

**THIS LICENCE AGREEMENT** (this "Agreement") is made as of 05  
November 2021 (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 Varembe 7, CH-1202 Geneva (the "Licensor"); and
- (2) **SUN PHARMACEUTICAL INDUSTRIES LIMITED**, a company incorporated under the laws of India and having its registered office at SPARC, Tandalja, Vadodara - 390020 and corporate office at Sun House, 201 B/1, Western Express Highway, Goregaon East, Mumbai - 400 063, India (the "Licensee"),

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

**WITNESSETH THAT:**

**WHEREAS** the Licensor has been granted by ViiV (as defined below) the right to sublicense certain patents and patent applications, which relate to the compounds known as dolutegravir and abacavir for adult use;

**WHEREAS** the Licensee desires to obtain a licence from the Licensor to use the aforesaid patents 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;

**WHEREAS** the intent of this Agreement is to provide access to Patents (and therefore facilitate access to medicines for adult persons living with HIV in certain middle-income countries), 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**

- 1.1 "ABC Compound" shall mean the chemical compound known generically as abacavir, whose more specific chemical name is set out in Appendix A.
- 1.2 "ABC Patents" shall mean those patents and patent applications in the Territory relating to both the ABC Compound and the Products owned by ViiV as are set out in Part A of Appendix C.
- 1.3 "Abuse" shall mean persistent or sporadic intentional excessive use of a Product by a patient or clinical trial subject accompanied by harmful physical and/or psychological effects.
- 1.4 "Adult Patients" shall mean patients of age eighteen years or more.
- 1.5 "Adverse Event" or "AE" shall mean any untoward medical occurrence in a patient or clinical trial subject administered a 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 Product, whether or not considered related to the Product.

In addition to the foregoing, in the context of clinical trials an AE will also mean events associated with and/or possibly attributable to the clinical trial protocol design or clinical trial procedures.

- 1.6 “**Affiliate**”, in relation to an entity, 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 entity. 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 an entity are conducted in accordance with the wishes of such corporation, firm, partnership or other entity.
- 1.7 “**Agreement Quarter**” shall mean any period of three months ending on the last day of March or June or September or December.
- 1.8 “**ALHIV On Treatment**” shall mean, in relation to each country of the Territory, the estimated number of adult persons living with HIV on antiretroviral treatment for HIV in that country according to the most recent figures published by UNAIDS on its AIDS info website at [Aidsinfo.unaids.org](http://Aidsinfo.unaids.org) or, where such data are not available, using an alternative independent source determined by the Licensor and ViiV and notified to the Licensee in writing.
- 1.9 “**Approval Date**” shall mean, in relation to each Product, the date on which that Product first receives Regulatory Approval from a Relevant Regulatory Authority.
- 1.9A “**Approved Affiliate**” shall mean an Affiliate of the Licensee (i) which the Licensee has demonstrated by means of appropriate supporting documents is an Affiliate of the Licensee, and (ii) approved in writing by the Licensor and ViiV to sell the Products of the Licensee in the Territory, such approval not to be unreasonably withheld. The Licensor and ViiV shall respond to any requests for approval within thirty (30) days of receipt by ViiV of the appropriate supporting documents from the Licensor.
- 1.9B “**Approved Distributor**” shall mean a Third Party approved in writing by the Licensor to distribute the Products in the Territory, such approval not to be unreasonably withheld. The Licensor shall respond to any requests for approval from the Licensee within thirty (30) days of receipt by the Licensor of all appropriate supporting documents, as reasonably determined by the Licensor, specifying the proposed distribution arrangement. For the avoidance of doubt, the Licensor may withdraw such approval at any time by written notice to the Licensee specifying at least one reasonable ground for the withdrawal of approval, which may include, without limitation, a reasonable suspicion on the part of the Licensor that Product(s) distributed by the Approved Distributor has or have been sold or supplied in breach of any term of this Agreement.
- 1.10 “**Approved Public Market Procurement**” shall have the meaning given to it in Clause 2.4.
- 1.11 “**Award**” shall mean, in relation to a sale or supply of Product(s) in a country of the Territory, the award to the Licensee of the tender (or execution of the purchase agreement aligned with a Government purchase order or request where applicable) pursuant to which the sale or supply of Product(s) is made.
- 1.12 “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.

- 1.13 **“Calendar Month”** shall mean a period from a specified day in one month to the day numerically corresponding to that day in the following month, less one.
- 1.14 **“Calendar Year”** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.15 **“Compounds”** shall mean the DTG Compound and the ABC Compound.
- 1.16 **“Confidential Information”** shall mean 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, without limitation, 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, and shall include Appendix D to this Agreement and the information contained therein.
- 1.17 **“Development Activity”** shall mean any of the following:
- (a) initiating, conducting, sponsoring, supporting or providing Products for use in any clinical research relating to the Products;
  - (b) engaging with guideline bodies or external experts in relation to development of the Products; and/or
  - (c) developing a Licensed Combination Product in accordance with this Agreement.
- 1.18 **“DTG Compound”** shall mean the chemical compound known generically as dolutegravir, whose more specific chemical name is set out in Appendix A.
- 1.19 **“DTG Patents”** shall mean those patents and patent applications owned by ViiV as are set out in Part B of Appendix C.
- 1.20 **“Effective Date”** shall mean the date of this Agreement.
- 1.21 **“Event of Force Majeure”** shall have the meaning given in Clause 16.
- 1.22 **“Existing Adult Licence”** shall mean the licence agreement entered into between the Licensor and the Licensee (or ViiV and the Licensee) relating to the manufacture and supply of products containing the DTG Compound for use in antiretroviral therapy for HIV / AIDS in Adult Patients in ViiV’s access territory.
- 1.23 **“Existing Paediatric Licence”** shall mean the licence agreement, if any, entered into between the Licensor and the Licensee (or ViiV and the Licensee) relating to the manufacture and supply of products containing the DTG Compound for use in antiretroviral therapy for HIV / AIDS in child patients in ViiV’s access territory.
- 1.24 **“Existing Product”** shall mean DTG Compound-containing product sold pursuant to the Existing Adult Licence or an Existing Paediatric Licence.
- 1.25 **“Head Licence”** shall mean the licence agreement entered into between ViiV and the Licensor dated November 2020 under which the Licensor’s right to license the Patents in the Territory under this Agreement is derived.
- 1.26 **“Human Safety Information”** shall mean information relating to human health and/or wellbeing arising following exposure of humans to a Medicinal Product including:

- Adverse Events
- failure to produce expected benefits (i.e. lack of therapeutic efficacy);
- reports of Medication Errors or Misuse, including drug Overdose, whether accidental or intentional;
- reports of drug Abuse or effects of drug withdrawal;
- reports of Occupational Exposure;
- reports of patients taking a Product whilst pregnant (Pregnancy Report) or breastfeeding;
- reports of drug interaction;
- reports of paternal exposure to a Product;
- Suspected transmission of an infectious agent via a Product;
- information received as part of a product complaint
- unexpected therapeutic benefits – an unexpected improvement in a concurrent condition other than the one being treated and
- reports of Off-label Use

- 1.27 **"Misuse"** shall mean a situations where the Product is intentionally and inappropriately used not in accordance with the authorised product information
- 1.28 **"Occupational Exposure"** shall mean Exposure to a Product as a result of one's occupation
- 1.29 **"Off-label Use"** shall mean Intentional use of a Product for a medical purpose not in accordance with the authorised product information.
- 1.30 **"Overdose"** shall mean 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.
- 1.31 **"Import Waiver"** shall mean, in respect of a country of the Territory in which, at the time of the intended sale or supply, the Product(s) do(es) not have Regulatory Approval, all export and import licences, authorisations, permits, consents or approvals necessary to supply, sell and/or offer for sale that Product (or those Products) in that country.
- 1.32 **"Improvement"** shall mean any new or improved process, any new or improved manufacturing techniques or any further invention which relate to the manufacture or formulation of the Products and/or Compound or incorporate or are based on the Patents.
- 1.33 **"Improvement Patents"** shall mean any patents or patent applications which generically or specifically claim any Improvements which are developed by the Licensee, or to which the Licensee otherwise has the right to grant licences, now or in the future.
- 1.34 **"Licensed Combination Products"** shall mean pharmaceutical combinations and compositions that have been prepared and are in a tablet form containing 50mg of DTG Compound ready for administration to Adult Patients solely for antiretroviral therapy for HIV/AIDS which contain the DTG Compound as an active ingredient in combination with (a) the ABC Compound and/or (b) other active ingredients (subject to the limitation set out in Clause 2.8) and in each case where the resulting combination product has been recommended by the World Health Organisation or the United States Department of Health and Human Services, in each case for supply to and use by Adult



Patients.

- 1.35 **“Licensed Mono Products”** shall mean pharmaceutical compositions that are in a tablet form containing 50mg of DTG Compound which have been prepared and are ready for administration to Adult Patients solely for antiretroviral therapy for HIV/AIDS which contain the DTG Compound as their sole active ingredient.
- 1.36 **“Medication Error”** shall mean 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.
- 1.37 **“Non-Territory Patents”** shall mean, in relation to those countries falling outside of the Territory, any patents and patent applications in such countries equivalent to the Patents.
- 1.38 **“OFAC”** shall have the meaning given in the definition of “Sanctions Target” in this Agreement.
- 1.39 **“Patents”** shall mean the ABC Patents and the DTG Patents set out in AppendixC.
- 1.40 **“Pharmacovigilance”** shall mean 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 public health.
- 1.41 **“Pregnancy Report”** shall mean a report of pregnancy in a patient or trial subject to whom a Product or investigational Product has been administered.
- 1.42 **“Private Market”** shall mean any entity that is not in the Public Market.
- 1.43 **“Products”** shall mean each Licensed Mono Product and each Licensed Combination Product that are subject to this Agreement.
- 1.44 **“Public Market”** shall mean (A) the following organisations to the extent that they are not for profit organisations: (i) the government of any country in the Territory, including without limitation 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”**); and (ii) UNITAID, PEPFAR, USAID or Global Fund or procurement agencies acting on their behalf, to the extent that they support (an) HIV treatment program(s) for Adult Patients run or funded by the Government of the applicable country; and (B) Approved Distributors, solely to the extent that such Approved Distributors distribute Product(s) to one or more entities identified in (A) of this Clause 1.44.

- 1.45 **“Raw Materials”** shall mean, as the context admits and requires, the active ingredients which are protected by the Patents and which (i) are required to prepare the Products in final consumer package form as envisaged under the licences granted under Clauses 2.1 and 2.2; and (ii) are solely for use in the Products.
- 1.46 **“Regulatory Approval”** shall mean, in relation to each country of the Territory and each Product, the receipt of a marketing authorisation associated with that Product for that country.
- 1.47 **“Relevant Regulatory Authority”** shall mean (i) in relation to a particular country in the Territory, any applicable federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaux, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Products in that country, or (ii) WHO pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).
- 1.48 **“Reporting Guidance”** shall mean the guidance on reporting (as required in Clauses 4.5, 11.2 and 11.3 of this Agreement) on, inter alia, regulatory activities, manufacturing and sales of Products, that will be issued by the Licensor to the Licensee, and as may be amended from time to time.
- 1.48 A **“Royalty Payment Guidance”** means any guidance on the payment of royalties under Clause 3, issued by the Licensor and approved by ViiV, as amended from time to time.
- 1.49 **“Sanctions”** shall have the meaning given in the definition of “Sanctions Target”.
- 1.50 **“Sanctions Authorities”** shall have the meaning given in the definition of “Sanctions Target”.
- 1.51 **“Sanctions Target”** shall mean an individual or entity that is, or is owned or controlled by, an individual or entity which is: (i) the target of any sanctions administered or enforced by the U.S. Department of Treasury’s Office of Foreign Assets Control (“OFAC”), Her Majesty’s Treasury, the United Nations Security Council, the European Union or other relevant sanctions authority (together, the “Sanctions Authorities”) (collectively “Sanctions”); or (ii) located, organized or resident in a country or territory that is the target of country-wide or territory-wide Sanctions (which, at the date of this Licence, includes without limitation Cuba, Iran, Dem. Rep. Korea, Crimea and Syrian Arab Republic); or (iii) listed on OFAC’s List of Specially Designated Nationals and Blocked Persons or any equivalent list of parties designated by the European Union, or the United Kingdom.
- 1.52 **“Serious Adverse Event (SAE)”** shall mean an AE which:
- i. results in death;
  - ii. is life-threatening; that is, an event where the patient/Clinical Trial subject was at risk of death at the time of the event: it does not refer to an event that, hypothetically, might have caused death if it had been more severe;
  - iii. requires hospitalisation or prolongation of existing hospitalisation
  - iv. results in persistent or significant disability or incapacity;
  - v. is a congenital anomaly or birth defect in the foetus/child, foetal death, spontaneous abortion and serious adverse reactions in the neonate;
  - vi. involves Transmission via a Medicinal Product of an Infectious Agent; or

vii. is an Important Medical 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 1.2.56 (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.

- 1.53 **"Territory"** shall mean all those countries as are set out in Appendix B, as may be amended from time to time in accordance with Clause 25.
- 1.54 **"Third Party(ies)"** shall mean any party other than a party to this Agreement.
- 1.55 **"Trade Dress Guidance"** shall mean guidance on trade dress, elaborating the requirements in Clauses 8 and 10 of this Agreement, issued by the Licensor and ViiV, as amended from time to time. For the avoidance of doubt, the Trade Dress Guidance under this Agreement shall be identical to the "Trade Dress Guidance" as defined under, and issued pursuant to, the Existing Adult Licence.
- 1.56 **"Unit Number"** shall mean, in relation to each country, the number of Units of Product(s) subject to the relevant Award.
- 1.57 **"Unit of Product"** shall mean thirty (30) tablets of Product, irrespective of whether packaged as one pack, as part of a pack, as multiple packs, or sold, supplied or packaged in any other way.
- 1.58 **"Usage Period"** shall mean, in relation to each proposed sale or supply, or each Award, as applicable, the calendar period within which the Product(s) subject to such proposed sale or supply, or Award, as applicable, are intended to be used, in each instance as indicated by the relevant Government.
- 1.59 **"ViiV"** shall mean ViiV Healthcare Company and/or its Affiliates, as the context admits.
- 1.60 **"WHO"** shall mean the World Health Organization.
- 1.61 **"WIPO Mediation Rules"** shall mean the mediation rules adopted by the World Intellectual Property Organization from time to time.
- 1.62 References to "this Agreement" shall mean this licence agreement and shall include the Appendices.
- 1.63 References to "Clauses" and "Appendices" are references to clauses and appendices of and to this Agreement and references to sub-clauses or paragraphs are, unless otherwise stated, references to sub-clauses or paragraphs of the Clauses or Appendices in which the reference appears.
- 1.64 Unless the context otherwise requires, the singular shall include the plural and vice versa and the masculine includes the feminine and neuter genders and vice versa.
- 1.65 The headings and sub-headings used in this Agreement are for convenience only and shall not affect the construction or the interpretation of this Agreement.
- 1.66 References to "party" or "parties" shall, unless otherwise stated or unless the context otherwise admits or requires, mean a party or parties to this Agreement.

- 1.67 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 GRANT OF SUBLICENCE

- 2.1 Subject to the terms and conditions of this Agreement (including without limitation Clause 2.4) and to the extent to which the Licensor has the right to grant a licence in respect of the Patents, the Licensor hereby grants to the Licensee a non-exclusive, royalty-bearing, non-sublicensable, non-transferable licence under the Patents to:
- (a) manufacture, have manufactured, use, import or export in the Territory Raw Materials for use in the manufacture of Products to be supplied to the Public Market in the Territory solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients; and
  - (b) manufacture, have manufactured, use, sell to the Public Market, have sold by an Approved Affiliate to the Public Market, supply to the Public Market, import or export Products in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients.
- 2.2 Subject to the terms and conditions of this Agreement (including without limitation Clause 2.4) and to the extent to which the Licensor has the right to grant a licence in respect of the Non-Territory Patents, the Licensor hereby grants to the Licensee a non-exclusive, royalty-bearing, non-sublicensable, non-transferable licence under the Non-Territory Patents to:
- (a) manufacture, have manufactured, use, sell, have sold by an Approved Affiliate, supply, import or export outside the Territory Products exclusively for use, sale to the Public Market, supply to the Public Market, import or export of such Products in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients;
  - (b) manufacture, have manufactured, use, import or export outside the Territory Raw Materials exclusively for supplying into the Territory for use in the manufacture of Products in the Territory to be supplied to the Public Market in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients; and
  - (c) manufacture, have manufactured, use, import or export outside the Territory Raw Materials for the manufacture of Products outside the Territory exclusively for use, sale to the Public Market, supply to the Public Market, import or export in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients.
- 2.3 Notwithstanding anything contained in this Agreement, nothing in this Agreement shall be construed to:
- (a) prevent the Licensee 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 the Licensee a positive obligation to (i) restrict the sales of Product to the Public Market only, (ii) pay any royalties pursuant to Clause 3, (iii)

obtain approval for an Approved Public Market Procurement pursuant to Clause 2.4, (iv) have packaging that carries the statements specified in Clause 8.2 or (v) provide the reports contemplated by Clauses 11.2 and 11.3, 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.

- 2.4 The Licensee must obtain prior written approval from the Licensor for any sale or supply of Product(s) by the Licensee within the Territory, with such approval to be deemed provided five (5) Business Days after receipt by the Licensor of a written request for approval, unless the Licensor has expressly indicated that approval is not granted (an "Approved Public Market Procurement"). Any such written request for approval shall include (i) copies of the relevant Public Market procurement documentation regarding the proposed sale or supply and (ii) appropriate documentary evidence (as reasonably determined by the Licensor) of the Usage Period. Where the Licensee's request for approval includes a request that ViiV agrees that a special increased Product Access Percentage should apply pursuant to Clause 3.5, the Licensee must provide all necessary documentation for the Licensor and ViiV to consider the same. For the avoidance of doubt, approval from ViiV that a special increased Product Access Percentage be applied shall not be deemed provided unless ViiV has expressly agreed in writing to said request.
- 2.5 Other than as set out in Clauses 2.1 and 2.2, no rights are granted to the Licensee under this Agreement to manufacture, sell or supply either Raw Materials or Products inside or outside the Territory. The licence granted under this Agreement is subject to the intellectual property rights of any Third Party anywhere inside or outside the Territory. For the avoidance of doubt, it shall not be a breach of this Agreement for the Licensee 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 the Licensee is authorised to supply such country under the compulsory licence and such use is within the scope of the compulsory licence.
- 2.5A The Licensee's licence to have manufactured by a Third Party Raw Materials and Products in accordance with Clauses 2.1 and 2.2 shall be limited solely to manufacture on behalf of the Licensee of (i) Raw Materials for supply to the Licensee and (ii) Products for supply to the Licensee and/or an Approved Affiliate. Clauses 2.1 and 2.2 shall not be construed as conferring any right for a Third Party to manufacture Raw Materials and/or Products for supply to any party other than the Licensee and/or an Approved Affiliate (as applicable).
- 25 B For the avoidance of doubt, this Agreement confers no rights on the Licensee to sublicense its rights hereunder, which is expressly prohibited. The Licensee shall procure that any Third Party manufacturer and/or any Approved Affiliate shall comply with the terms of this Agreement as if it was the Licensee, and the Licensee shall remain fully liable for the acts and omissions of such Third Party manufacturer and/or Approved Affiliate.
- 26 It is expressly acknowledged by the Licensee that this Agreement confers no intellectual property rights whatsoever on the Licensee other than those expressly granted in Clauses 2.1 and 2.2 for the term of this Agreement. Without prejudice to the generality of the foregoing, other than as expressly granted in Clauses 2.1 and 2.2, no licence is granted to the Licensee:

- (a) to perform any acts or omissions which infringe any rights (including, but not limited to, patent rights) of the Licensor, ViiV and/or any of their Affiliates and/or their sublicensees inside or outside the Territory;
  - (b) to perform any acts or omissions which infringe any rights of any Third Party (including, without limitation, ViiV and their Affiliates) inside or outside the Territory (including, without limitation, any rights relating to any active ingredient, other than the Compounds, used in the Licensed Combination Products); and/or
  - (c) in relation to the Patents for the use, manufacture, sale or supply of Products where such Products would be supplied directly or indirectly to (i) the Private Market in the countries of the Territory or (ii) any patient other than an Adult Patient.
- 27 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 (signed by the relevant parties) relating to Patents and/or Non-Territory Patents. 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.
- 28 Nothing in this Agreement shall be deemed to constitute a licence for the Licensee to manufacture, import, use or supply any active ingredient other than the Compounds.
- 29 Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to supply, sell or offer for sale a Product in a country of the Territory prior to the relevant Approval Date for that Product for that country, unless the supply, sale or offer for sale is made pursuant to an Import Waiver and the Licensee:
- has filed for Regulatory Approval for that Product in that country; or
  - has provided a written undertaking to the Licensor that it will file for Regulatory Approval for that Product in that country as soon as reasonably practicable and in any event within 12 months of the first supply or sale of that Product in that country.
- 210 Where this Agreement requires the Licensee to obtain approval from ViiV, the Licensee shall request such approval through the Licensor.

### 3 ROYALTIES

- 3.1 In consideration for the grant of the licence set out in Clauses 2.1 and 2.2, the Licensee agrees to pay royalties to ViiV (or to such other person as ViiV may nominate in writing) subject to, and in accordance with, this Clause 3 and confidential Appendix D to this Agreement.
- 3.2 The Licensee shall pay royalties quarterly for Products sold in the Territory on a Product-by-Product and country-by-country basis, starting on the date of first sale of a Product in the relevant country and continuing until the expiration of the last-to-expire Patent containing a valid claim covering the manufacture, use, import, export, supply, offer for sale or sale of DTG Compound and/or Product in such country. ViiV may provide the Licensor with approved Royalty Payment Guidance and the Licensor agrees to issue any such guidance to the Licensee without delay.

- 3.3 The royalty fee payable under Clause 3.2 in relation to each Unit of Product sold in each country of the Territory shall be determined based on the Product Access Percentage applicable to that Unit of Product (as defined under Clause 3.4) as follows:
- Where the Product Access Percentage is less than 20%, the Licensee shall pay royalty fee A set out in confidential Appendix D in relation to every Unit of Product sold;
  - Where the Product Access Percentage is equal to or greater than 20% but less than 35%, the Licensee shall pay royalty fee B set out in confidential Appendix D in relation to every Unit of Product sold; and
  - Where the Product Access Percentage is equal to or greater than 35%, the Licensee shall pay royalty fee C set out in confidential Appendix D in relation to every Unit of Product sold.
- 3.4 Subject to Clause 3.5, for each Award, the Product Access Percentage applicable to each Unit of Product sold shall be calculated as follows:

$$\text{Product Access Percentage} = \frac{(\text{Unit Number} \times \text{number of full Calendar Months in Usage Period})}{\text{ALHIV On Treatment}} * 100$$

where the value for ALHIV On Treatment shall be the most recent figure as at the date of the Award.

- 3.5 The Parties do not anticipate that in any country of the Territory the Usage Period for an Award will overlap with the Usage Period for a subsequent proposed sale or supply. Notwithstanding the aforesaid, in the event that in any country of the Territory the Usage Period for an Award overlaps by one full Calendar Month or more with the Usage Period for a subsequent proposed sale or supply, the Licensee may, as part of the approval process under Clause 2.4 for that subsequent proposed sale or supply, request that ViiV agrees that a special increased Product Access Percentage (reflecting the increased access to Product in the period of overlap between the two Usage Periods) be applied to (i) Units of Product(s) subject to the proposed sale or supply attributable to said period of overlap and (ii) Units of Product(s) sold pursuant to the preceding Award attributable to said period of overlap (in each case with such attribution to be determined pro-rata based on the period of overlap between the two Usage Periods). The Licensee shall forward such request to ViiV without delay. For the avoidance of doubt, the Licensee acknowledges that ViiV is under no obligation to approve such request, and that pending ViiV's express approval in writing the request shall be considered not approved. If ViiV does not approve the request, the Product Access Percentage applicable to all Units of Product(s) sold under the Award and any Award regarding the subsequent proposed sale or supply referenced in this Clause 3.5 shall be calculated in accordance with Clause 3.4.
- 3.6 When providing the information specified in Clause 11.3, the Licensee shall also provide to the Licensor (or the Licensor's nominee) its calculation of the royalties payable to ViiV pursuant to this Clause 3 in relation to the relevant Agreement Quarter. Where a special increased Product Access Percentage approved by ViiV applies, any such calculation shall, where applicable, reflect said increased Product Access Percentage and include any calculation of any rebate due to the Licensee relating to any previous calculations of royalties submitted to the Licensor (or the Licensor's nominee)

pursuant to this Clause 3.6. Such rebate, if correctly calculated, will be reflected in the relevant invoice(s).

- 3.7 If upon examination of a royalty calculation provided pursuant to Clause 3.6, 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 Steering Committee meeting. If the Steering Committee cannot reach consensus, the Steering Committee Chair shall escalate the matter to the Parties' respective Chief Executive Officers or Executive Directors in accordance with Clause 7A.8.
- 3.8 ViiV shall invoice the Licensee (through the Licensor) in US dollars for the royalties payable pursuant to this Agreement for the immediately preceding Agreement Quarter as soon as reasonably practical following receipt by ViiV of the report under Clause 11.3 from the Licensor and in any event within twenty (20) Business Days of such receipt. ViiV shall calculate the amount due under each invoice in US dollars 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.
- 3.9 The Licensee shall, on or before the thirtieth (30<sup>th</sup>) 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) in US dollars the amount due under that invoice. The Licensee shall make such payments by way of telegraphic transfer to such bank account as ViiV shall nominate.
- 3.10 In the event of any delay in the Licensee paying to ViiV (or ViiV's nominee) any sum due under this Clause 3 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.
- 3.11 If an examination pursuant to Clause 11 reveals an underpayment by the Licensee, the Licensee shall promptly, and in any event within sixty (60) days of the determination of such shortfall, pay to ViiV (or ViiV's nominee) the amount of such shortfall (including any interest payable pursuant to Clause 3.10) together with all costs incurred by ViiV and/or the Licensor in carrying out the examination.
- 3.12 Without prejudice to Clause 3.11, if at any point the Licensee becomes aware of it having made an underpayment, it shall promptly, and in any event within sixty (60) days of it becoming so aware, pay to ViiV (or ViiV's nominee) the amount of such shortfall (including any interest payable pursuant to Clause 3.10).
- 3.13 All amounts payable pursuant to this Agreement shall be made subject to 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.



- 3.14 This Clause 3 shall remain in force and effect after termination or expiry of this Agreement, until the settlement or final resolution of all subsisting claims against the Licensee by each of the Licensor and ViiV.

#### 4 DEVELOPMENT AND REGISTRATION

- 4.1 As of the Effective Date and subject always to ViiV's retained rights to the Patents and Non-Territory Patents (and those of its licensees), the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation of the Products to be sold or supplied by the Licensee in the Territory under this Agreement.
- 4.2 The Licensee agrees that it will manufacture Raw Materials and Product in a manner consistent with (i) WHO pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority, defined as 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. Where such standards are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.
- 4.3 The Licensee shall, or shall procure that its Approved Affiliate (if applicable) shall, obtain from the relevant authorities in each country of 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 Products (including but not limited to Import Waivers where applicable) which are necessary to enable the Products to be sold or supplied in each country of the Territory in accordance with this Agreement. The Licensee shall file, or procure that its Approved Affiliate files, for Regulatory Approval for a Licensed Mono Product before the Relevant Regulatory Authority in each country of the Territory as soon as possible and in any event not later than 12 months from the Effective Date, in each case using the fastest approval route possible.
- 4.4 If the Licensee sells, supplies or otherwise disposes of any Product in the Territory but has not obtained the necessary approvals pursuant to Clauses 4.2 and 4.3, the Licensor shall be entitled to immediately terminate this Agreement by providing written notice to the Licensee.
- 4.5 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report on all regulatory activities regarding the Products in the Territory in relation to that Agreement Quarter. Such reporting shall be made in accordance with the Reporting Guidance issued by the Licensor and shall cover (a) the regulatory filing plan for every Product in the Territory, and (b) a list of the countries in the Territory in which applications for Regulatory Approval have been filed and/or Regulatory Approvals have been obtained for any Product. The Parties agree to confer on a quarterly basis regarding such reports and also review the filing status of Products. For avoidance of doubt, ViiV and the Licensor agree that information contained in quarterly and other such reports shall be treated as Confidential Information.
- 4.6 The Licensee will manufacture and sell the Products in accordance with all laws and regulations relevant to the manufacture and sale of the Products and in accordance with

good industry practice.

4.7 Prior to engaging in any Development Activity, the Licensee shall:

- provide the Licensor and ViiV with not less than one (1) month's written notice of its intention to carry out such Development Activity;
- meet with the Licensor and/or ViiV at such times and with such frequency as is reasonably requested by them to discuss the proposed activity; and
- comply with the Licensor's and ViiV's reasonable requests in relation to the design and conduct of such Development Activity.

**5 SUPPLY, DISTRIBUTION AND LABELLING**

- 5.1 The Licensee shall be solely responsible for providing its own clinical, promotional and commercial infrastructure to support the manufacture and sale of the Products in the Territory. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Products.
- 5.2 The Licensee shall be solely responsible for the distribution in the Territory of all Products to be sold in the Territory under this Agreement.
- 5.3 In each country of the Territory the Licensee shall, acting in compliance with all applicable laws and regulations, use its best endeavours to commercialise and maximise access to the Product(s) as soon as it has obtained Regulatory Approval for such Product(s) in the relevant country.
- 5.4 If the Licensee has Regulatory Approval for more than one Product in any country within the Territory, the Licensee shall (where applicable) offer all such Products for sale to the relevant Public Market in that country.

**6 EXCHANGE OF INFORMATION AND CONFIDENTIALITY**

- 6.1 Each Party shall hold the 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.
- 6.2 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.

- 6.3 Neither Party shall disclose any Confidential Information received from the other Party (or ViiV and/or any of their Affiliates where applicable) 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 officers, employees, agents, representatives, Affiliates, 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 6 and (ii) enforceable by the Disclosing Party (and where the Confidential Information belongs or relates to ViiV or its Affiliates, enforceable by ViiV).
- 6.4 The obligations in Clauses 6.1, 6.2 and 6.3 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; or
  - (b) information which, after its disclosure, becomes part of the public domain by publication or otherwise, except by breach of this Agreement; or
  - (c) information that a Party can demonstrate was lawfully possessed by it prior to disclosure under or in connection with this Agreement; or
  - (d) information that a Party receives from a Third Party which is not legally prohibited from disclosing such information; or
  - (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.
- 6.5 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.
- 6.6 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 ViiV or its Affiliates 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 and the Confidential Information belongs to ViiV or 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 6. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.
- 6.7 All Confidential Information shall remain the property of the Disclosing Party, except for Confidential Information disclosed under or in connection with this Agreement relating to the business or affairs of ViiV and/or any of its Affiliates, in which case such Confidential Information belongs to and shall remain the property of ViiV and/or its Affiliates. 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 (or ViiV and/or its Affiliates as applicable); and
  - (b) of the confidentiality obligations under this Agreement.
- 6.8 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.
- 6.9 Prior to submitting for written or oral publication any manuscript, abstract or the like which includes data or other information generated and provided under the terms of, or in relation to, this Agreement or relating to Products, the Licensee shall provide a copy of such publication to ViiV and shall take into account ViiV's reasonable comments in connection therewith.
- 6.10 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.
- 6.11 The obligations under this Clause 6 shall remain in full force and effect:
- (a) in perpetuity in relation to Appendix D to this Agreement and the information contained therein; and
  - (b) for the duration of this Agreement plus five (5) years in relation to all other Confidential Information.

## **7 ADVERSE EVENT REPORTING**

- 7.1 The responsibilities of the Parties for reporting of Human Safety Information related to the Product(s) to Relevant Regulatory Authorities 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.
- 7.2 Without prejudice to Clause 7.1:
- 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.
  - The Licensee undertakes that it will ensure that it will comply with all applicable laws and regulations regarding the Product(s) in the Territory including without limitation 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

- The Licensee will hold and maintain a safety database regarding the Products in the Territory, which shall contain all Human Safety Information (for marketed Product(s)) and all Serious Adverse Events (SAEs) and Pregnancy Reports (for investigational Product(s)) of which the Licensee becomes aware either directly or from another source.
- The Licensee shall provide the Licensor and ViiV with a report containing information regarding Human Safety Information which are associated with the Products and which have been received by the Licensee, from any source, including spontaneous, solicited, and clinical trial sources. Such report shall be provided annually and otherwise on reasonable request by the Licensor and/or ViiV.
- 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.
- On conclusion of any clinical research relating to the Products, the Licensee undertakes to submit to Licensor and ViiV copies of the clinical trial reports generated by or on behalf of the Licensee relating to such clinical research.
- Notwithstanding Clause 21, notices to be provided pursuant to this Clause 7 shall, in addition, also be sent to:

VP, Safety & Pharmacovigilance  
ViiV Healthcare  
980 Great West Road  
Brentford  
Middlesex, TW8 9GS.

With a copy to: oxa63163@viihealthcare.com

- ViiV and the Licensor shall have the right to monitor compliance with this Clause 7. The Licensee shall, when contacted by the Licensor or ViiV 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 7.

## 7A GOVERNANCE

- 7A.1 The Parties shall establish a steering committee (the “**Steering Committee**”) within thirty (30) days of the Effective Date composed of appropriate employees, officers, directors or representatives of each Party (“**members**” of the Steering Committee).

Appointment of each member of the Steering Committee shall require the written consent of both Parties.

- 7A.2 The Steering Committee shall be responsible for reviewing operational elements of, and compliance with, this Agreement, including but not limited to performance of the Parties' respective obligations under this Agreement.
- 7A.3 The Steering Committee shall meet at least once in every Agreement Quarter (and more frequently should the Parties deem it appropriate to do so). To be quorate, a meeting of the Steering Committee requires the attendance (whether in person or using video conferencing facilities) of at least one member appointed by each Party. A meeting must be quorate for the Steering Committee to carry out the responsibilities and duties specified in this Clause 7A.
- 7A.4 A member of the Steering Committee appointed by the Licensor shall chair each Steering Committee meeting (the "**Steering Committee Chair**").
- 7A.5 The Steering Committee Chair shall prepare and distribute a draft agenda for each Steering Committee meeting in advance.
- 7A.6 The Steering Committee Chair shall prepare and distribute draft minutes of each Steering Committee meeting within five (5) Business Days after the meeting.
- 7A.7 The Steering Committee shall approve or disapprove the draft agenda and draft minutes referenced in Clauses 7A.5 and 7A.6 in the Steering Committee meeting following their distribution. Where such a draft is disapproved, it shall be revised as necessary at the same meeting until it is approved.
- 7A.8 All decisions taken by the Steering Committee shall be by unanimous consent of members present and voting. If the Steering Committee cannot reach consensus on any given matter within 10 (ten) 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 Steering Committee Chair shall escalate the matter to the Parties' respective Chief Executive Officers or Executive Directors.
- 7A.9 Each Party shall be responsible for all travel and related costs for its appointed members to attend meetings of and participate in the Steering Committee.

## **8 NON-DIVERSION**

- 8.1 Save as provided under this Agreement (and for the avoidance of doubt, without prejudice to the Licensee's rights under the Existing Adult Licence or an Existing Paediatric Licence to sell Existing Product(s)), and to the extent that such restrictions comply with applicable law, the Licensee shall not, directly or indirectly, sell or supply:
- (a) Products or Raw Materials outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
  - (b) Raw Materials in the Territory;
  - (c) Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products outside the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent; and/or

(d) Products to the Private Market in the Territory, or to any Third Party that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products to:

- i. the Private Market in the Territory; and/or
- ii. any Third Party where the Products will be administered to any patient other than Adult Patients in the Territory, unless such sale or supply is performed in compliance with separate written agreement(s) that the Licensee may have with the Licensor and/or ViiV.

8.2 The Licensee shall ensure that packaging (whether external, intermediate or internal), data sheets and promotional materials for the Products to be sold or otherwise supplied by the Licensee under this Agreement shall carry clear statements in bold typethat:

- (a) the Products have been produced under a licence from the Medicines Patent Pool (and, where appropriate, ViiV Healthcare);
- (b) the Products are not authorised for supply to the Private Market; and
- (c) any other use is not authorised.

These obligations are further elaborated in the Trade Dress Guidance.

8.3 The Licensee agrees that:

- (a) the Products (including packaging) sold or supplied pursuant to this Agreement will be visually differentiated from Products sold or supplied by ViiV in a manner further elaborated under the Trade Dress Guidance; and
- (b) it will submit samples of the Products (including packaging) to ViiV (to such address and marked for the attention of such person as identified in the Trade Dress Guidance) for the Licensor's and ViiV's approval once trial batches are manufactured, and agrees not to manufacture exhibit batches of Products or to sell or supply Products pursuant to this Agreement until the Licensor and ViiV have approved the colour, shape, and packaging of the trial batches. Such approval will not be unreasonably withheld, delayed or conditioned. Once the Licensor and ViiV have approved the colour, shape, and packaging, of the trial batches, (i) the Licensor agrees not to make any additional requests for differentiation (except as provided in Clause 8.4 below), and (ii) the Licensee agrees only to sell and supply Products that conform to the colour, shape, and packaging of the trial batch approved by the Licensor and ViiV pursuant to this Clause 8.3. Notwithstanding the foregoing, the obligations of the Licensee in this Clause 8.3(b) shall not apply in relation to Product which is identical to Existing Product that has already been approved by ViiV for sale and supply by the Licensee under the Existing Adult Licence.

8.4 Without prejudice to Clause 8.3, the Licensee agrees to comply with such additional requirements for differentiation of the packaging of Product(s) as ViiV may request

and 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:

- 8.4.1 ViiV shall only be entitled to request such additional differentiation once during the term of this Agreement; and
- 8.4.2 the Licensee may continue to sell the Product(s) in the original packaging in each country within the Territory until such time as the variation for the differentiated packaging is approved for sale in that country.

8.5 The Licensee shall use reasonable efforts to ensure its compliance, and compliance by any Third Party to which it sells or supplies Product(s), with the terms of this Clause 8, including without limitation implementing the following measures:

- 8.5.1 The Licensee shall give written notice, prior to any sale or supply of Products, to any Third Party to which it sells or supplies Products of the restrictions contained in this Clause 8, and except where such sale or supply is made directly by the Licensee to a relevant Government, the Licensee shall obtain written undertakings from such Third Party that the Third Party will sell, supply and/or use the Product(s) in compliance with the restrictions imposed by this Agreement, including without limitation the restrictions regarding Territory and Public Market;
- 8.5.2 The Licensee shall assist the Licensor and ViiV in securing compliance by any Third Party to which it sells or supplies Products with this Clause 8 and the restrictions which it contemplates;
- 8.5.3 The Licensee shall keep true and accurate records relating to all Products supplied or sold, including but not limited to the identity of the Third Party to which each Product is sold or supplied and corresponding Product batch number(s), and permit each of ViiV and the Licensor to inspect such records on demand;
- 8.5.4 The Licensee shall maintain a quick and efficient batch trace procedure following the GS1 Global Traceability Standard so as to enable the identification and location of Products from individual batches with minimal delay;
- 8.5.5 The Licensee shall implement the batch trace procedure referred to in Clause 8.5.4 at the request of the Licensor or ViiV if at any time the Licensor or ViiV is of the opinion that any batch or batches of the Product have been, or may have been, diverted outside the Public Market or Territory; and
- 8.5.6 The Licensee shall ensure, before each sale or supply of Product(s), that the number of Units of Product(s) it intends to sell or supply is commensurate with the demand for Product(s) to treat ALHIV On Treatment in the Public Market in the relevant country of the Territory in the applicable Usage Period, as such demand is reasonably estimated by the Licensee. Where the number of Units of Product(s) 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 without limitation the restrictions regarding Territory and Public Market. In no event shall the Licensee sell or supply Product(s) for use in a country of the Territory, where such sale or supply would result in an applicable Product Access Percentage exceeding 100%.

8.6 If at any time the Licensee becomes aware that it, or a Third Party to which it has sold or supplied Product(s), has sold or supplied Product(s) for use outside the Public Market, or otherwise in breach of the terms of this Agreement, the Licensee shall:

- immediately notify the Licensor and ViiV in writing, providing details of such



breach; and

- provide to the Licensor and ViiV, within thirty (30) days of such notification, details of a mitigation plan to ensure that such sale or supply in breach of this Agreement is not repeated.

## 9 INTELLECTUAL PROPERTY

- 9.1 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.
- 9.2 The Licensee hereby grants to the Licensor and ViiV a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use any Improvement, Improvement Patent 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 sublicense. ViiV shall be entitled to grant sublicences (without further right to sublicense) under such licence only to its:
- Affiliates; and/or
  - contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercialising ViiV products.
- 9.3 The Licensee shall have no rights in relation to the conduct of any matter relating to the Patents or Non-Territory Patents, including the filing, prosecution and maintenance thereof.
- 9.4 If any suit or claim by a Third Party is instituted against the Licensor or the Licensee for patent infringement involving the Products and/or the Raw Materials, the party sued shall promptly notify the Licensor and ViiV in writing. 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.
- 9.5 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.

## 10 TRADE MARKS AND NON-PROPRIETARY NAMES

- 10.1 Subject always to Clauses 10.2 and 10.3, the Licensee, at its expense, shall be responsible for the selection, registration and maintenance of all trade marks which it employs in connection with the Products to be sold by the Licensee in the Territory under this Agreement 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 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

the trade marks owned by the Licensor, ViiV, and/or any of their Affiliates anywhere in the world for any purpose.

- 10.2 The Licensee shall not use or seek to register (or, where it is possible to do so, apply to use or register) any trade or service mark, trade dress (where applicable), symbol or device in relation to any Products or any of their packaging (whether external, intermediate or internal) or promotional material which incorporates or is identical or confusingly similar to any trade or service mark, trade dress, symbol or device used by the Licensor, ViiV and/or any of their Affiliates anywhere in the world. If the Licensor and/or ViiV become aware that the Licensee is in breach of this Clause 10.2, the Licensee shall immediately stop any such use and withdraw any such trade mark application and/or registration upon request by the Licensor and/or ViiV. This Clause shall be without prejudice to any legal rights the Licensee may have in relation to the use of a trade or service mark, trade dress, symbol or device which is identical or confusingly similar to any trade or service mark, trade dress, symbol or device 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.
- 10.3 The Licensee shall obtain the prior written approval, such approval not to be unreasonably withheld or conditioned, of the Licensor and ViiV for all trade or service marks, trade dress (where applicable), symbols or devices which the Licensee proposes to use in relation to the Products or any of their packaging (whether external, intermediate or internal) or promotional material before seeking to register any such trade marks, before offering to sell, selling or otherwise disposing of any Products, and before applying for government or relevant regulatory authorisation to do so. The Licensor and ViiV shall respond to any request for approval from the Licensee within thirty (30) days of receipt by ViiV (from the Licensor) of all the relevant documentation necessary to consider the Licensee's request, with an approval or a written statement of why the request is not being approved by ViiV. For the avoidance of doubt, the Trade Dress Guidance does not limit in any way the Licensor and/or ViiV's right to refuse to provide approval under this Clause 10.3, and the basis of ViiV's refusal to provide approval under this Clause 10.3 shall not be limited to breaches of Clauses 10.2.
- 10.4 For the avoidance of doubt, any approval provided by the Licensor and/or ViiV under Clause 10.3 is not to be interpreted as acquiescence by the Licensor and/or ViiV that any packaging and/or labelling complies with any local legal or regulatory requirements, which remains the Licensee's responsibility.

## 11 STATEMENTS AND REMITTANCES

- 11.1 At all times the Licensee shall keep, and shall require its Affiliates and any Third Party manufacturers and Third Parties making sales on its behalf, to keep, complete and accurate records for a period of five (5) years of all quantities of Raw Materials and Products manufactured, sold and/or supplied under the licences granted by this Agreement, together with that information contemplated by Clauses 11.2 and 11.3 and such information of the type and in sufficient detail to determine the calculation of royalties payable under this Agreement. The Licensor and ViiV shall each have the right (and the Licensee shall procure such right), through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the term of this Agreement and for six months after its termination or expiry; provided, however, that such examination shall be at the expense of the person exercising such right (save where such examination reveals a breach of this Agreement by the Licensee, in which case the Licensee shall pay for all costs incurred by ViiV and/or the Licensor in carrying out the examination), not take place more often than twice in any Calendar Year and shall not cover such records for more than the preceding

two Calendar Years and provided further that such accountant or like person shall report to ViiV only as to:

- (a) the accuracy of the manufacturing, sales and royalty statements of the Licensee (and/or its Affiliates and/or its Third Party manufacturers contemplated by this Agreement) in relation to such manufacture and sales;
  - (b) the appropriateness of quantities of Raw Materials and Products imported or manufactured pursuant to this Agreement by reference to what quantities of Raw Materials and Products would reasonably be required to meet demand for actual sales made and sales forecasted by the Licensee;
  - (c) verification that all sales and other supplies of Products and Raw Materials made by the Licensee have been made (i) in the Territory, except for Products and Raw Materials made outside the Territory as expressly provided for in this Agreement and (ii) otherwise in accordance with Clause 8; and
  - (d) verification that all sales and other supplies of Products and Raw Materials made by Third Party manufacturers contemplated by this Agreement have been made to the Licensee in accordance with this Agreement.
- 11.2 Within ten (10) Business Days following the end of each Calendar Month, the Licensee shall provide the Licensor with a written report of all Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Calendar Month. Such report shall be made in accordance with the Reporting Guidance issued by the Licensor and show the smallest unit, pack size, gross sales and Net Sales Value in US Dollars on a Product-by-Product, country-by-country and purchaser-by-purchaser basis. Such report shall also include copies of the relevant Public Market procurement documentation in relation to which Approved Public Market Procurement the relevant Products were supplied.
- 11.3 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a written quarterly aggregated sales report covering all Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter (each a **"Quarterly Aggregated Sales Report"**). Each Quarterly Aggregated Sales Report shall be made in accordance with the Reporting Guidance issued by the Licensor and show the smallest unit and pack size on a Product-by-Product, country-by-country and purchaser-by-purchaser basis.

## 12 SANCTIONS

- 12.1 The Parties acknowledge that a number of organisations and countries including the United Nations, the United States, the United Kingdom and the European Union have adopted sanctions legislation relating to the Territory and/or entities and individuals which or who are resident or operate in the Territory and that such sanctions are varied or amended from time to time.
- 12.2 The Licensee represents and warrants to the Licensor and ViiV that (a) neither the Licensee nor, to the knowledge of the Licensee, any Affiliate, director, officer, or employee of the Licensee, is a Sanctions Target, or (b) that it has obtained a licence or other authorisation from OFAC and/or any other relevant Sanctions Authorities in relation to such an entity which is a Sanctions Target.

12.3 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 will obtain a license or other authorization, either directly or through the Licensor, from OFAC and/or any other relevant Sanctions Authorities.

12.4 In the event that performance of this Agreement by either Party or the Head Licence would (or might) in the reasonable opinion of the Licensor and/or ViiV breach any Sanctions, any applicable export control regime or other similar applicable laws of any jurisdiction (whether or not such Sanctions, controls or laws were in existence at the date of this Agreement and whether or not there have been any other changes in circumstance from those that existed at the date of this Agreement), the Licensor shall be entitled to suspend the operation of such provisions of the Agreement (including any payment or supply provisions) which require or permit performance by either or both parties where, in the reasonable opinion of the Licensor and/or ViiV, such performance would result in a breach of any such Sanctions, controls or laws until, in the reasonable discretion of ViiV and the Licensor, such time as all necessary approvals or licences have been obtained to enable the Agreement to continue in a lawful and compliant manner and, notwithstanding any provision of this Agreement, the Licensor shall not be obliged to pay any compensation to the other party or otherwise indemnify the other party in respect of any losses or costs which that other party may suffer or incur as a result of such suspension and/or termination.

### 13 TERM AND TERMINATION

13.1 This Agreement shall be deemed to come into effect on the Effective Date and shall continue thereafter subject to the further provisions of this Clause 13.

13.2 Unless otherwise terminated, this Agreement shall expire, on a country-by-country basis, upon the expiration, lapse or invalidation of the last remaining Patent in the Territory.

13.3 Save as otherwise provided in this Agreement, if the Licensee breaches any provision of this Agreement and if such breach is material and (i) is incapable of correction; or (ii) is capable of correction but is not corrected within thirty (30) days after the Licensee receives written notice with respect to such default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the party in default.

13.3 A Breach by the Licensee of Clause 3, 5.3 or 5.4 shall be a material breach of this Agreement.

13.4 If:

- the Licensor becomes aware of an actual or threatened claim that the Licensee's use of the Patents in the Territory infringes the intellectual property rights of a

Third Party; or

- the Licensor receives notice from ViiV that ViiV's right to grant licences of the Patents is challenged,

the Licensor shall (and ViiV shall be entitled to) notify the Licensee in writing, detailing the nature of such claim or challenge. The Licensee shall, within ten (10) Business Days of receipt of such notice, and without prejudice to any of the Licensee's other obligations or liabilities under this Agreement or the Licensor's rights (including without limitation under Clause 13.5), elect to:

- (i) suspend the terms of this Licence in respect of the relevant Patent until such issue is resolved; or
- (ii) confirm in writing that it will indemnify the Licensor and ViiV against any Losses (as defined in Clause 15.5) incurred by the Licensor and/or ViiV in connection with the Licensee's continued use of such Patent pursuant to this Licence.

If the Licensee does not so notify the Licensor within ten (10) Business Days of Licensor's (or ViiV's) initial notice, the licence shall be deemed suspended pending resolution of the issue.

13.5 If:

- (a) the Licensee breaches any of the provisions of Clause 8;
- (b) it is determined that the Licensee's use of the Patents in the Territory or Non-Territory Patents outside of the Territory infringes the intellectual property rights of a Third Party;
- (c) ViiV's right to grant licences of the Patents or Non-Territory Patents expires or is terminated;
- (d) ViiV or the Licensor receives a Third Party claim or demand for royalty payments relating to sales of the Products or Raw Materials by the Licensee, unless the Licensee agrees to satisfy the claim should such a claim or demand become payable;
- (e) the legal or beneficial ownership or control of the Licensee and/or any of its Affiliates changes in such a manner as ViiV shall in its sole discretion consider significant; or
- (f) the Licensee repeatedly fails to comply with or to timely provide the Licensor with any report or statement such as those contained in Clauses 11.2 and 11.3 of this Agreement;
- (g) any time after the second (2<sup>nd</sup>) anniversary of the Effective Date and in its reasonable opinion, ViiV or the Licensor considers that the price(s) at which the Licensee offers the Product(s) for sale in the Territory do(es) not enable sufficient access to Product(s) in the Territory, as determined by ViiV and/or the Licensor in their reasonable opinion;

the Licensor may terminate this Agreement, either in whole or in relation to a particular Patent, with immediate effect by notice in writing to the Licensee.

- 13.6 The provisions of Clauses 13.5(a), 13.5(b) and 13.5(d) are without prejudice to the Licensor's or ViiV's rights to claim all damage and loss suffered by the Licensor, ViiV and/or any of their Affiliates arising out of, or in relation to, the event giving rise to termination. In respect of such damage or loss under Clauses 13.5 (a), 13.5(b) and/or 13.5(d) the Licensee hereby agrees to indemnify the Licensor and ViiV subject to the Licensor and ViiV (each of which shall be entitled to conduct the defence of such claims against them) taking reasonable account of the Licensee's input in the conduct of the claim to which such loss or damage relates. For the avoidance of doubt, the provisions of Clause 29.3 apply to any dispute between the Parties, or between ViiV and the Licensee, in relation to the indemnities given under this Clause 13.6.
- 13.7 Either Party may terminate this Agreement with immediate effect by providing a written termination notice to the other Party if, at any time, the other Party shall compound or make arrangements with its creditors or be adjudicated bankrupt or have a receiver appointed over all or any part of its assets or go into liquidation (whether voluntary or otherwise) otherwise than as part of a bona fide amalgamation or reconstruction without insolvency or suffer any insolvency event or analogous process under foreign laws.
- 13.8 Any change in the legal or beneficial ownership or control of the Licensee shall be immediately notified in writing to the Licensor and ViiV by the Licensee. For the purposes of this Clause 13.8, "control" shall mean the ability of a person, entity or corporation to ensure, whether through ownership of shares or otherwise, that the affairs of a party are conducted in accordance with the wishes of such person, entity or corporation.
- 13.9 If the Licensee fails to file, or fails to procure that its Approved Affiliate files, for Regulatory Approval in accordance with Clause 4.3, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.
- 13.10 Unless notice to the contrary is given by ViiV, this Agreement shall terminate immediately in the event that the Head Licence is terminated or expires. This Agreement shall be converted into a licence between ViiV and the Licensee on the same terms and provisions agreed in this Agreement, provided that the Licensee is not in breach of this Agreement and that ViiV has notified both the Licensor and Licensee of such conversion.
- 13.11 The Licensee may terminate this Agreement at any time by providing thirty (30) days' written notice to the Licensor.
- 13.12 If the Licensee's Existing Adult Licence is terminated on grounds other than expiry or lapse of the applicable patents, this Agreement shall automatically terminate.

#### **14 RIGHTS AND DUTIES UPON TERMINATION OR EXPIRY**

- 14.1 Upon termination or expiry of this Agreement in accordance with Clauses 13.5(e), 13.7, 13.9, 13.10 and/or 13.12, the Licensee shall immediately notify the Licensor and ViiV of the amount of Product the Licensee then has available to it and, provided that such amount is, in the opinion of ViiV, reasonable in all the circumstances, the Licensee shall be permitted to sell that amount of Product in the Territory. This provision shall only apply to the extent that such termination would deprive the Licensee of legal rights with respect to Product and Raw Materials.

- 14.2 Termination or expiry of this Agreement shall not affect those provisions of this Agreement which are expressly or by implication intended to survive the termination or expiration of this Agreement, in particular, but without limitation, Clause 3 (subject to Clause 3.14), Clauses 6 (subject to Clause 6.11), 8.6, 9.2-9.5, 11.1, 15.5, 15.6, 15.7, 18, 21, 29 and the relevant provisions of this Clause 14. In addition, any other provisions required to interpret and enforce the parties' rights and obligations under this Agreement shall also survive, but only to the extent that such survival is required for the full observation and performance of this Agreement by the Parties. Expiration or termination of this Agreement shall not affect any rights or remedies, 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.
- 14.3 Termination of this Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available in law or equity and shall be without prejudice to any rights that any person may have pursuant to this Agreement for antecedent breaches.
- 14.4 Subject to Clause 2.3, upon termination or expiry of this Agreement, the Licensee shall cease all exploitation of the Patents in relation to the Territory.
- 14.5 Upon termination or expiry of this Agreement, all outstanding sums due from the Licensee to ViiV under this Agreement shall become immediately payable to ViiV.
- 14.6 Upon termination or expiry of this Agreement, or at any time upon the request (whichever is the earliest), the receiving Party shall cease all use of Confidential Information disclosed to it under or in connection with this Agreement, and shall, at the disclosing Party's cost and direction, promptly return to the disclosing Party all such Confidential Information (including all copies thereof), which is in tangible form (including electronic imaging), or destroy such Confidential Information and certify that all such Confidential Information has been destroyed, except that the Receiving Party shall be permitted to retain one (1) copy of the Confidential Information so that any continuing obligations may be determined.

## 15 WARRANTIES AND INDEMNITIES

- 15.1 Each of the Parties warrants that, to the best of its knowledge and belief:
- (a) it has power to execute and deliver this Agreement and to perform its obligations under it and has taken all action necessary to authorise such execution and delivery and the performance of such obligations; and
  - (b) this Agreement constitutes legal, valid and binding obligations of that Party in accordance with its terms.
- 15.2 Nothing in this Agreement shall be construed as a warranty that (a) the information set out in Appendix C accurately reflects the status of ViiV's patents and patent applications relating to the Compounds and/or Products, (b) any of the Patents or Non-Territory Patents are valid or enforceable or (c) their exercise does not infringe any patent rights of any Third Parties.
- 15.3 The Licensee acknowledges that, in entering into this Agreement, the Licensee has independently evaluated any information supplied by the Licensor and ViiV (including, but not limited to, such information related to the Products), 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.

- 15.4 The Licensee acknowledges that the Licensor and ViiV do not in any way endorse the use of any Products sold or manufactured by the Licensee containing the Compounds or other active ingredient (including without limitation that used in the Licensed Combination Products), whether as single compounds or in combination with each other, or whether in combination with other compounds.
- 15.5 The Licensee hereby agrees to indemnify the Licensor, ViiV, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgments, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("**Losses**"), that arise in connection with (i) the Licensee's breach of this Agreement; or (ii) the Licensee's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Products manufactured by or on behalf of the Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Clause shall not apply to the extent such Losses arise out of negligence or wilful misconduct by ViiV, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. ViiV shall, or shall procure that the Indemnified Person shall, provide the Licensee with prompt written notice of such claims. Subject to Clauses 9.4 and 13.6, 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.
- 15.6 Clause 15.5 may be enforced by each Indemnified Person against the Licensee under the Contracts (Rights of Third Parties) Act 1999.
- 15.7 Immediately upon the first administration of a Product to a human in accordance with 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 Raw Materials and 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 and ViiV upon request from either therefor and shall monitor such policy on a monthly basis to ensure that any cover is revised to take account of any currency fluctuations.

## 16 FORCE MAJEURE

If the performance of any part of this Agreement by any Party, or of any obligation under this Agreement (other than those provisions which in any respect concern the payment under any indemnity or otherwise under this Agreement) is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform (an "**Event of Force Majeure**"), unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable endeavours to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are



removed. If the Event of Force Majeure continues for a period of more than six (6) months, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party. Without limitation as to the possible types of Event of Force Majeure, an epidemic (excluding HIV epidemics), pandemic (excluding HIV pandemics), government collapse, government-imposed isolation or government-imposed quarantine shall be capable of constituting an Event of Force Majeure, provided that the elements of the definition of that term specified in this Clause 16 are satisfied.

#### **17 RIGHT OF SET OFF**

- 17.1 All amounts due by the Licensee under this Agreement shall be paid in full in US Dollars or such other currency as may be agreed in full without any set-off or counterclaim and free and clear of all taxes, deductions, withholdings and other charges of whatever nature other than as required by law and the Licensee shall not be entitled to assert any set off or counterclaim in order to justify withholding payment of any such amount in whole or in part.
- 17.2 The Licensor and ViiV shall be entitled at any time, without notice to the Licensee, to set off any liability of the Licensor or ViiV to the Licensee (for example, in connection with the purchase of stock in hand and/or Raw Materials pursuant to Clause 14), against any liability of the Licensee to the Licensor or ViiV and may for such purpose convert or exchange any currency. Any exercise by the Licensor or ViiV of their rights under this Clause 17.2 shall be without prejudice to any other rights or remedies available to the Licensor or ViiV under this Agreement.

#### **18 THIRD PARTY RIGHTS**

- 18.1 Except for ViiV and ViiV's Affiliates or as otherwise expressly provided under this Agreement, a person who is not a party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.
- 18.2 ViiV and/or any of its Affiliates have the right under the Contracts (Rights of Third Parties) Act 1999 to enforce and rely on the terms of this Agreement. The Licensee expressly agrees that ViiV and/or any of their Affiliates shall be entitled to enforce any of the provisions of this Agreement as if they were named as a party to this Agreement in place of the Licensor.
- 18.3 The rights of the Licensor under this Agreement shall be applicable to ViiV to the same extent as for the Licensor and the Licensor shall exercise such rights on behalf of ViiV if so requested by ViiV.

#### **19 SEVERABILITY**

- 19.1 In the event that any portion of this Agreement is or is held by any court or tribunal of competent jurisdiction to be illegal, void, unenforceable or ineffective, the remaining portions hereof shall remain in full force and effect.
- 19.2 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to the minimum extent necessary to procure conformity with such statute or rule of law.

- 19.3 In the event that the terms and conditions of this Agreement are materially altered as a result of Clauses 19.1 or 19.2, the Parties and ViiV will seek to renegotiate the terms and conditions of this Agreement to resolve any inequities. If the Parties cannot reach an agreement, they agree to submit their dispute to mediation in accordance with Clause 29.3 of this Agreement. In the event that the dispute remains unresolved, either Party may terminate this Agreement by providing a written termination notice to the other Party.

## 20 ENTIRE AGREEMENT

- 20.1 This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous writings and understandings between the parties relating to the transactions contemplated by this Agreement.
- 20.2 Subject to Clause 20.3, each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of any other party before the date of this Agreement. Each Party waives all rights and remedies which, but for this Clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 20.3 Nothing in this Clause 20 limits or excludes any liability for fraud.

## 21 NOTICES

- 21.1 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 21.3.
- 21.2 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;
- 21.3 Notices shall be sent to:
- (a) the Licensor at:  
  
Rue de Varembe 7  
CH-1202 Geneva  
Switzerland,  
  
marked for the attention of General Counsel,
  - (b) the Licensee at:  
  
SPARC, Tandalja, Vadodara - 390020 and corporate office at  
Sun House, 201 B/1, Western Express Highway, Goregaon  
East, Mumbai - 400 063, India,  
  
marked for the attention of Head of Legal,
  - (c) to ViiV at:

ViiV Healthcare,  
980 Great West Road,  
Brentford,  
Middlesex TW8 9GS,  
UK,

marked for the attention of the Head of International,

copied to the Head of Legal for International, at ViiV Healthcare, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom..

21.4 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;
- (b) if no date is so specified, three (3) Business Days after the notice is deemed to be received

21.5 All references to time shall be to the local time at the place of deemed receipt.

21.6 The provisions of this Clause 21 shall not apply to notices given in legal proceedings or arbitration.

21.7 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 ASSIGNMENT AND SUB-CONTRACTING

22.1 Neither this Agreement nor any interest arising out of or under this Agreement shall be assignable by the Licensor or the Licensee.

22.2 Save as expressly set out in Clauses 2.1, 2.2 and 2.5, and subject to those Clauses, neither the Licensor nor the Licensee shall be entitled to subcontract any of its rights or obligations under this Agreement.

## 23 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.

## 24 COSTS

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

## 25 AMENDMENTS

The Parties agree that any amendment of this Agreement shall not be effective unless set out in writing, expressed to amend this Agreement and signed by authorised

representatives of: (a) each of the Parties; and (b) ViiV. Notwithstanding the aforesaid, the Licensor (pursuant to approval from ViiV) shall have the right to amend Appendix C of this Agreement at any time without the Licensee's consent in order to include additional patents in Appendix C.

## **26 WAIVER**

The rights of each Party and ViiV under this Agreement: (a) may be exercised as often as necessary; (b) are cumulative and not exclusive of rights or 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.

## **27 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 ViiV as the agent of either Party).

## **28 EXECUTION IN COUNTERPARTS**

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

## **29 GOVERNING LAW AND JURISDICTION**

- 29.1 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.
- 29.2 Subject to Clause 29.3, the English courts shall 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.
- 29.3 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 sixty (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.
- 29.4 The Parties waive any objection to the English courts on the grounds that they are an inconvenient or inappropriate forum to settle any such dispute.
- 29.5 Without prejudice to the foregoing in relation to the Licensee, nothing in this Clause 29 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 Licensor and the Licensee hereby agree.

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

## **APPENDIX A**

### **SPECIFIC CHEMICAL NAME OF THE COMPOUNDS**

DTG Compound (dolutegravir): (4*R*,9*aS*)-5-hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9*a*,10-hexahydro-2*H*-1-oxa-4*a*,8*a*-diazanthracene-7-carboxylic acid 2,4-difluorobenzylamide

ABC Compound (abacavir): (1*S*,4*R*)-cis-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1)

**APPENDIX B**

**LIST OF COUNTRIES FORMING THE TERRITORY**

1. Azerbaijan
2. Belarus
3. Kazakhstan
4. Malaysia

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**APPENDIX C**  
**THE PATENTS**

**Appendix C, Part A: ABC Patents:**

| Country    | Application Number | Application Date | Patent Number |
|------------|--------------------|------------------|---------------|
| Belarus    | EA001809           | 29-Jul-2011      | EA001809      |
|            | 000626             | 21-Jul-2011      | 000626        |
| Kazakhstan | EA1999.00944       | 14-May-1998      | EA001809      |
|            | EA001809           | 12 Sep 2017      | EA001809      |
| Malaysia   | PI99000389         | 04-Feb-1999      | MY-121043-A   |
|            | PI98004673         | 13-Oct-1998      | MY-127470-A   |

**Appendix C, Part B: DTG Patents:**

| Country    | Application Number | Application Date | Patent Number |
|------------|--------------------|------------------|---------------|
| Azerbaijan | 200702080          | 28-Apr-2006      | 14162         |
|            | 014162             | 25-Feb-2016      | 014162        |
|            | 201290583          | 24-Jan-2011      | EA025176      |
|            | EA025176           | 31 May 2017      | EA025176      |
|            | 201892277          | 07-Nov-2018      |               |
| Belarus    | 200702080          | 28-Apr-2006      | 14162         |
|            | 014162             | 19-Jan-2016      | 014162        |
|            | 201290583          | 24-Jan-2011      | EA025176      |
|            | 201892277          | 07-Nov-2018      |               |
| Kazakhstan | 200702080          | 28-Apr-2006      | 14162         |
|            | 014162             | 03-Aug-2015      | EA/KZ014162   |
|            | 201290583          | 24-Jan-2011      | EA025176      |
|            | 201892277          | 07-Nov-2018      |               |
|            | 025176             | 30 May 2017      | 025176        |
| Malaysia   | PI20071883         | 31-Oct-2007      | MY-149571-A   |
|            | PI2012003346       | 24-Jan-2011      |               |

**APPENDIX D**  
**ROYALTY RATES**  
**CONFIDENTIAL**

**Royalty fee A**  
**Royalty fee B**  
**Royalty fee C**





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**SIGNATORIES**

**For and on behalf of THE MEDICINES PATENT POOL FOUNDATION**

Signature:

*Charles Gore*

Name (Printed):

Charles Gore

Position:

Executive Director

Date:

05/11/2021

**For and on behalf of SUN PHARMACEUTICAL INDUSTRIES LIMITED**

Signature:

*Aalok Shanghvi*

Name (Printed):

Aalok Shanghvi

Position:

EVP, Emerging Markets

Date:

02 November 2021