

FOURTH AMENDMENT AND RESTATEMENT AGREEMENT in relation to a **LICENCE AGREEMENT** dated 31 March 2014 as amended and restated on 22 April 2016, 20 July 2018 and on 5 May 2021.

THIS FOURTH AMENDMENT AND RESTATEMENT AGREEMENT (the “**Fourth Amendment**”) is made by and between ViiV Healthcare Company, a company headquartered under the laws of Delaware and having its registered office at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware, 19808 (“**ViiV**”) and 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 Varembe 7, CH-1202 Geneva (“**MPPF**”), and is entered into as of the date that it is executed by both parties (the “**Amendment Date**”).

RECITALS

WHEREAS, ViiV and MPPF entered into a licence agreement dated 31 March 2014 (the “**Original Agreement**”) to promote access to the antiretroviral drugs dolutegravir for adult patients in a number of low-and middle-income countries;

WHEREAS, ViiV and MPPF entered into an amendment and restatement agreement dated 22 April 2016 (the “**Amendment**”), which restated the Original Agreement (including the Form of Sublicence set forth in Schedule 1 to the Original Agreement) as amended by the Amendment (the “**2016 Restated Agreement**”);

WHEREAS, ViiV and MPPF entered into a Second amendment and restatement agreement dated 20 July 2018 (the “**Second Amendment**”), which restated the 2016 Restated Agreement (including the Form of Sublicence as set forth in Schedule 1 to the 2016 Restated Agreement) as amended by the Second Amendment (the “**2018 Restated Agreement**”);

WHEREAS, ViiV and MPPF entered into a Third amendment and restatement agreement dated 5 May 2021 (the “**Third Amendment**”), which restated the 2016 Restated Agreement (without amending the Form of Sublicence set forth in Schedule 1 to Third Amendment) as amended by the Third Amendment (the “**2021 Restated Agreement**”);

WHEREAS, ViiV and MPPF wish to amend and restate the 2021 Restated Agreement to amend the Sublicence Form of Sublicence attached as Schedule 1 to the 2021 Restated Agreement.

NOW THEREFORE, based on the foregoing premises and the mutual covenants and obligations set forth below, and the consideration of £1 paid by MPPF to ViiV, the receipt and sufficiency of which is hereby acknowledged by ViiV, the Parties hereby agree as follows:

AGREEMENT

1. **Definitions.** All capitalised terms not otherwise defined herein shall have the meanings assigned to them in the 2021 Restated Agreement.
2. **Amendment and Restatement.** The 2021 Restated Agreement is, with effect from the Amendment Date, amended to take the form set out in Annex 1 to this Fourth Amendment, which restates the 2021 Restated Agreement as amended by this Fourth Amendment (the “**2024 Restated Agreement**”).
3. **General.**

- 3.1. Amendments. No provision of this Fourth Amendment may be modified or amended except expressly in a writing signed by both Parties.
- 3.2. Governing Law and Jurisdiction. The provisions of Clause 7 (Governing Law and Jurisdiction) of the 2021 Restated Agreement are hereby incorporated into this Fourth Amendment as if set out herein.
- 3.3. Counterparts. This Fourth Amendment may be executed in any number of counterparts, and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Fourth Amendment, but all the counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF the Parties have executed this Fourth Amendment by their duly authorized officers.

Signed for and on behalf of:

VIIV HEALTHCARE COMPANY

Signature: 
.....

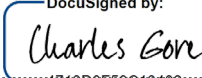
Name: **Crystal Baker**
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Title: **Secretary**
.....

Date: **8 January 2025**
.....

Signed for and on behalf of:

THE MEDICINES PATENT POOL

Signature: 
.....
4713D0F59C13482...

Name: **Charles Gore**
.....

Title: **Executive Director**
.....

Date: **02/12/2024**
.....

Annex 1
2024 Restated Agreement

LICENCE AGREEMENT

THIS LICENCE AGREEMENT (this “**Agreement**”) is made on 31 March 2014 (the “**Effective Date**”) and is amended and restated on 22 April 2016, on 20 July 2018 and 5 May 2021 (the “**Effective Amendment Date**”), and re-amended and restated on the last of the Parties’ signature hereto.

BETWEEN:

ViiV HEALTHCARE COMPANY, a company incorporated under the laws of Delaware and having its registered office at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware, 19808 (“**ViiV**”);

and

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 Varembe 7, CH-1202 Geneva (the “**MPPF**”),

with ViiV and the MPPF collectively referred to as the “**Parties**”.

WITNESSETH THAT:

WHEREAS the MPPF is a non-profit organisation with a mission to improve the health of people living in the developing world by increasing access to quality, safe efficacious and affordable medicines by facilitating access to intellectual property on these medicines;

WHEREAS ViiV or its Affiliates own certain rights, title and interest in and/or have the right to sublicense the Patents (as defined below);

WHEREAS the MPPF desires to obtain a licence from ViiV under the Patents solely to allow it to grant sublicences of the Patents to various third parties in order to promote access to adult formulations of antiretroviral drugs in the Territory (as defined below);

WHEREAS the MPPF and ViiV desire to explore the feasibility of expanding the number of developing countries that can benefit from generic competition in the public sector through the implementation of a tiered royalty scheme in a number of middle-income countries;

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

WHEREAS the intent of this Agreement is to provide access to Patents, and not to create any non-patent-related barriers where Patents or Non-Territory Patents (as defined below) do not exist;

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

For the purposes of this Agreement:

- (a) “**Adult Patients**” has the meaning given to such term in the Sublicence;
- (b) “**Affiliate**”, in relation to a party, shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such party. For the purposes of this definition, “control” shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of a party hereto are

conducted in accordance with the wishes of such corporation, firm, partnership or other entity;

- (b') "**Approved Affiliate**" has the meaning given to such term in the Sublicence. ViiV shall respond to any requests for approval of an Approved Affiliate pursuant to the Sublicence within thirty (30) days of receipt by ViiV of the appropriate supporting documents from the MPPF.
- (c) "**Agreement Quarter**" has the meaning given to such term in the Sublicence;
- (d) "**Approval Date**" has the meaning given to such term in the Sublicence;
- (e) "**Approved Local Distributor**" has the meaning given to such term in the Sublicence;
- (f) "**Approved Public Market Procurement**" has the meaning given to such term in the Sublicence;
- (g) "**Business Day**" has the meaning given to such term in the Sublicence;
- (h) "**Confidential Information**" has the meaning given to such term in the Sublicence;
- (i) "**FDA**" means the United States Food and Drug Administration;
- (j) "**First US Application**" means, in respect of a Product of a Sublicensee, the first application made by that Sublicensee 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 that Product in accordance with the terms and conditions of the applicable Sublicence.
- (k) "**Letter of Indemnity**" means a letter of indemnity in the form set out in schedule 2 hereto;
- (l) "**Licensed Combination Product**" has the meaning given to such term in the Sublicence;
- (m) "**Licensed Mono Product**" has the meaning given to such term in the Sublicence;
- (n) "**NCE Exclusivity Period**" means the period described in section 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) applicable to and dating from the first approval of NDA 204790 for TIVICAY (dolutegravir) tablets 50 mg on August 12, 2013, including any applicable extension of paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the U.S. Food, Drugs and Cosmetics Act;
- (o) "**Non-Territory Patents**" has the meaning given to such term in the Sublicence;
- (p) "**OFAC**" has the meaning given to such term in the Sublicence;
- (q) "**Paragraph III Certification**" has the meaning given to such term in the Sublicence
- (r) "**Paragraph IV Certification**" has the meaning given to such term in the Sublicence
- (s) "**Patents**" has the meaning given to such term in the Sublicence;
- (t) "**Private Market**" and "**Public Market**" have the meaning given to such terms in the Sublicence;
- (u) "**Products**" has the meaning given to such term in the Sublicence;
- (v) "**Raw Materials**" has the meaning given to such term in the Sublicence;
- (u') "**Reporting Guidance**" has the meaning given to such term in the Sublicence;
- (w) "**Royalty Country**" has the meaning given to such term in the Sublicence;

- (v') "**Royalty Countries Payment Guidance**" has the meaning given to such term in the Sublicence.
- (x) "**Relevant ANDA**" means an Abbreviated New Drug Application in relation to a Product submitted to the FDA by a Sublicensee under section 505(j) of the U.S Food, Drugs and Cosmetics Act during the NCE Exclusivity Period which is a First US Application by such Sublicensee for that Product;
- (y) "**Relevant NDA**" means a New Drug Application in relation to a Product submitted to the FDA by a Sublicensee under section 505(b)(2) of the U.S Food, Drugs and Cosmetics Act during the NCE Exclusivity Period which is a First US Application by such Sublicensee for that Product;
- (z) "**Sanctions**" has the meaning given to such term in the Sublicence;
- (aa) "**Sanctions Authorities**" has the meaning given to such term in the Sublicence;
- (bb) "**Sanctions Target**" has the meaning given to such term in the Sublicence;
- (cc) "**Selective Waiver Letter**" means a letter submitted by ViiV to the FDA pursuant to Clause 5.8A which authorizes the FDA to receive, review and tentatively approve a Relevant NDA or Relevant ANDA submitted by a Sublicensee during the NCE Exclusivity Period;
- (dd) "**Sublicence**" means a licence agreement in the form set out in schedule 1 hereto;
- (ee) "**Sublicensee**" means a third party which:
- (i) in the opinion of the MPPF (acting reasonably) has demonstrated willingness and capacity to (a) manufacture Raw Materials and/or Products in a manner consistent with World Health Organization ("WHO") pre-qualification standards or the standards of any Stringent Regulatory Authority, defined as regulatory agencies which are members, observers, or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time; and (b) make Products widely available at terms that will facilitate access to Products in the Territory for administration to Adult Patients; and
 - (ii) has entered into a Sublicence;
- (ff) "**Territory**" has the meaning given to such term in the Sublicence;
- (gg) "**Third Party(ies)**" shall mean any party other than a party to this Agreement.
- (ff') "**Trade Dress Guidance**" has the meaning given to such term in the Sublicence;
- (hh) "**WIPO Mediation Rules**" means the mediation rules adopted by the World Intellectual Property Organization from time to time.

2. GRANT OF LICENCE

- 2.1 Subject to the terms and conditions of this Agreement, ViiV hereby grants to the MPPF a non-exclusive, non-transferable licence under the Patents to enter into Sublicences with Sublicensees. No rights are hereby granted for any other purpose and the MPPF agrees that it will not use the Patents itself or grant sublicences: (i) to entities other than Sublicensees; and/or (ii) other than in the form of the Sublicence.
- 2.1A The MPPF acknowledges that the number of Sublicences granted to Sublicensees pursuant to this Agreement must be commensurate with the need for Products in the Territory or in specific countries of the Territory. Accordingly, the right of the MPPF to enter into further Sublicences pursuant to Clause

- 2.1 after the Effective Amendment Date is subject to both Parties agreeing that such need for Products exists in the Territory or in specific countries of the Territory. The existence of need for Products shall be determined by taking into account the Sublicensees' manufacturing capacity and local regulatory registration plans, demand forecasts, the need to promote a competitive market within each country in the Territory, and the need for local manufacturing capacity. For this purpose, prior to opening an expression of interest process to prospective sublicensees, the MPPF shall notify ViiV in writing of its intention to grant further Sublicences setting out the reasons for the need to grant such Sublicences. Within thirty (30) days from receipt of such notification, ViiV shall inform the MPPF in writing of (i) its agreement with the course of action proposed by the MPPF or (ii) its disagreement with the course of action proposed by the MPPF, in the latter case providing its reasons for considering that a need for Products has not been established by the MPPF. In the event of disagreement, the Parties shall seek to resolve the disagreement in good faith. If the Parties cannot resolve the disagreement within 60 days, the matter shall be handled in accordance with Clause 6.3 of this Agreement.
- 2.2 The MPPF shall procure that at the same time as any Sublicence is entered into the relevant Sublicensee enters into a Letter of Indemnity and that within 30 days of the execution of such Sublicence:
- (a) a fully executed copy of the relevant Sublicence; and
 - (b) two originals of the relevant Letter of Indemnity,
- are provided to ViiV.
- 2.3 ViiV hereby covenants with the MPPF that it shall not bring legal action against a Sublicensee for infringement of any Non-Territory Patents where such Sublicensee is carrying on activities outside of the Territory solely for purposes which are expressly permitted by the relevant Sublicence.
- 2.3 A For the avoidance of doubt, nothing in Clause 2.3 shall be construed as a waiver of, or prevent ViiV from exercising, any rights it may have in connection with any application by a Sublicensee to the FDA for a New Drug Application or Abbreviated New Drug Application that does not comply with Clause 4A of the relevant Sublicence (and ViiV expressly reserves all rights not granted under Clause 4A of each relevant Sublicence).
- 2.4 For avoidance of doubt, it shall not be a breach of the Sublicence for Sublicensees to manufacture, use, sell or supply Products or Raw Materials outside the Territory where such activities would not infringe Non-Territory Patents, including, without limitation, where a country outside the Territory has issued a compulsory licence on Non-Territory Patent(s) provided that Sublicensee is authorised to supply such country under the compulsory licence and such use is within the scope of the compulsory licence.
- 2.5 Notwithstanding anything contained in the Sublicence, no term of the Sublicence shall be construed to:
- (a) prevent Sublicensees from engaging in any activities within any country of the Territory that would not infringe a Patent granted and in force in such country of the Territory, or
 - (b) impose on Sublicensees a positive obligation to (i) restrict the sales of Product to the Public Market only, (ii) pay any royalties pursuant to Clause 3 of the Sublicence, (iii) obtain approval for an Approved Public Market Approval pursuant to Clause 2.4 of the Sublicence, (iv) have packaging that specifies that products are not authorised for supply to the Private Market pursuant to Clause 8.2 of the Sublicence or (v) provide the statements contemplated by Clause 11.2 of the Sublicence, in each case in relation to the supply of Product into a country of the Territory where such supply would not infringe a Patent granted and in force in such country of the Territory.
- 2.6 In the event that the MPPF can demonstrate that within twelve months of the first Approval Date relevant to a particular Royalty Country, demand for Product in such Royalty Country in the Private Market is

not met by supply (other than due to temporary supply interruptions), then the Parties shall enter into good faith discussions with the intention of amending one or more Sub-Licences as they apply to that jurisdiction to include such Private Market within the scope of its licence to address such a shortfall.

- 2.7 The MPPF and ViiV together commit to meet and review on an annual basis the operational elements of this Agreement and will work in good faith to ensure effective use of the resources of both Parties.

3. OBLIGATIONS OF THE MPPF

- 3.1 The MPPF agrees to be primarily liable for any breach of a Sublicence by any Sublicensee and undertakes to indemnify ViiV and its Affiliates in respect of any and all liabilities, costs, damages and expenses (including, but not limited to, legal costs) incurred by ViiV and/or its Affiliates arising out of, or in connection with any breach of a Sublicence by any Sublicensee. Where ViiV exercises its rights under this Clause, ViiV shall (i) provide MPPF with prompt written notice of such claims, (ii) grant MPPF the right to control the defence or negotiation of settlement of such claims (except to the extent such claims relate to the validity or enforcement of Patents or Non-Territory Patents) and (iii) make available all reasonable assistance in defending any claims. For the avoidance of doubt, the MPPF shall bear no liability for (a) the supply of Product into the Private Market in a Royalty Country by a person other than the Sublicensee or (b) the consumption of Product by patients other than Adult Patients, in each case where such supply or consumption does not result from the breach by the MPPF or the Sub-Licensee of obligations under this Agreement or the Sublicence respectively.
- 3.2 By no later than 1 April in each calendar year following supply in the previous calendar year of Products under the first Sublicence granted, and without prejudice to the MPPF's other obligations, the MPPF shall deliver a written report in a form reasonably satisfactory to ViiV setting out, in relation to each jurisdiction in the Territory where such information is available, details of (i) the estimated number of adults living with HIV that have been treated with a Product in the previous calendar year (assuming continuous treatment of such adults), broken down by reference to the different Product types (including Licensed Mono Products and any Licensed Combination Products), (ii) the volume of each such Product supplied in relation to such adults for such period and (iii) the total volume of each such Product supplied by Sub-Licensees (broken down by Sublicensee) for such period;
- 3.2A The MPPF shall provide ViiV a copy of the annual forecast for global demand of antiretroviral medicines prepared by the AIDS Medicines and Diagnostic Service of the World Health Organisation (the "AMDS Forecast") within ten (10) Business Days of receipt of the same by the MPPF, if the ADMS Forecast for that calendar year is not publicly available.
- 3.2B By no no later than 1 April in each calendar year following supply in the previous calendar year of Products under the first Sublicence granted, and without prejudice to MPPF's other obligations, MPPF shall deliver a written report in a form reasonably satisfactory to ViiV setting out, in relation to each jurisdiction in the Territory where such information is available, details of (i) the estimated number of adults living with HIV that have been treated with a Product in the previous calendar year (assuming continuous treatment of such adults), broken down by reference to the different Product types (including Licensed Mono Products and any Licensed Combination Products), (ii) the volume of each such Product supplied in relation to such adults for such period and (iii) the total volume of each such Product supplied by Sub-Licensees (broken down by Sublicensee) for such period;
- 3.2C The MPPF shall within ninety (90) days of the expiry of the ten (10) Business Day period referred to in Clause 11.2 of the Sublicence, send to ViiV a consolidated report summarising the reports provided to MPPF under Clause 11.2 of the Sublicence, ensuring that such consolidated report does not include any information that relates to countries outside the Territory.

- 3.2D The MPPF s MPPF shall within thirty (30) days of the expiry of the ten (10) Business Day period referred to in Clause 11.2 of the Sublicence, send to ViiV a consolidated report summarising the reports provided to MPPF under Clause 11.2 of the Sublicence, ensuring that such consolidated report does not include any information that relates to countries outside the Territory.
- 3.3 The MPPF agrees to monitor compliance with each Sublicence by each Sublicensee, including but not limited to by:
- (i) using reasonable endeavours to procure that Sublicensees provide the reports to the MPPF in accordance with Clauses 4.5 and 11.2 of the Sublicence and with the Reporting Guidance document, reviewing with all reasonable skill and care any such reports;
 - (i-a) Within thirty (30) days following expiry of the ten (10) Business Day period referred to in Clause 4.5 and 11.2 of the Sublicence, report to ViiV which Sublicensees (if any) have not complied with their obligations under Clauses 4.5 and/or 11.2 of the Sublicence and what action the MPPF has taken to facilitate compliance of such Sublicensees;
 - (i-b) Within ninety (90) days following the expiry of the ten (10) Business Day period referred to in Clause 4.5 of the Sublicence, send to ViiV a copy of any reports provided to the MPPF under Clause 4.5 of the Sublicence, redacting any information in the reports that relate to countries outside the Territory.
 - (ii) Within ninety (90) days of the expiry of the ten (10) Business Day period referred to in Clause 11.2 of the Sublicence, assessing with all reasonable skill and care in relation to each Sublicensee whether the supplies of Product made in the relevant Agreement Quarter in relation to the Royalty Countries were made in accordance with an Approved Public Market Procurement, and reporting in writing with all reasonable skill and care the outcome of such assessment to ViiV within such ninety (90) day period in a form reasonably satisfactory to ViiV;
 - (iii) Comparing with all reasonable skill and care the annual volumes of Products sold in the Territory under all existing Sublicences reported under Clause 11.2 of the Sublicences, broken down by Product types (including Licensed Mono Products and any Licensed Combination Products) but not by Sublicensee against the volumes forecast for the Territory for the equivalent calendar year as reported by the AMDS in the AMDS Forecast (as defined under clause 3.2A above), and reporting in writing with all reasonable skill and care the outcome of such comparison to ViiV within thirty (30) days of the publication or receipt by MPPF (whichever is the earliest) of the AMDS Forecast in a form reasonably satisfactory to ViiV; and
 - (iv) fully exercising the audit right set out in Clause 11.1 of the Sublicence at MPPF's own cost as soon as MPPF has reasonable cause to believe (and/or as soon as ViiV has notified MPPF that ViiV has reasonable cause to believe) an audit is necessary (including without limitation where such a party has reasonable grounds for suspecting non-compliance with the Sublicence).
 - (v) assessing with all reasonable skill and care whether any requests for prior written approval for trade or service marks, trade dress (where applicable), symbols or devices provided to the MPPF by Sublicensees under to Clause 10.3 of the Sublicence comply with the Trade Dress Guidance and do not fall within the categories listed under Clauses 10.4 (i)-(ii) of the Sublicence, and submitting to ViiV for written approval, those (and only those) requests which the MPPF considers meet the criteria provided in the Trade Dress Guidance. ViiV shall respond to any request for approval within thirty (30) days of receipt by ViiV of all the relevant documentation necessary to consider the Licensees' request.

ViiV agrees to treat any information of Sublicensees provided to it under this Clause 3.3 as Confidential Information and the confidentiality obligations of Clauses 6.1 to 6.4 of the Sublicence shall apply, *mutatis mutandis*, to ViiV with respect to such information.

- 3.4 A Where the Sublicence requires the Sublicensees to obtain approval from ViiV, the MPPF shall facilitate the provision of such approval in accordance with Clause 2.11 of the Sublicence.
- 3.4 The MPPF shall not provide its approval (or allow approval to be deemed provided) in relation to Approved Public Market Procurements in accordance with Clause 2.4 of the Sublicence unless it has reviewed a copy of the relevant tender documentation.
- 3.5 If the MPPF becomes aware of any act or omission of a Sublicensee which constitutes a breach of the relevant Sublicence the MPPF shall immediately notify ViiV and (i) if the breach is capable of correction and does not give rise to an immediate right of termination under the Sublicence, direct the relevant Sub-licensee in writing to cure the breach, with a copy of that writing to ViiV; and (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the Sublicence, and in each case if so requested by ViiV, procure the termination of the relevant Sublicence in accordance with its terms.
- 3.6 The MPPF agrees to exercise the rights of ViiV as granted under Clause 18.3 of any Sublicence only as requested in writing by ViiV. For the avoidance of doubt, this shall not affect ViiV exercising its rights directly under any Sublicence.
- 3.7 The MPPF's obligations under this Clause 3 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.
- 3.8 MPPF shall ensure that the royalties (together with any interest due) as contemplated by Clause 3 of each Sublicence are paid by each Sublicensee as an aggregated single quarterly sum to ViiV (or to such other person as ViiV may nominate in writing) in US dollars, by way of telegraphic transfer to such bank account as ViiV shall nominate, within sixty days of the expiry of the relevant Agreement Quarter. MPPF shall, within sixty seven days of the expiry of the relevant Agreement Quarter, provide to ViiV the individual Sublicensee statements as contemplated by Clause 3.4 of the Sublicence, together with a consolidated statement summarising such individual statements. For the avoidance of doubt and without prejudice to the audit rights set out in Clause 11.1 of the Sublicence, the MPPF is not required to verify that the amounts of royalties paid under Clause 3 of the Sublicence are correct for every payment made by the Licensees under that clause; however, for each Agreement Quarter, the MPPF shall monitor compliance with Clause 3 of the Sublicence by verifying that the royalty calculations relating to at least 20% of royalty payments made in that Agreement Quarter are correct. In the event that an error in royalty calculations is identified, the MPPF shall inform ViiV as soon as reasonably practical, and in any event within 5 working day of discovering such error, and shall take all the necessary steps to ensure that the error is rectified and that the correct amount of royalty is paid to ViiV by the Licensee.
- 3.9 The MPPF shall provide the Sublicensees the Royalty Countries Payment Guidance. Where applicable, the MPPF and ViiV hereby commit to determining by mutual agreement the fair market values referred to in Clause 3.3.3. of the Sublicence and to providing the Sublicensees a statement containing such values on an annual basis.
- 3.10 ViiV shall provide the MPPF the Trade Dress Guidance and shall keep it up to date by including information regarding specific tablet shapes, tablet colours and 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.

4. COMPLIANCE

- 4.1 The MPPF acknowledges receipt of GSK's "Prevention of Corruption – Third Party Guidelines" and agrees to perform its obligations under this Agreement in accordance with the principles set out therein.
- 4.2 The MPPF shall comply fully at all times with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territories in which the MPPF conducts business with ViiV and/or grants Sublicences.
- 4.3 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 Clause 4. The MPPF shall have no claim against ViiV or any of their Affiliates for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause 4. To the extent (and only to the extent) that applicable law provides for any such compensation to be paid to the MPPF upon the termination of this Agreement, the MPPF hereby expressly agrees to waive (to the extent possible under applicable law) or repay to ViiV any such compensation or indemnity.
- 4.4 The responsibilities of the parties for reporting of adverse drug experiences related to the Products to regulatory authorities in the Territory shall be performed in accordance with local laws and regulations. The responsibilities of the parties for safety related or Product related inquiries shall be performed in accordance with local laws and regulations. The MPPF hereby undertakes to (a) use reasonable efforts to monitor the activities and duties of the Sublicensee as regards pharmacovigilance obligations as set out in Clause 7 of the Sublicence, and (b) otherwise procure compliance by the Sublicensee with such Clause 7.
- 4.5 MPPF represents that neither MPPF nor, to the knowledge of MPPF, any Affiliate, director, officer, or employee of MPPF, is a Sanctions Target.
- 4.6 MPPF represents and covenants that, prior to directly or indirectly (a) making the Patents available or granting a Sublicence to any Sanctions Target or (b) engaging in a transaction in a country or territory that is the target of country-wide or territory-wide Sanctions, where relevant and/or applicable, it will obtain a license or other authorization from OFAC and/or any other relevant Sanctions Authority.

5A PUBLIC AND EXTERNAL COMMUNICATIONS

- 5A.1 Each Party shall seek each other Party's written approval of any initial press release or public announcement concerning the grant, scope or terms of this Agreement (the "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.
- 5A.2 The MPPF shall not refer to ViiV and/or its Affiliates, or ViiV's and/or its Affiliate(s)' trademarks and/or logos 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 patents 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.
- 5A.3 Subject to Clauses 5A.1 and 5A.2, neither Party shall be required to obtain the other Party's prior consent for any external communication relating to this Agreement.
- 5A.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, subsequent communications made by MPPF regarding its analysis of the economic and public health impact of this Agreement that are based on the methodology already reviewed by ViiV shall not require additional requests for review, 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.

- 5A.5 Each Party shall ensure that any external communication relating to this Agreement is accurate and not misleading.
- 5A.6 Each Party acknowledges that it is solely responsible and liable for its communications relating to this Agreement, including compliance with any applicable codes, laws and/or regulations.

5. GENERAL

- 5.1 The term of this Agreement shall commence on the Effective Date and expire upon the later of the expiration, lapse or invalidation of the last remaining Patent in the Territory (unless terminated earlier in accordance with its terms).
- 5.2 Upon the expiry of this Agreement, or in the event that this Agreement is terminated earlier in accordance with its terms, the MPPF shall procure that any Sublicences already granted shall be immediately terminated in accordance with their terms (if that Sublicensee is in breach of the Sublicence) or 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(s) under the same terms and conditions of the Sublicence if that Sublicensee is not in breach of the Sublicence. This Clause 5.2 shall survive any termination of this Agreement.
- 5.3 Other than as set out under Clause 2.1, this Agreement confers: (a) no intellectual property rights whatsoever on the MPPF; and (b) no rights on the MPPF to sublicense its rights hereunder, which is expressly prohibited.
- 5.4 The MPPF shall have no rights in relation to the conduct of any matter relating to the Patents, including the filing, prosecution and maintenance thereof.
- 5.5 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.
- 5.6 ViiV agrees only to exercise the rights granted to it under Clause 9.2 of the Sublicence in accordance with the licence granted therein. ViiV shall treat any information disclosed under Clause 11 of the Sublicence as Confidential Information and the confidentiality obligations of Clauses 6.1 to 6.4 of the Sublicence shall apply, *mutatis mutandis*, to ViiV with respect to such information provided, for the avoidance of doubt, that ViiV shall be entitled to disclose information about the quantities of Products manufactured by Sub-Licensees on an aggregate basis.
- 5.7 ViiV shall provide any Sublicensee with NCE Exclusivity or other regulatory exclusivity waivers to the extent required by the applicable regulatory authorities in order to manufacture or sell Product in the Territory in accordance with the terms of the Sublicence. ViiV shall further provide to any Sublicensee 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.

- 5.7A If a request for a Selective Waiver Letter is made to the MPPF by a Sublicensee in accordance with Clause 4A of the relevant Sublicence:
- (i) the MPPF shall notify ViiV and provide ViiV with the information required by ViiV to prepare the requested Selective Waiver Letter;
 - (ii) provided that the Sublicensee has complied with all the requirements of Clause 4A of the relevant 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 30 days of receiving all the information required to prepare the requested Selective Waiver Letter, from the MPPF.
- 5.7B For the avoidance of doubt, 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 4A of the relevant Sublicence.
- 5.7C ViiV shall provide a copy of each Selective Waiver Letter as submitted by it to the FDA to the MPPF within 10 Business Days of its submission to the FDA.
- 5.7D The provisions of Clauses 5.7A to 5.7C (inclusive) are without prejudice to the provisions of Clause 5.7.
- 5.8 This Agreement may only be amended in writing signed by duly authorised representatives of each Party. For the avoidance of doubt, and notwithstanding the rights of the MPPF pursuant to Clause 25 of the Sublicence, The MPPF shall not amend Appendix D or Appendix E of the Sublicence without ViiV's express consent in writing.
- 5.9 The rights of each Party under this Agreement: (a) may be exercised as often as necessary; (b) except as otherwise expressly provided in this Agreement, are cumulative and not exclusive of rights and remedies provided by law; and (c) may be waived only in writing and specifically. Delay in exercising or non-exercise of any such right is not a waiver of that right.
- 5.10 This Agreement may be executed in counterparts, which taken together shall constitute one and the same agreement, and any Party (including any duly authorised representative of a Party) may enter into this agreement by executing a counterpart.
- 5.11 This Agreement sets forth the entire agreement between the Parties and supersedes all prior agreements, arrangements and understandings, oral or written, between the Parties with respect to the subject matter hereof.
- 5.12 A person who is not a Party may not enforce any of the terms of this Agreement under the Contracts (Rights of Third Parties) Act 1999.
- 5.13 Nothing in this Agreement shall be construed as a warranty that (a) the information set out in Appendix D or Appendix E of the Sublicence accurately reflects the status of ViiV's patents and patent applications relating to the Compound and/or Products, (b) any of the Patents or Non-Territory Patents are valid or enforceable or (c) that their exercise does not infringe any patent rights of any Third Parties.

6. GOVERNING LAW AND JURISDICTION

- 6.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by English law.
- 6.2 Subject to Clause 6.3, the English courts have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement (including a dispute relating to any non-contractual obligations arising out of or in connection with this Agreement) and the Parties submit to the exclusive jurisdiction of the English courts.
- 6.3 The Parties agree that in the event of a dispute they shall submit such dispute to mediation in accordance with the WIPO Mediation Rules. In the event that the dispute remains outstanding after 60 days from the date when it was first discussed (in any manner) between the Parties, either Party may commence court proceedings. The foregoing however shall not prevent any person from seeking and obtaining injunctive relief at any time.
- 6.4 Without prejudice to the foregoing in relation to the Licensee, nothing in this Agreement shall prevent or restrict ViiV from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country outside England, to which election the MPPF hereby agrees.

7. NOTICES

- 7.1 Any given by a Party under this Agreement shall be:
 - (a) in writing and in English;
 - (b) signed by, or on behalf of, the Party giving it; and
 - (c) sent to the relevant Party at the address set out in Clause 8.3.
- 7.2 Notices may be given, and are deemed received:
 - (a) by hand: on receipt of a signature at the time of delivery;
 - (b) by pre-paid recorded delivery or registered post: on the third (3rd) Business Day after posting.
- 7.3 Notices shall be sent to:
 - (a) MPPF for the attention of the General Counsel at:

The Medicines Patent Pool
rue de Varembe
CH-1202 Geneva
Switzerland
 - (b) ViiV for the attention of the Head of International and copied to the Head of Legal for International, at:

ViiV Healthcare

79 New Oxford Street
London
WC1A 1DG
United Kingdom

- 7.4 Any changes to the contact details of a Party as set out in Clause 8.3 shall be notified to the other Party in accordance with Clause 8.1 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.
- 7.5 All references to time are the local time at the place of deemed receipt.
- 7.6 The provisions of this Clause 7 shall not apply to notices given in legal proceedings or arbitration.
- 7.7 For the avoidance of doubt, and although a notice given under this Agreement is not valid if sent by e-mail this Clause 8 is not intended to prohibit use of e-mail for day-to-day operational communications between the Parties, including where this requirement requires written approval by a Party.

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

Signed for and on behalf of:

VIIV HEALTHCARE COMPANY

Signature:

Crystal Baker

Name:

Crystal Baker

Title:

Secretary

Date:

8 January 2025

Signed for and on behalf of:

THE MEDICINES PATENT POOL

Signature:

DocuSigned by:
Charles Gore

Name:

Charles Gore

Title:

Executive Director

Date:

02/12/2024

SCHEDULE 1
FORM OF SUBLICENCE