withholding or deduction is required by law, the Licensee shall, when making the payment to which the withholding or deduction relates, pay to ViiV (or to such other person as ViiV may nominate in writing) the net amount and provide a certificate equivalent to the amount withheld. The amount due in US dollars under each invoice issued by ViiV shall be calculated using the three (3) month average of the exchange rates published by Bloomberg for the three (3) months ending on the last Business Day of the relevant Agreement Quarter. The Licensee shall make such payments by way of telegraphic transfer to such bank account as ViiV shall nominate.

9.11 **Adjustment for combination products sold as a co-pack**. For the purposes of calculating royalties in accordance with this Clause 9, if Licensee sells in a particular country Licensed Product that consists of a Combination Antiretroviral Therapy wherein all components of the Combination Antiretroviral Therapy are sold as a single unit (that is, the Compound-containing component and the Rilpivirine-containing component are sold in a single package as a co-packaged product) (a "**Co-Pack**"), the Net Sales Value of such Co-Pack in such country will be calculated by multiplying the actual Net Sales Value of such Co-Pack by the fraction A/(A+B), where "A" is the invoice price of such Licensed Product if sold separately in such country, and "B" is the invoice price of the Rilpivirine-containing component if sold separately in such country.

If, on a country-by-country basis:

(a) such Rilpivirine-containing component is not sold separately in such country—the denominator "(A+B)" may be replaced by the invoice price of the Co-Pack; and

(b) such Compound-containing component is not sold separately in such country—"A" shall be replaced by the fair market value of the Compound-containing component in such country and "B" shall be replaced by the fair market value of the Rilpivirine-containing component in such country, as such fair market values are determined by mutual agreement of the Parties, assent to which shall not be unreasonably withheld.

10 NON-DIVERSION

10.1 **Restrictions**. Save as provided under this Agreement and without prejudice to Clause 3.6, and to the extent that such restrictions comply with Applicable Law, the Licensee shall not:

10.1.1 register, manufacture, offer for sale, sell or otherwise supply Licensed Product for use outside the Permitted Market; or

10.1.2 offer for sale, sell or otherwise supply Licensed Product for use outside the Field, unless Licensee has prior written consent from the Licensor; or

10.1.3 offer for sale, sell or otherwise supply Licensed Product to any Third Party that the Licensee knows, believes or ought reasonably to suspect will sell or supply the Licensed Product for the uses set out in Clauses 10.1.1 and 10.1.2 above; or

10.1.4 offer for sale, sell or otherwise supply any Licensed Compound to any Third Party other than a Cabotegravir Licensee for use under a Cabotegravir Licence.

10.2 **Compliance measures**. The Licensee shall use reasonable efforts to ensure its compliance, and compliance by any Third Party to which it sells or supplies Licensed Product, with the terms of this Clause 10, including implementing the following measures:

10.2.1 Prior to any sale or supply of Licensed Product, the Licensee shall give written notice to a Third Party to which it intends to sell or supply Licensed Product of the restrictions contained in this Clause 10, and except where such sale or supply is made directly by the Licensee to a relevant Government (as defined under Clause 1.491.49), and without prejudice to its obligations under Clause 10.1.3, the Licensee shall obtain written

undertakings from such Third Party that the Third Party will sell, supply and/or use the Licensed Product in compliance with the restrictions imposed by this Agreement, including the restrictions regarding Permitted Market and Field;

10.2.2 The Licensee shall assist the Licensor to secure compliance by a Third Party to which it has sold or supplied Licensed Product with this Clause 10 and the restrictions which it contemplates;

10.2.3 The Licensee shall maintain a quick and efficient batch trace procedure following the GS1 Global Traceability or comparable standards so as to enable the identification and location of Licensed Product from individual batches with minimal delay;

10.2.4 The Licensee shall implement the batch trace procedure referred to in Clause 10.2.3 at the request of the Licensor if at any time the Licensor is of the opinion that any batch or batches of the Licensed Product have been, or may have been, diverted outside the Permitted Market, or Field; and

10.2.5 The Licensee shall ensure, before each sale or supply of Licensed Product, that the volume of Licensed Product it intends to sell or supply is commensurate with the demand for Licensed Product for the proposed Usage Period in the Permitted Market, as such demand is reasonably estimated by the Licensee. Where the volume of Licensed Product to be sold or supplied exceeds such demand (as reasonably estimated by the Licensee), the Licensee shall take all reasonable steps to ensure that the relevant sale or supply will not breach the terms of this Agreement, including the restrictions regarding Permitted Market.

10.3 **Breach**. Without prejudice to the Licensor's rights under Clause 21, if at any time the Licensee becomes aware that it, or a Third Party to which it has sold or supplied Licensed Product, has sold or supplied Licensed Product in breach of the terms of this Clause 10, the Licensee shall:

10.3.1 immediately notify the Licensor in writing, providing details of such breach; and

10.3.2 provide to the Licensor, within thirty (30) days of such notification, details of a mitigation plan to prevent any repeated sale or supply in breach of this Agreement.

11 CONFIDENTIALITY

11.1 Each Party shall hold Confidential Information disclosed to it under or in connection with this Agreement in strict confidence, and shall not use such Confidential Information for any other purpose than the performance of this Agreement.

11.2 The Party that releases, exchanges, or discloses Confidential Information (the "**Disclosing Party**") shall use reasonable efforts to mark such Confidential Information as "Confidential." In the event that Confidential Information is disclosed and not so marked, the receiving Party agrees to treat such information as confidential to the extent that a reasonable person would consider such information to be confidential given the content and circumstances of the disclosure.

11.3 Neither Party shall disclose any Confidential Information received from the other Party under or in connection with this Agreement, or otherwise developed by any Party in the performance of activities in furtherance of this Agreement, except to such of its, and its Affiliates' officers, employees, agents, representatives, advisors and consultants (and in the case of the Licensor to ViiV and/or any of its Affiliates) to whom disclosure is necessary to exercise the Party's rights or perform the Party's obligations under this Agreement (and in the case of the Licensor, under the terms of the Head Licence), and who are bound by confidentiality and non-use obligations (i) no less onerous than those contained in this Clause 11 and (ii) enforceable by the Disclosing Party.

11.4 The obligations in Clauses 11.1, 11.2 and 11.3 shall not apply to the following as established by reasonable, written proof:

11.4.1 information which at the time of disclosure is in the public domain;

11.4.2 information which, after its disclosure, becomes part of the public domain by publication or otherwise, except by breach of this Agreement;

11.4.3 information that a Party can demonstrate was lawfully possessed by it prior to disclosure under or in connection with this Agreement;

11.4.4 information that a Party receives from a Third Party which is not legally prohibited from disclosing such information;

11.4.5 information a Party is required by law to disclose, provided that the other Party is promptly notified of any such requirement; or

11.4.6 information which is independently developed by the receiving Party or its Affiliates who had no knowledge of the Disclosing Party's Confidential Information.

11.5 If a receiving Party becomes obligated by law to disclose Confidential Information received under or in connection with this Agreement, or any portion thereof, to any Third Party, governmental authority or court, that Party shall immediately notify the Disclosing Party of each such requirement and identify the Confidential Information to be disclosed so that such Disclosing Party (or ViiV or its Affiliates where the Confidential Information relates to or belongs to ViiV or its Affiliates) may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and, to the extent necessary, waive the receiving Party's compliance with the confidentiality obligations of this Agreement.

11.6 The Parties acknowledge that disclosure of any Confidential Information in breach of this Agreement could give rise to irreparable injury to the non-breaching Party and that such injury will not be adequately compensated by damages. Accordingly, the non-breaching Party, and ViiV and its Affiliates where the non-breaching Party is the Licensor, shall be entitled to the remedies of specific performance and injunctive relief or other equitable relief for any threatened or actual breach of this Clause 11. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.

11.7 All Confidential Information shall remain the property of the Disclosing Party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement, based on the insolvency or bankruptcy of such Party (or based on any other analogous or similar status of that Party under foreign laws), the bankrupt or insolvent Party shall promptly notify the court or other tribunal (a) that Confidential Information remains the property of the Disclosing Party and (b) of the confidentiality obligations under this Agreement. In addition, the bankrupt or insolvent Party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of such Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

11.8 Nothing in this Agreement shall be construed as preventing or in any way inhibiting the Licensee from complying with statutory and regulatory requirements relating to, or arising out of, its rights under this Agreement.

11.9 The obligations under this Clause 11 shall remain in full force and effect for the duration of this Agreement plus five (5) years.

12 PUBLICITY AND EXTERNAL COMMUNICATIONS

12.1 Each Party shall ensure that any external communication in relation to this Agreement is accurate and not misleading.

12.2 Each Party acknowledges that it is solely responsible and liable for its communications relating to this Agreement, including compliance with any Applicable Law.

12.3 Each Party shall seek the other Party's written approval of any initial press release or public announcement concerning the entry into this Agreement ("**Initial Sublicence Announcement**") prior to such press release, or any other publication regarding this Agreement, being made. Following the Initial Sublicence Announcement, neither Party shall be required to seek the other

Party's consent to respond to reactive statements to the Initial Announcement, provided such statements are accurate and not misleading.

12.4 The Licensee shall provide the Licensor the opportunity to review and comment on any written or oral publication, manuscript, abstract or the like which (i) includes data or other information generated under or in connection with this Agreement or (ii) otherwise relates to Licensed Product ("**Materials**"), at least twenty (20) Business Days prior to publication of any such Materials. The Licensee shall take into account any reasonable comments of the Licensor (and/or of ViiV, as communicated to the Licensor) on such Materials.

12.5 Prior to the Licenssee engaging with any guideline bodies or external experts in relation to the development of Licenced Product, the Licensee shall (a) inform the Licensor in writing of its intention to do so, (b) meet with the Licensor to discuss such engagement and (c) comply with any reasonable request of the Licensor (or of ViiV, as communicated to the Licensor) regarding the engagement.

12.6 Subject to Clauses 12.1-12.5, neither Party shall be required to obtain the prior consent of the other Party for any external communication relating to this Agreement.

13 PHARMACOVIGILANCE

13.1 The responsibilities of the Parties for reporting of Human Safety Information related to the Licensed Product to Relevant Regulatory Authorities shall be performed in accordance with local laws and regulations. The responsibilities of the Parties for safety related or Licensed Product related inquiries shall be performed in accordance with local laws and regulations.

13.2 Without prejudice to Clause 13.1:

13.2.1 the Licensee undertakes that it will maintain until the termination of this Agreement (or, as applicable, until the rights and obligations intended to survive termination of this Agreement have been fulfilled) pharmacovigilance and risk management systems, procedures, training programmes and documentation needed to perform and comply with its regulatory obligations and its related obligations under this Agreement;

13.2.2 the Licensee undertakes that it will ensure that it will comply with all Applicable Law regarding the Product including those laws and regulations relating to risk management, drug safety and pharmacovigilance. This includes but is not limited to collating Human Safety Information, expedited and periodic reporting to relevant Regulatory Authorities, literature review, performing safety evaluation and signal detection on all available Human Safety Information;

13.2.3 the Licensee will hold and maintain a safety database regarding Product, which shall contain all Human Safety Information (for marketed Product) and all Serious Adverse Events (SAEs) and Pregnancy Reports (for investigational Product) of which the Licensee becomes aware either directly or from another source;

13.2.4 the Licensee shall provide the Licensor a report containing information regarding Human Safety Information which are associated with the Product and which have been received by the Licensee, from any source, including spontaneous, solicited, and clinical trial sources. Such report shall (i) be provided every six (6) months, within ten (10) Business Days after the end of the Agreement Quarters ending 30 June and 31 December, and shall (ii) cover the two Agreement Quarters immediately preceeding the due date of such report, or as otherwise requested by the Licensor;

13.2.5 on conclusion of any clinical research relating to the Licensed Products, the Licensee shall submit to Licensor copies of the clinical trial reports generated by or on behalf of the Licensee relating to such clinical research promptly after such reports are generated;

13.2.6 the Licensee shall notify the Licensor and ViiV forthwith of the receipt of an enquiry from a Relevant Regulatory Authority relating to the Product that concerns any safety issue. If the Licensee becomes aware of action that may or will be or has been taken by a regulatory authority for a safety reason connected with the Product, it shall

immediately and in any event no later than twenty-four (24) hours after receiving such notice from a regulatory authority notify the Licensor and ViiV in writing (including, but not limited to email communications) with available details regarding the same; and

13.2.7 notwithstanding Clause 27, notices to be provided pursuant to Clause 13.2.6 shall, in addition, also be sent to:

oxa63163@viivhealthcare.com

For the attention of VP, Safety & Pharmacovigilance, ViiV Healthcare

13.3 Notwithstanding and without prejudice to the Licensor's rights under Clause 19, the Licensor shall have the right to monitor compliance with this Clause 13. The Licensee shall, when contacted by the Licensor regarding such monitoring, promptly provide any requested relevant information, and will promptly take corrective actions in relation to any identified non-compliance with this Clause 13.

14 IMPROVEMENTS AND PATENT PROSECUTION, ENFORCEMENT AND DEFENCE

14.1 **Improvements.** If at any time during the Term of this Agreement the Licensee (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it shall communicate such Improvement to the Licensor and ViiV in full together with all available information concerning the mode of working and using the same. The Licensor and ViiV shall treat this information as Confidential Information.

14.2 **Improvements Licence**. The Licensee hereby grants to the Licensor and ViiV a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use any Improvement, Improvement Patent Rights and related know-how (and shall promptly execute such document as ViiV may reasonably request accordingly). The Licensor shall not sublicense such rights to any Third Party, provided, however, that should the Licensor desire to sublicense any such rights, the Licensee and the Licensor agree to enter into good-faith negotiations regarding such sublicence. ViiV shall be entitled to grant sublicences (without further right to sublicense) under such licence only to its:

14.2.1 Affiliates; and/or

14.2.2 contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercialising ViiV products.

14.3 **Patent Prosecution.** The Licensee shall have no rights in relation to the conduct of any matter relating to the Patent Rights, including the filing, prosecution and maintenance thereof.

14.4 **Patent Enforcement and Defence.** If any suit or claim by a Third Party is instituted against the Licensee for patent infringement involving the Licensed Product and/or Licensed Compound, the Licensee shall promptly notify the Licensor in writing. Where such claim relates to any aspect of the Licensed Product and/or Licensed Compound that falls within the scope of a Patent Right, ViiV shall have the right, but not the obligation, to defend or to conduct the defence of such suit or claim at its own expense. The Licensee shall assist ViiV and co-operate in any such litigation at ViiV's request and expense. ViiV (and in no circumstances the Licensee) shall be entitled to bring infringement action at its own expense. To the extent ViiV decides not to bring any such infringement action, ViiV shall not be liable to the Licensee in any respect for such decision. The Licensee shall assist ViiV and co-operate in any such litigation at ViiV's request without expense to the Licensee.

15 REPRESENTATIONS AND WARRANTIES

15.1 **Mutual representations and warranties.** Each Party represents and warrants that:

15.1.1 it has power, capacity and authority to enter into and perform its obligations under this Agreement; and

15.1.2 this Agreement will be executed by its duly authorised representative(s) and, once executed, will constitute its legal, valid and binding obligations.

15.2 **Licensee representations and warranties.** Licensee represents and warrants that:

15.2.1 All information provided by Licensee to Licensor during the Selection Process is complete, truthful and accurate in all respects; and

15.2.2 It has the experience, capacity and capability to manufacture, sell or otherwise supply the Licensed Products to enable broad access to the Licensed Product in the Permitted Market.

15.3 **Disclaimer. Except as provided by Licensor under Clause 15.1, Licensor, make no representations and extend no warranties of any kind, express or implied, including any express or implied warranties of merchantability or fitness for a particular purpose, with respect to (a) the Patent Rights, (b) license granted by Licensor hereunder, (c) the Licensed Compound, (d) the Licensed Products, or any other matter. Furthermore, nothing in this Agreement shall be construed as a warranty that the information set out in Appendix C accurately reflects the status of ViiV's patents and patent applications relating to the Compound and/or Products, or that any Patent Rights is valid or enforceable, or that the Licensor's or Licensee's use of the Patent Rights, Licensed Compound, or Licensed Product as contemplated hereunder will not infringe any patent rights or other intellectual property rights of any Third Party. Licensor, also make no representation or warranty that Licensee's use of the Licensed Compound, or Licensed Product will not infringe any patent rights or other intellectual property rights (other than the Patent Rights) of ViiV or its Affiliates. Licensor also does not give any warranty, express or implied, with regard to the safety or efficacy of the Compound, or Product and it shall be the sole responsibility of Licensee to ensure such safety or efficacy with regard to the Licenced Compound and Licenced Product.** Notwithstanding the foregoing, nothing in this Agreement shall limit or exclude the liability of either Party for death or personal injury resulting from negligence or fraud or fraudulent misrepresentation or other matters, the exclusion of liability for which is not allowable under Applicable Law.

15.4 **Licensee acknowledgment.** The Licensee acknowledges:

15.4.1 Clause 9.5 of the Head Licence;

15.4.2 that in entering into this Agreement, the Licensee has independently evaluated any information supplied by the Licensor (including, but not limited to, such information related to the Product), as well as the viability of this Agreement, before making its decision to enter into this Agreement and to undertake the commitments and obligations set forth herein; and

15.4.3 neither ViiV or the Licensor in any way endorse the use of any Licensed Product sold or manufactured by the Licensee.

16 EXCLUSION OF LIABILITY

Neither Licensor nor ViiV shall be responsible to Licensee or to any Third Party for any damages or losses resulting, directly or indirectly from Licensee's or any Approved Sublicensee's manufacture, packaging, labelling, receipt, shipping, handling, storage, use, importation, marketing, or sale of the Licensed Compound or Licensed Product or any other acts or omissions of Licensee arising out of this Agreement.

17 INDEMNIFICATION

17.1 Subject to Clause 17.2, the Licensee will indemnify, defend and hold harmless the Licensor, ViiV, each of their Affiliates and each of their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") for any loss, liability and cost, including reasonable attorney's and expert's fees ("**Losses**"), that arise from or in connection with the Licensee's:

17.1.1 breach of this Agreement; or

17.1.2 exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Licensed Product manufactured by or on behalf of the Licensee pursuant to this Agreement).

17.2 The indemnification obligation under Clause 17.1 shall not apply to the extent any Losses arise out of negligence or wilful misconduct by Licensor, ViiV, any of their Affiliates or any of their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns.

17.3 Licensor shall, or shall procure that the Indemnified Person shall, promptly notify the Licensee when it becomes aware of any claim under Clause 17.1. Subject to Clauses 14.4, the Indemnified Person and the Licensee will agree on the appropriate party to assume control of the defence or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.

17.4 Clause 17.1 may be enforced by each Indemnified Person against the Licensee under the Contracts (Rights of Third Parties) Act 1999.

18 INSURANCE

Immediately upon the first Regulatory Approval for a Licensed Product pursuant to this Agreement, and for a period of ten years after the expiration or earlier termination of this Agreement, the Licensee shall obtain and/or maintain, at its sole cost and expense, product liability insurance in amounts which are reasonable and customary in the pharmaceutical industry of the countries in which the Licenced Compound and Licensed Products are manufactured, distributed and sold (as relevant), subject always to a minimum limit equivalent to U.S.$10,000,000 per occurrence (or claim) and in the aggregate annually. Such product liability insurance shall insure against all liability, including product liability, personal liability, physical injury or property damage. The Licensee shall provide written proof of the existence of such insurance to the Licensor upon request from either thereof and shall monitor such policy on a monthly basis to ensure that any cover is revised to take account of any currency fluctuations.

19 RECORDS AND AUDIT RIGHTS

19.1 **Records.** During the Term and for a period of five (5) years following the expiry and termination of this Agreement, Licensee shall keep complete, accurate and systematic records of all transactions under or in connection with this Agreement, including the batch number and identity of the purchaser for every Licensed Compound and Licensed Product sold and/or supplied under this Agreement.

19.2 **Audit rights**. During the Term and for a period of three (3) years thereafter, Licensor shall have the right (and the Licensee shall procure such right), during normal business hours and through a certified public accountant or like person appointed by Licensor, to audit Licensee (including the Licensee's records under Clause 19.1) for compliance with all provisions of this Agreement. Such audit shall be at the expense of the Licensor save where such audit reveals a breach of this Agreement by the Licensee, in which case the Licensee shall pay for all costs incurred by Licensor in carrying out the audit. The right to audit under this Clause 19.2 shall not take place more often than twice in any Calendar Year.

20 COMPLIANCE WITH APPLICABLE LAW AND ETHICAL BUSINESS PRACTICES

Licensee shall perform all activities under this Agreement in compliance with all Applicable Law and the provisions of Appendix D.

21 TERM AND TERMINATION

21.1 **Term.** Unless otherwise terminated by the operation of law or by acts of the Parties in accordance with the terms of this Agreement, this Agreement shall come into force on the Effective Date and shall remain in effect on a country-by-country basis until the expiration, lapse

or invalidation of the last remaining Patent Right in the Territory and, where the country of manufacture of Licensed Compound or Licensed Product is outside the Territory, in such country of manufacture (the "**Term**").

21.2 **Mutual termination rights.** In addition to any other rights to terminate at law or as expressly provided in this Agreement, either Party may terminate this Agreement immediately (or on such date that it set out in the notice of termination) upon written notice to the other Party:

21.1.1 **Insolvency** - if the other Party is affected by an insolvency or adjudication of bankruptcy, the filing of a voluntary petition in bankruptcy, the making of an assignment for the benefit of creditors, any substantial part of a Party's assets coming under the jurisdiction of a receiver, administrator, liquidator, trustee or similar officer in an insolvency proceeding authorised by law or if proceedings are instituted against the other Party for winding up or reorganisation or other relief under any insolvency law. For the purposes of this Clause, "**insolvency**" means either the Party's liabilities exceed its assets, each fairly stated; or the Party's inability to pay its business obligations in the regular course of business; or

21.1.2 **Force Majeure** – in accordance with Clause 23.

21.3 **Licensee termination rights.** The Licensee may terminate this Agreement at any time by providing thirty (30) days' written notice to the Licensor.

21.4 **Licensor termination rights.** The Licensor may terminate this Agreement, in whole or in part, immediately (or on such date that is set out in the notice of termination) upon written notice to the Licensee if:

21.4.1 **Material breach** – the Licensee commits a material breach of any provision of this Agreement that is not capable of being remedied, or if capable of being remedied, fails to remedy such material breach within thirty (30) days following receipt of a written notice specifying the nature of the breach. For the avoidance of doubt, breaches of the following Clauses are, without limitation, deemed material breaches of the Agreement: Clauses 4 (Development, Registration and Commercialisation), 6 (Selective Waiver Letter), 9 (Royalties), 10 (Non-Diversion), 13 (Pharmacovigilance Pharmacovigilance), and 20 (Compliance with Applicable Law and Ethical Business Practices);

21.4.2 **Repeated breach** – the Licensee repeatedly and/or persistently (meaning more than once) breaches this Agreement (whether or not such breaches is or are material);

21.4.3 **Infringement of Third Party intellectual property** – the Licensor or ViiV receives a Third Party claim that the Licensee's use of any Patent Rights under this Agreement infringes the intellectual property rights of a Third Party, unless the Licensee confirm in writing that it will indemnify any and all Indemnified Persons (as defined in Clause 17.1) against any and all Losses (as defined in Clause 17.1) in connection with the Licensee's continued use of the Patent Rights pursuant to this Agreement;

21.4.4 **Ownership or control of Licensee** – the legal or beneficial ownership or control of the Licensee and/or any of its Affiliate's changes in such a manner as Licensor shall in its sole discretion consider significant;

21.4.5 **Misrepresentation** – if the representations under Clause 15.2 amount to a substantive misrepresentation; or Licensee subsequently fails to substantially meet its projections (including projections regarding the countries in which Licensee intends to commercialise Licensed Product, the efforts and resources that Licensee intends to devote to the commercialisation of Licensed Product in each country and the extent to which Licensee's supply is sufficient to meet demand in each country); or

21.4.6 **Failure to make progress** – any time after the second (2nd) anniversary of the Effective Date the Licensor, in its reasonable opinion, believes that the Licensee has not made satisfactory progress towards the goal of filing for Regulatory Approval for a Licensed Product before at least one Relevant Regulatory Authority not later than 60 months from the Effective Date.

21.5 **Termination of Head Licence.** Upon termination of the Head Licence, and provided that the Licensee is not in breach of this Agreement, this Agreement shall be converted (by way of the

Licensor, ViiV and the Licensee entering into a novation agreement transferring the rights and obligations of the Licensor under this Agreement to ViiV) into a licence between ViiV and the Licensee on the same terms and provisions agreed in this Agreement.

22 EFFECT OF TERMINATION OR EXPIRY

22.1 **Duties upon termination or expiry**. Upon termination or expiry of this Agreement:

22.1.1 the Licensee shall cease all exploitation of the Patent Rights;

22.1.2 the Licensee shall immediately pay all outstanding sums due from the Licensee to ViiV under this Agreement;

22.1.3 each Party shall, upon request by, and at no charge to, the other Party, (a) promptly return to the other Party all Confidential Information in its possession that belongs to the other Party (or any of their Affiliate) or has been provided by or on behalf of such other Party (or any of their Affiliate) under the Agreement ("**Returnable Material**") or, (b) if directed to do so, promptly delete or render permanently inaccessible Returnable Material and provide evidence to the other Party of the same having been done, except that the Party shall be permitted to retain one (1) copy of the Confidential Information its possession so that any continuing obligations may be determined; and

22.1.4 the Licensee shall immediately notify the Licensor of the amount of Licensed Compound and/or Licensed Product the Licensee then has available to it. The Licensor shall consider, acting reasonably and taking into account demand in the Territory as reasonably estimated by the Licensor, if the Licensee should be permitted to sell that amount of Licensed Compound and/or Licensed Product in accordance with the terms of this Agreement (and subject to any additional conditions as reasonably determined by the Licensor), and shall inform the Licensee of its decision on the same.

22.2 **Survival**. Any provision of this Agreement which expressly survives expiry or termination of the Agreement or which, by its terms, requires performance after the termination or expiry of the Agreement, or has application to events that may occur after the termination or expiry of the Agreement, will survive such expiry or termination (including Clauses 11 (Confidentiality), 17 (Indemnification), 19 (Records and Audit Rights), and 34 (Governing Law and Dispute Resolution)).

22.3 **Rights and remedies**. Termination or expiry of this Agreement (in whole or in part) shall be without prejudice to any other rights or remedies available to a Party or a Third Party beneficiary, and shall not affect any obligations or liabilities of either Party that have accrued up to the date of termination or which later accrues from an act or omission which occurred prior to the expiration or termination date.

23 FORCE MAJEURE

Neither Party will be liable to the other for its failure or delay in performing its obligations to the extent that such failure or delay is caused by a Force Majeure Event; provided the affected party promptly notifies the other party of the Force Majeure Event; gives the other Party details of the known or anticipated impact of the Force Majeure Event on the performance of their obligations under this Agreement; and takes commercially reasonable action to mitigate the effects of the Force Majeure Event. This Clause will not relieve a Party of any obligation to implement or comply with a business continuity plan. If any Force Majeure Event prevents the affected Party from carrying out its obligations for more than six (6) months, the other Party may terminate the Agreement by written notice to the affected Party. To the extent the affected Party is excused from performance of its obligations under this Clause, the other Party will be relieved of its corresponding obligations.

"**Force Majeure Event**" means any circumstances beyond the reasonable control of the affected Party including: flood, fire, earthquake or other acts of God; war, threat of or preparation for war, armed conflict, imposition of sanctions, embargo, breaking off of diplomatic relations or similar actions; terrorist attack, civil war, civil commotion or riots, epidemic or pandemic; strikes, labour stoppages or slowdowns; and any law or government order, rule, regulation or direction, or any action taken by a government or public authority, including imposing an embargo, export or import restrictions.

24 THIRD PARTY RIGHTS

24.1 The Parties expressly agree that the rights of the Licensor under this Agreement shall be applicable to ViiV to the same extent as for the Licensor and ViiV shall have the right to enforce any of the rights afforded to the Licensor under this Agreement as if it was a party to this Agreement.

24.2 Subject to Clause 24.1, no person or entity other than the Parties has the right to enforce any of the terms of this Agreement or has any third party beneficiary rights, except that any Indemnified Person will be Third Party beneficiaries under this Agreement, and each will have the rights and benefits accorded to them under this Agreement and will subsequently be entitled to enforce any relevant terms as if they were named a party to this Agreement. Upon demand by Licensor, Licensee will fulfil the Third Party beneficiary rights directly to such Third Party beneficiaries (without further conditions), even where Licensor is entitled to the fulfilment of the corresponding obligations. The rights of the parties to rescind, vary or terminate this Agreement are not subject to the consent of any person who is not a Party.

25 SEVERABILITY

The Parties intend each provision of this Agreement to be distinct and severable. If any provision of this Agreement is found to be unenforceable, the enforceability of the remaining provisions will not be affected.

26 ENTIRE AGREEMENT

This Agreement contains the entire agreement between the Parties in relation to its subject matter and supersedes all prior representations and understandings, whether oral or written.

27 NOTICES

27.1 Any notice given by a Party under this Agreement shall:
(a) be in writing and in English;
(b) be signed by, or on behalf of, the Party giving it; and
(c) and be sent to the relevant Party at the address set out in Clause 27.3.

27.2 Notices may be given and are deemed received:
(a) by hand: on receipt of a signature at the time of delivery; or
(b) by pre-paid recorded delivery or registered post: on the third (3rd) Business Day after posting.

27.3 Notices shall be sent to:

(a) the Licensor at:
Rue de Varembé 7
CH-1202 Geneva
Switzerland,
marked for the attention of General Counsel,

Copied to: the Head of Government Affairs and Global Public Health, at ViiV Healthcare, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

(b) the Licensee at:
[*Licensee address*],
marked for the attention of [*Licensee contact*],

27.4 Any change to the contact details of a Party as set out in Clause 27.3 shall be notified to the other Party in accordance with Clause 27.3 and shall be effective:

(a) on the date specified in the notice as being the date of such change, provided such date is on or after the date the notice is deemed to be received; or

(b) if no date is so specified, three (3) Business Days after the notice is deemed to be received

27.5 All references to times are to the local time at the place of deemed receipt.

27.6 The provisions of this Clause 27 shall not apply to notices given in legal proceedings or arbitration.

27.7 For the avoidance of doubt, and although a notice given under this Agreement is not valid if sent by e-mail, this Clause 27 is not intended to prohibit the use of e-mail for day-to-day operational communications between the Parties, including where this Agreement requires written approval by a Party.

28 ASSIGNMENT AND SUB-CONTRACTING

28.1 Neither Party shall have the right to assign this Agreement or any interest arising out of or under this Agreement.

28.2 Save as expressly set out in Clauses 3.1, 3.3 and 3.4, neither Party shall be entitled to subcontract any of its rights or obligations under this Agreement.

29 NO COMPENSATION

To the extent that such exclusion is permitted by Applicable Law, no compensation, whether for loss of profit or any other reason whatsoever, shall be payable by any Party arising from any lawful amendment or lawful termination or expiry of this Agreement.

30 COSTS

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

31 WAIVER AND AMENDMENTS

31.1 The Parties may only amend or vary this Agreement or waive any rights or remedies under this Agreement in writing and signed by a duly authorised representatives of: (a) each of the Parties; and (b) ViiV.

31.2 Notwithstanding Clause 31.1, the Licensor shall have the right, without the Licensee's consent to amend Appendices B and C of this Agreement at any time provided such amendment is to expand the scope of the licence granted by this Agreement.

31.3 Notwithstanding Clause 31.1, the Licensor shall have the right, without the Licensee's consent to amend Appendix B of this Agreement to remove a country from the Territory where such country has been accepted as an official candidate for membership of the European Union and in Licensor's reasonable opinion there is a risk that the Licensed Product will become subject to free movement of goods within the European common market (also known as the European single market). In the event a country becomes part of the European common market, it shall automatically be removed from the Territory. **Nothing in this Licence shall be deemed as consent to place Licensed Product on the European common market.**

32 NO PARTNERSHIP OR AGENCY

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties (or between either Party and ViiV), nor constitute either Party as the agent of the other Party (or either Party as the agent of ViiV or its Affiliate, or ViiV or its Affiliates as the agent of either Party).

33 EXECUTION IN COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which will be considered an original, and together will constitute one agreement, and any part of this Agreement may be executed using an electronic signature and an electronic record (e.g. a photographic, scanned or facsimile copy of a signature) of the Agreement will have the same effect as an original hardcopy.

34 GOVERNING LAW AND DISPUTE RESOLUTION

34.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of England and Wales.

34.2 The Parties wish to facilitate the resolution of any dispute arising out of or relating to this Agreement including but not limited to the breach, termination, interpretation or validity thereof (a "**Dispute**") in an expedient manner by mutual cooperation and agree to follow the procedures set forth in this Clause 34 to resolve any such Dispute.

34.3 ESCALATION – If a Dispute cannot be resolved between the Parties within thirty (30) days of written notice by one Party to another, such Dispute shall be referred in writing to the Parties' respective executive officers or their designees for attempted resolution by good faith negotiations which shall take place within thirty (30) days after such referral (or within such other time period as may be agreed by the Parties in writing).

34.4 MEDIATION – Any Dispute remaining unresolved thirty (30) days (or such other time period as may be agreed by the Parties in writing) after referral to the Parties' executive officers pursuant to Clause 34.3 shall first be submitted to mediation in accordance with WIPO mediation Rules. Such mediation shall be attended on behalf of each Party for at least one session by a senior executive with authority to resolve the dispute and shall be held in Geneva, Switzerland, except where the claim is brought by ViiV, its Affiliates and/or any Indemnified Person (pursuant to the rights granted under Clause 24), in which such mediation shall be held in London, UK.

34.5 ARBITRATION – Any Party may refer any Dispute not resolved by mediation within forty-five (45) days (or such other time period as may be agreed by the Parties in writing) after the appointment of a mediator pursuant to Clause 34.4, for resolution by final and binding arbitration conducted in accordance with the WIPO Arbitration Rules. The arbitration shall be conducted in English and the arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Geneva, Switzerland, except where the claim is brought by ViiV, its Affiliates and/or any Indemnified Person (pursuant to the rights granted under Clause 24), in which case the place of arbitration shall be London, United Kingdom. Parties do not object to arbitration proceedings being held online.

34.6 INJUNCTIVE RELIEF – Notwithstanding the foregoing, nothing in this Clause 34 shall be construed as precluding a Party (or any Third Party beneficiary under this Agreement) from bringing an action in court for interim injunctive relief or other interim equitable relief.

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Agreement.

[signatures follow on next page]

SIGNATORIES

For and on behalf of THE MEDICINES PATENT POOL FOUNDATION

Signature: ……

Name (Printed): Charles Gore

Position: Executive Director

Date: ……

For and on behalf of [*INSERT NAME OF LICENSEE*]

Signature: ……

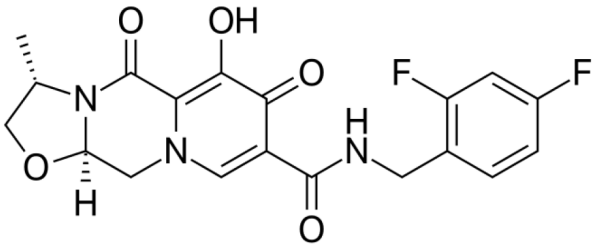
Name (Printed): ……

Position: ……

Date: ……

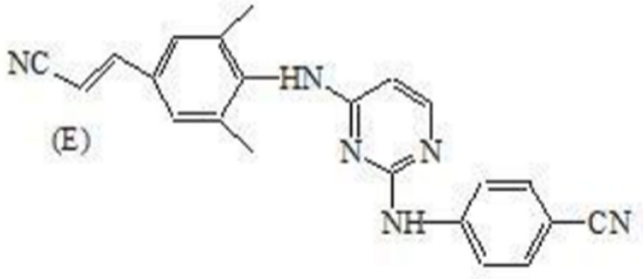
APPENDIX A (1)

Cabotegravir



APPENDIX A-(2)

Rilpivirine



APPENDIX B

LIST OF COUNTRIES FORMING THE TERRITORY

COUNTRY	ROYALTY COUNTRY	PERMITTED MARKET	
		Public Market	Private Market
Afghanistan	No	Yes	Yes
Algeria	Yes	Yes	Yes
Angola	No	Yes	Yes
Bangladesh	No	Yes	Yes
Benin	No	Yes	Yes
Bhutan	No	Yes	Yes
Bolivia	No	Yes	Yes
Botswana	No	Yes	Yes
Burkina Faso	No	Yes	Yes
Burundi	No	Yes	Yes
Cabo Verde	No	Yes	Yes
Cambodia	No	Yes	Yes
Cameroon	No	Yes	Yes
Central African Republic	No	Yes	Yes
Chad	No	Yes	Yes
Comoros	No	Yes	Yes
Congo, Dem. Rep.	No	Yes	Yes
Congo, Rep.	No	Yes	Yes
Côte d'Ivoire	No	Yes	Yes
Djibouti	No	Yes	Yes
Egypt, Arab Rep.	Yes	Yes	Yes
El Salvador	No	Yes	Yes
Equatorial Guinea	No	Yes	Yes
Eritrea	No	Yes	Yes
Eswatini	No	Yes	Yes
Ethiopia	No	Yes	Yes
Gabon	No	Yes	Yes
Gambia, The	No	Yes	Yes
Ghana	No	Yes	Yes
Guinea	No	Yes	Yes
Guinea-Bissau	No	Yes	Yes
Haiti	No	Yes	Yes
Honduras	No	Yes	Yes
India	Yes	Yes	Yes
Indonesia	Yes	Yes	Yes
Iran, Islamic Rep.	No	Yes	Yes
Kenya	No	Yes	Yes

Kiribati	No	Yes	Yes
Korea, Dem. People's Rep.	No	Yes	Yes
Kyrgyz Republic	Yes	Yes	Yes
Lao PDR	No	Yes	Yes
Lebanon	No	Yes	Yes
Lesotho	No	Yes	Yes
Liberia	No	Yes	Yes
Madagascar	No	Yes	Yes
Malawi	No	Yes	Yes
Mali	No	Yes	Yes
Mauritania	No	Yes	Yes
Mauritius	No	Yes	Yes
Micronesia, Fed. Sts.	No	Yes	Yes
Mongolia	No	Yes	Yes
Morocco	Yes	Yes	Yes
Mozambique	No	Yes	Yes
Myanmar	No	Yes	Yes
Namibia	No	Yes	Yes
Nepal	No	Yes	Yes
Nicaragua	No	Yes	Yes
Niger	No	Yes	Yes
Nigeria	No	Yes	Yes
Pakistan	No	Yes	Yes
Papua New Guinea	No	Yes	Yes
Philippines	Yes	Yes	Yes
Rwanda	No	Yes	Yes
Samoa	No	Yes	Yes
São Tomé and Príncipe	No	Yes	Yes
Senegal	No	Yes	Yes
Seychelles	No	Yes	Yes
Sierra Leone	No	Yes	Yes
Solomon Islands	No	Yes	Yes
Somalia	No	Yes	Yes
South Africa	No	Yes	Yes
South Sudan	No	Yes	Yes
Sri Lanka	No	Yes	Yes
Sudan	No	Yes	Yes
Syrian Arab Republic	No	Yes	Yes
Tajikistan	Yes	Yes	Yes
Tanzania	No	Yes	Yes
Timor-Leste	No	Yes	Yes
Togo	No	Yes	Yes
Tunisia	No	Yes	Yes
Tuvalu	No	Yes	Yes

Uganda	No	Yes	Yes
Ukraine	Yes	Yes	Yes
Uzbekistan	No	Yes	Yes
Vanuatu	No	Yes	Yes
Vietnam	Yes	Yes	Yes
West Bank and Gaza	No	Yes	Yes
Yemen, Rep.	No	Yes	Yes
Zambia	No	Yes	Yes
Zimbabwe	No	Yes	Yes

ROYALTY FEE FOR ROYALTY COUNTRIES:

The royalty fee payable under Clause 9.1 is:

five per cent (5%) of the Net Sales Value of Licensed Product sold or otherwise supplied for use in the **Public Market** of a Royalty Country; and

ten per cent (10%) of the Net Sales Value of Licensed Product sold or otherwise supplied for use in the **Private Market** of a Royalty Country.

APPENDIX C

THE PATENT RIGHTS

PCT/US2006/016604	WO2006/116764
PCT/US2011/022219	WO2011/094150
PCT/US2011/029369	WO2011/119566
PCT/US2011/051713	WO2012/037320
PCT/EP2018/051819	WO2018/149608

APPENDIX D

COMPLIANCE WITH APPLICABLE LAWS AND ETHICAL BUSINESS PRACTICES

1 SANCTIONS

1.1 Licensee represents and warrants that it is aware of and, in carrying out its obligations under the Agreement, will comply with and not become exposed to penalties or other retaliatory measures under any sanctions, export control, and anti-boycott laws, regulations, orders, directives, designations, licenses, and decisions of the European Union, the United Kingdom, the U. S., and of any other country with jurisdiction over activities undertaken in connection with the Agreement ("**Sanctions & Trade Controls**").

1.2 Licensee represents and warrants that, in the performance of its obligations under the Agreement, it will not take any action that causes Licensor and/or ViiV to violate or otherwise become exposed to penalties or other retaliatory measures under any Sanctions & Trade Controls.

1.3 Licensor will not be required pursuant to this Agreement, and ViiV will not be required pursuant to the Head Licence, to take or refrain from taking any action, nor will it be required to furnish any information, that would be prohibited, penalisable, or sanctionable under any Sanctions & Trade Controls.

1.4 Licensee represents and warrants to the Licensor and ViiV that: (i) neither it nor any of its Affiliates nor any of its or their respective directors, officers, agents, or employees is a Sanctions Target; (ii) it will not act, in connection with the performance of its obligations under the Agreement, for or on behalf of, or facilitate any activity of or with, any Sanctions Target; and (iii) it will not engage or otherwise deal directly or indirectly with, in connection with the performance of its obligations under the Agreement, (whether as a sub-distributor, a supplier, a service provider, a member of the team or otherwise), any person or entity which is a Sanctions Target, including by: (iv) making, directly or indirectly, any payments or other benefits available to or for the benefit of any person or entity which is a Sanctions Target, or (v) selling or otherwise supplying, directly or indirectly, any products to or for the benefit of any person or entity which is a Sanctions Target. "**Sanctions Target**" means any person or entity that is: (vi) listed on the EU Consolidated List of Designated Parties, maintained by the European Union; the Consolidated List of Asset Freeze Targets, maintained by HM Treasury (UK); the UK Sanctions List or any other list of designated parties maintained by the EU or its Member States; the U.S. List of Specially Designated Nationals and Blocked Persons (the "SDN List") or the U.S. Foreign Sanctions Evaders List, maintained by the U.S. Treasury Department's Office of Foreign Assets Control ("OFAC"); the U.S. Entity List or the U.S. Denied Persons List, maintained by the U.S. Commerce Department's Bureau of Industry and Security ("BIS"); or any list of parties subject to asset-freezing measures issued by the United Nations; (vii) 50% or more owned or controlled, directly or indirectly, by any one or more parties on the foregoing lists; or (viii) otherwise subject to U.S. property-blocking sanctions, including as a result of being owned or controlled by a government that is subject to such sanctions (at the Effective Date of this Agreement the governments of Cuba, Iran, North Korea, Syria, and Venezuela).

1.5 Licensee further represents and warrants to the Licensor and ViiV that: (i) it has disclosed to Licensor whether it is an SSI Party; (ii) it will not act, in connection with the performance of its obligations under the Agreement, for or on behalf of, or facilitate any activity of or with, any SSI Party or Military End User without consent in writing from Licensor and ViiV; and (iii) it will not engage or otherwise deal with, in connection with the performance of its obligations under the Agreement (whether as a sub-distributor, a supplier, a service provider, a member of the team or otherwise), any person or entity which is an SSI Party or Military End User without consent in writing from Licensor and ViiV. "SSI Party" means someone listed on the U.S. Sectoral Sanctions Identifications List or subject to EU or UK sectoral sanctions targeting Russia, or 50% or more owned or controlled, directly or indirectly, by any one or more SSI Parties; or a Military End User (i.e., listed on the U.S. Military End User List or otherwise meeting the definition of a "Military End User" set out in Section 744.21 of the U.S. Export Administration Regulations).

1.6 The Licensee represents and covenants that, prior to, directly or indirectly:

a. making the Patents or any Product available to, or contracting for Product manufacture with any Sanctions Target; or

b. making the Patents or any Product available to a country or territory that is the target of country-wide or territory-wide Sanctions;

it has obtained or will obtain a license or other authorization, either directly or through MPPF, from OFAC and/or any other relevant Sanctions Authorities.

1.7 If Licensee intends to make any distribution, sale, use, supply, import or export, of the Product in connection with this Agreement directly or indirectly to or within any country or territory which is or becomes, or whose government is or becomes, subject to comprehensive sanctions by the US, EU, UK or other country with jurisdiction over activities undertaken in connection with this Agreement, such as, currently, Cuba, Iran, North Korea, Syria, Venezuela, Crimea, the so-called Luhansk People's Republic, the so-called Donetsk People's Republic, and any territory within Kherson and Zaporizhzhia that are not under the control of the Ukrainian government, Licensee will consult with the Licensor and ViiV in advance and confirm to the Licensor and ViiV that it has the necessary licences or other authorisations, which includes but is not limited to specific licences and general licences, so that the Licensor and ViiV are not caused to violate or otherwise become exposed to penalties or other retaliatory measures under Sanctions. If the Licensor and ViiV are not satisfied that the Licensee has or will obtain the necessary licences or other authorisations in respect of these activities, the Licensee shall not proceed with such activities.

1.8 Notwithstanding the requirements of section 1.7 of Appendix D, nothing in this Agreement shall be construed to prevent the Licensee from benefiting from an exemption or general license for activities that would otherwise be sanctioned by US, EU and UK or other country with jurisdiction over activities undertaken in connection with this Agreement. This includes exemptions or general licenses authorising the distribution, sale, use, supply, import or export of the Product for humanitarian assistance. To the extent that such activities benefit from an exemption or general license, the Licensee shall only be required to notify the Licensor pursuant to the requirements of section 27 of this Agreement.

1.9 The Licensee represents and warrants to Licensor and ViiV that it will not develop and manufacture the Product in any of the following sanctioned countries and territories: Cuba, Iran, North Korea, Syria, Venezuela, Crimea, the so-called Luhansk People's Republic and the so-called Donetsk People's Republic and any territory within Kherson and Zaporizhzhia that are not under the control of the Ukrainian Government, or such other countries or territories that become or whose government becomes comprehensively sanctioned by the US, EU, UK or other country with jurisdiction over activities undertaken in connection with this Agreement.

1.10 Licensee further represents and warrants to the Licensor and ViiV that it has provided to Licensor complete and accurate details of the identities of the following parties: (i) its legal and ultimate beneficial owners, including all intermediate and ultimate parent entities; (ii) any parties that exercise legal or other control over it; its directors; (iii) its officers and other senior managers; (iv) any financial institutions involved in activity covered by the Agreement; (v) its sub-distributors (if applicable under the terms of the Agreement); and (vi) its subcontractors (if applicable under the terms of the Agreement).

1.11 Licensee further agrees that it will: (i) screen and conduct other due diligence, as appropriate, with respect to the persons and entities with which it intends to engage or otherwise deal in connection with the performance of its obligations under the Agreement to ensure that such persons and entities are not Sanctions Targets and to ascertain whether such persons and entities are SSI Parties or Military End Users; (ii) immediately notify Licensor and ViiV in writing if any person or entity with which it intends to engage or otherwise deal in connection with the performance of its obligations under the Agreement becomes a Sanctions Target, an SSI Party or a Military End User; and (iii) immediately notify Licensor and ViiV in writing of any changes to information provided pursuant to the paragraphs above.

1.12 Licensor may terminate the Agreement with immediate effect if, in Licensor and/or ViiV's sole discretion, Licensee breaches any of the foregoing representations and warranties or, in Licensor or ViiV's sole discretion, Licensor's performance of its obligations pursuant to the Agreement (or ViiV's performance of its obligations pursuant to the Head Licence) may breach or be penalisable or sanctionable under Sanctions & Trade Controls (whether or not in existence at the date of the Agreement and whether or not there have been any other changes in circumstance from those that existed at the date of the Agreement). If Licensor terminates the Agreement pursuant to this paragraph, it will not be obliged to make any payments, indemnify, or otherwise provide compensation to Licensee after the termination of the Agreement.

2 ANTI-BRIBERY AND CORRUPTION

2.1 "Government Official" (where "government" means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means any officer or employee of a government or any department, agency or instrumentality of a government (including public enterprises, and entities owned or controlled by the state); any officer or employee of a public

international organisation such as the World Bank or United Nations; any officer or employee of a political party, or any candidate for public office; any person defined as a government or public official under applicable local Laws (including anti-bribery and corruption laws) and not already covered by any of the above; or any person acting in an official capacity for or on behalf of any of the above. "Government Official" will include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting ViiV (and/or any ViiV Affiliate) business.

2.2 Licensee will, and will take reasonable measures to ensure its subcontractors, agents or any other third parties subject to its control or determining influence will, comply with anti-corruption laws and will not, in connection with the performance of this Agreement, directly or indirectly make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting Licensee or ViiV (and/or any ViiV Affiliate) in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which ViiV (and/or any ViiV Affiliate) is legally entitled.

2.3 Licensee represents and warrants that, except as disclosed to Licensor and ViiV in writing prior to the commencement of the Agreement: (i) none of its significant shareholders (>25% shareholding) or senior management has influence over ViiV's (and/or any ViiV Affiliate's) business; (ii) no significant shareholders, members of senior management, members of the Board of Directors, or key individuals who will be responsible for the provision of goods or services are currently or have been in the past 2 years a Government Official with actual or perceived influence which could affect ViiV (and/or any ViiV Affiliate) business; (iii) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed above having a public or private role which involves making decisions which could affect ViiV (and/or any ViiV Affiliate) business or providing services or products to, or on behalf of ViiV (and/or any ViiV Affiliate); (iv) it does not have any other interest which directly or indirectly conflicts with its proper and ethical performance of the Agreement; and (v) it will maintain arm's length relations with all third parties with which it deals for or on behalf of ViiV (and/or any ViiV Affiliate) in performance of the Agreement. Licensee will inform in writing at the earliest possible opportunity of any conflict of interest as described in this paragraph that arises during the performance of the Agreement.

2.4 Licensee, upon request by Licensor or ViiV, will certify that adequate anti-bribery and anti-corruption training has been provided to relevant Licensee personnel.

2.5 Licensor shall be entitled to terminate this Agreement immediately on written notice to the Licensee if the Licensee fails to perform its obligations in accordance with this Clause 2 of Appendix D. Notwithstanding any other provision in the Agreement, if Licensor terminates the Agreement due to Licensee breach of the anti-bribery and corruption requirements of this Clause 2 of Appendix D, Licensor will not be obliged to make any payments, indemnify, or otherwise provide compensation to Licensee subsequent to the termination of the Agreement.

3 ENVIRONMENT, HEALTH AND SAFETY

In its performance under the Agreement, Licensee will fulfil the following requirements:

3.1 EHS Management. Comply with all applicable environment, health and safety ("EHS") Laws and maintain all licenses, permits and registrations required by such EHS Laws; maintain an appropriate EHS management system for its business; provide processes to enable effective and timely communication with Licensor on all EHS matters and respond promptly to implement actions in Licensor and/or ViiV audit reports and/or engagements; ensure that EHS risks are identified and assessed, and that appropriate measures are implemented to manage such risks; report to Licensor and investigate all confirmed or suspected adverse health effects and/or EHS adverse events so that actions can be implemented to prevent recurrence (e.g. a fatality or serious injury; a requirement of notification to local or national regulators; significant property damage; environmental release with significant on-site clean-up costs or any offsite clean-up; evacuation of the site or community or initiation of community emergency response; or any adverse news coverage or public complaints); and collect, analyse and communicate EHS performance data (e.g. amounts of energy usage, air and water emissions and waste generation, EHS costs associated with the handling, manufacture and/or packaging of Licensed Products and intermediates).

3.2 Loss Prevention. Protect its physical assets from loss, damage or prolonged incapacity that may interrupt business-critical activities or seriously affect performance; provide plans, resources and capabilities to minimise the risk of events such as explosions, fires and release of materials arising from processes, bulk storage facilities or utilities and disruption arising from all such events in line with EHS risks; and provide adequate resources and capabilities to respond to emergencies and implement measures to safeguard the environment, people and property.

3.3 Employee Health. Ensure that risk assessments, health surveillance and controls identify and protect health of employees from workplace risks in accordance with EHS Laws, including susceptible subgroups within the population of workers who are likely to work with it (e.g., pregnant women if cytotoxics are present, asthmatics if respiratory irritants are present).

3.4 Environmental Risks. Manage site operations and ensure that any waste, including rejected or returned products declared as waste, are managed appropriately from the point of generation to the point of final disposal in a safe and responsible manner with environmentally sustainable waste disposal systems; ensure that any adverse environmental impacts or nuisances associated with air emissions are eliminated or minimised; ensure that water is used efficiently and that wastewater is treated and discharged in a way that minimises adverse impacts to the receiving environment; take all prudent measures to prevent contamination of soil and groundwater and address areas of contamination; ensure that effective measures to prevent and contain spillages and fire-water are in place; minimise, and ultimately eliminate, the use of ozone depleting substances and their release to the environment.

3.5 Hazardous Activities and Hazardous Agents. Ensure that EHS hazards associated with all materials are identified and that all materials are stored, handled, produced and transported securely so that EHS risks are minimised; ensure the appropriate selection, use, cleaning, maintenance and storage of personal protective equipment at all times; ensure that EHS risks and EHS adverse events, including adverse health effects are minimised for activities, including construction, operation, maintenance, cleaning, engineering tasks, repair of work equipment and systems by implementing a permit-to-work system; ensure that adequate occupational and environmental exposure limits or hazard categories are used in risk assessments and in the selection of control measures; ensure risks of exposure to materials are controlled to below occupational exposure limits under Applicable Law; prevent employees from becoming sensitised to materials in the workplace and minimise the adverse effects on any employees who do become sensitised; control exposures to chemical agents, biological agents and ionising radiation and prevent the uncontrolled release of chemical agents, biological agents and radioactive materials into the environment; and minimise the risk of noise-related adverse effects on personnel and on the local community.

4 LABOUR RIGHTS

Licensee represents and warrants, to the best of its knowledge, that in connection with the Agreement it: (i) respects the human rights of its staff and does not employ child labour, forced labour, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace; (ii) does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity); and (iii) pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates. Licensee will be respectful of its employees' right to freedom of association and will encourage compliance with these standards by any supplier that it uses in performing its obligations under the Agreement