

## LICENCE AGREEMENT

**THIS LICENCE AGREEMENT** (this "**Agreement**") is made as of 16 June 2014 (the "**Effective Date**") and is amended and restated on 29 April 2016, and re-amended and restated on 13 November 2018 (the "**Effective Amendment 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) **Cipla Limited**, a company incorporated under the laws of India, and having its registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, Maharashtra, India (the "**Licensee**"),

with Licensor and 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 patients in resource-limited jurisdictions), 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 D.
- 1.3 "**Adult Patients**" means patients of age eighteen years or more and who are not Child Patients.
- 1.4 "**Adverse Event**" or "**AE**" means any untoward medical occurrence in a patient or clinical trial subject administered a Product and 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. For a marketed Product, this can also include failure to produce expected benefits (i.e. lack of efficacy), and adverse events associated with circumstances of overdose, medication errors, abuse or misuse. 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.

- 1.5 “**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.
- 1.6 “**Agreement Quarter**” shall mean any period of three months ending on the last day of March or June or September or December.
- 1.6A “**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 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.
- 1.7 “**Approval Date**” shall mean:
- (a) in relation to the Licensed Mono Product, the date on which the DTG Compound first receives the relevant regulatory approval(s), and
  - (b) in relation to a Licensed Combination Product, the date on which that Licensed Combination Product first receives the relevant regulatory approval(s),
- in each case from a Relevant Regulatory Authority.
- 1.8 “**Approved Public Market Procurement**” shall have the meaning given to it in Clause 2.4.
- 1.9 “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.
- 1.10 “**Child Patients**” shall have the meaning given in the Paediatric Licence.
- 1.11 “**Compounds**” shall mean the DTG Compound and the ABC Compound.
- 1.12 “**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 party 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.
- 1.13 “**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 Licence Agreement.
- 1.14 “**DTG Compound**” shall mean the chemical compound known generically as dolutegravir, whose more specific chemical name is set out in Appendix A.
- 1.15 “**DTG Patents**” shall mean those patents and patent applications owned by ViiV as are set out in Part B of Appendix D.
- 1.16 “**Effective Date**” shall mean the date of this Licence Agreement.
- 1.17 “**Event of Force Majeure**” has the meaning given in Clause 16.
- 1.18 “**FDA**” means the United States Food and Drug Administration.
- 1.19 “**First US Application**” means, in respect of a Product, the first application made by the Licensee to the FDA during the NCE Exclusivity Period for tentative approval of either an Abbreviated New Drug Application or a New Drug Application, in relation to that Product in accordance with the terms and conditions of this Agreement.
- 1.20 “**Head Licence**” means the Licensor’s agreement with ViiV dated 31 March 2014 (as subsequently amended and restated) under which its right to licence the Patents is derived.
- 1.21 “**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.
- 1.22 “**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 party otherwise has the right to grant licences, now or in the future.
- 1.23 “**Jurisdiction-Specific Packaging**” means the packaging of a Product which is specific to a particular jurisdiction.
- 1.24 “**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 2.9) 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.
- 1.25 “**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.
- 1.26 “**Listed Patents**” means US Patent No. 8,129,385 and any other patents listed in the



FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the *Orange Book*) or its online database for the TIVICAY NDA.

- 1.27 “**NCE Exclusivity Period**” means the period described in section 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) applicable to and dating from the first approval of the TIVICAY NDA, including any applicable extension of paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the U.S Food, Drugs and Cosmetics Act.
- 1.28 “**Net Sales Value**” shall mean gross sale price of the Licensee or its Affiliates (or any person acting on their behalf) to their customers multiplied by the number of units sold less value of the sales taxes, returned/rejected products, clearing and forwarding, freight and insurance charges.
- 1.29 “**Non-Territory Patents**” shall mean:
- 1.29.1 in relation to those jurisdictions falling outside of the Territory but being a jurisdiction listed in Appendix C (low and middle income jurisdictions), those patents owned by ViiV as are set out in Appendix E; and
- 1.29.2 in relation to those jurisdictions falling outside of the Territory but not being a jurisdiction listed in Appendix C (low and middle income jurisdictions), any patents equivalent to those specified in Clause 1.29.1 owned by ViiV or its Affiliates which have been granted in such jurisdictions.
- 1.30 “**OFAC**” has the meaning given in the definition of “Sanctions Target” in this Agreement;
- 1.31 “**Paediatric Licence**” shall mean the licence agreement entered into between ViiV and the Licensor for the manufacture and supply of products containing the DTG Compound for use in antiretroviral therapy for HIV / AIDS in child patients and dated on or around the date of the Head Licence.
- 1.32 “**Patents**” shall mean the ABC Patents and the DTG Patents.
- 1.33 “**Paragraph III Certification**” means a certification described in section 505(j)(2)(A)(vii)(III) and 505(b)(2)(A)(iii) of the U.S Food, Drugs and Cosmetics Act.
- 1.34 “**Paragraph IV Certification**” means a certification described in section 505(j)(2)(A)(vii)(IV) and 505(b)(2)(A)(iv) of the U.S Food, Drugs and Cosmetics Act.
- 1.35 “**Permitted Market**” shall mean (i) in respect of the Royalty-Free Countries, the Public Market and the Private Market; and (ii) in respect of the Royalty Countries, the Public Market only.
- 1.36 “**Pregnancy Report**” means a report of pregnancy in a patient or trial subject to whom a Product has been administered or a report of a pregnancy where the father is a patient or trial subject to whom a Product has been administered.
- 1.37 “**Private Market**” shall mean any entity that is not in the Public Market.
- 1.38 “**Products**” shall mean the Licensed Mono Products and each Licensed Combination Product.



- 1.39 **“Public Market”** shall mean (a) the following organisations to the extent that they are not for profit organisations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and agencies based outside of an applicable country to the extent that they are supporting implementation locally in an applicable country, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) of this Clause.
- 1.40 **“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.
- 1.41 **“Relevant ANDA”** means an Abbreviated New Drug Application in relation to a Product submitted to the FDA by the Licensee under section 505(j) of the U.S Food, Drugs and Cosmetics Act during the NCE Exclusivity Period which is a First US Application for that Product.
- 1.42 **“Relevant NDA”** means a New Drug Application in relation to a Product submitted to the FDA by the Licensee under section 505(b)(2) of the U.S Food, Drugs and Cosmetics Act during the NCE Exclusivity Period which is a First US Application for that Product.
- 1.43 **“Relevant Regulatory Authority”** means (i) in relation to a particular jurisdiction in the Territory, the local regulatory authority having jurisdiction over the manufacture and/or commercialisation of the Products in that jurisdiction, or (ii) WHO pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).
- 1.43A **“Reporting Guidance”** means the guidance on reporting (as required in Sections 4.5 and 11.2 of this Agreement on, inter alia, development timelines, regulatory activities, manufacturing and sales of Raw Materials and Products, that will be issued by Licensor to Licensee, and as may be amended from time to time.
- 1.44 **“Royalty Countries”** means those countries as identified in Appendix B as “Royalty Countries”.
- 1.44A **“Royalty Countries Payment Guidance”** means guidance on the payment of royalties under Clause 3.3, issued by the Licensor and approved by ViiV, as amended from time to time.
- 1.45 **“Royalty-Free Countries”** means those countries as identified in Appendix B as “Royalty-Free Countries”.
- 1.46 **“Sanctions”** shall have the meaning given in the definition of “Sanctions Target”.



- 1.47 **“Sanctions Authorities”** shall have the meaning given in the definition of “Sanctions Target”.
- 1.48 **“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 License, includes without limitation Cuba, Iran, Dem. Rep. Korea, Sudan 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.
- 1.49 **Selective Waiver Letter**” means a letter submitted by ViiV to the FDA pursuant to Clause 4A which authorizes the FDA to receive, review and tentatively approve a Relevant NDA or Relevant ANDA submitted by the Licensee during the NCE Exclusivity Period.
- 1.50 **“Territory”** shall mean all those countries as are set out in Appendix B (comprising the Royalty Countries and Royalty-Free Countries), as may be amended from time to time in accordance with Clause 25.
- 1.51 **“Third Party(ies)”** shall mean any party other than a party to this Agreement.
- 1.52 **“TIVICAY NDA”** means New Drug Application number 204790 for TIVICAY (dolutegravir) tablets 50 mg as approved by the FDA on August 12, 2013.
- 1.52A **“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.
- 1.53 **“ViiV”** means ViiV Healthcare Company and/or its Affiliates, as the context admits.
- 1.54 **“WHO”** means the World Health Organization.
- 1.55 **“WIPO Mediation Rules”** means the mediation rules adopted by the World Intellectual Property Organization from time to time.
- 1.56 References to “this Agreement” shall mean this licence agreement and shall include the Appendices.
- 1.57 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.
- 1.58 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.





- 1.59 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.
- 1.60 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.

## 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 (in relation to the Royalty Countries), non-sublicensable, non-transferable licence under the Patents to:
- (a) manufacture, have manufactured, use, sell, supply, import or export in the Territory Raw Materials for use in the manufacture of Products to be supplied to the Permitted Markets in the Territory solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients; and
  - (b) manufacture, have manufactured, use, sell, have sold by an Approved Affiliate to the Permitted Markets, supply to the Permitted Markets, 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 (in relation to the Royalty Countries), 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 Permitted Markets, supply to the Permitted Markets, 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, sell, supply, 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 Permitted Markets in the Territory and solely for use in antiretroviral therapy for HIV / AIDS in Adult Patients; and
  - (c) manufacture, have manufactured, use, sell, supply, import or export outside the Territory Raw Materials for the manufacture of Products outside the Territory exclusively for use, sale to the Permitted Markets, supply to the Permitted Markets, 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 Approval pursuant to Clause 2.4, (iv) have packaging that specifies that products are not authorised for supply to the Private Market pursuant to Clause 8.2 or (v) provide the statements contemplated by Clause 11.2, 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 may supply Product pursuant to and in accordance with this Agreement in the Public Market of any jurisdiction within the Royalty Countries pursuant to a procurement process of any Public Market entity, only if the supply contemplated by that procurement is approved in writing by the Licensor, with such approval to be deemed provided after five (5) Business Days after receipt of the request for approval, unless the Licensor has expressly indicated that approval is not granted (an “**Approved Public Market Procurement**”).
- 2.5 Other than as set 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 avoidance of doubt, it shall not be a breach of this Agreement for 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 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).
- 2.5B 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.
- 2.6 The Licensee shall, acting in compliance with all applicable laws and regulations, use its best endeavours to maximise access to the Products in the Territory for administration to Adult Patients.
- 2.7 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 Clause 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 Royalty Countries or (ii) any patient other than a Adult Patient.
- 2.8 This Agreement is without prejudice to any other rights and/or obligations that Licensee may have pursuant to separate written agreement(s) with ViiV and/or MPPF (signed by the relevant parties) relating to Patents and/or Non-Territory Patents. Notwithstanding anything contained in this Agreement, activities of Licensee performed in compliance with such other agreement(s) shall not constitute a breach of this Agreement.
- 2.9 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.
- 2.10 Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or offer for sale a Product in a jurisdiction of the Territory prior to the relevant Approval Date for that Product for that jurisdiction.
- 2.11 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 in relation to the Royalty Countries, the Licensee agrees to pay, subject to Clauses 3.1A, 3.2 and 3.3, the following royalties to the Licensor (acting on ViiV's behalf) in accordance with the following royalty tiers, which have been determined according to the per capita gross domestic product of each Royalty Country:
- 3.1.1 Tier 1: Five per cent (5%) of the Net Sales Value of all Products supplied in each Tier 1 country;
  - 3.1.2 Tier 2: Seven and a half percent (7.5%) of the Net Sales Value of all Products supplied in each Tier 2 country; and
  - 3.1.3 Tier 3: ten percent (10%) of the Net Sales Value of all Products supplied in each Tier 3 country.

The designated tier for each Royalty Country is set out in Appendix B, as may be amended from time to time in accordance with Clause 25. For the avoidance of doubt, royalties shall be paid in relation to the DTG Patents only, and not the ABC Patents.



- 3.1A In the event that a transaction contemplated by this Clause 3 is not conducted on an arm's length basis, then for the purposes of calculating such royalties for such a transaction, the Net Sales Value shall be deemed to be what it would have been had the transaction been conducted on an arm's length basis (irrespective of the actual Net Sales Value for that transaction).
- 3.2 Royalty payments shall be paid to Licensor on a Product-by-Product and country-by-country basis starting on the date of first sale of a Product in the relevant Royalty Country and continuing until the expiration of the last-to-expire patent (excluding the ABC Patents) containing a valid claim covering the manufacture, use, import, offer for sale or sale of DTG Compound and/or the Product in such country. The Licensor shall provide the Licensee the Royalty Countries Payment Guidance.
- 3.3 For the purpose of calculating the Net Sales Value of Licensed Combination Products, if the Licensee sells Licensed Combination Products in a particular Royalty Country, the Net Sales Value of such Licensed Combination Product in such country for the purpose of determining the royalty due to Licensor will be calculated by multiplying actual Net Sales Value by a value calculated as follows:
- 3.3.1 the fraction  $A/(A+B)$ , where A is the mean average invoice price invoiced by the Licensee in the relevant Agreement Quarter in respect of Licensed Mono Product if sold in such country in the relevant Agreement Quarter, and B is the total invoice price of products containing the other active pharmaceutical ingredient(s) (calculated as a mean average in relation to each such other active pharmaceutical ingredient product(s) in the relevant Agreement Quarter) in the combination if sold separately by the Licensee in such country;
- 3.3.2 if, on a country-by-country basis, and Agreement Quarter-by-Agreement Quarter basis, such other active pharmaceutical ingredient or ingredients in the Licensed Combination Product are not sold separately in such country in the relevant Agreement Quarter by the Licensee, but the Licensed Mono Product is sold separately in such country in the relevant Agreement Quarter by the Licensee, the Net Sales Value for the purpose of determining royalties due to Licensor for the Licensed Combination Product will be calculated by multiplying the actual Net Sales Value of such Licensed Combination Product by the fraction  $A/C$ , where A is the mean average invoice price invoiced by the Licensee in the relevant Agreement Quarter in respect of Licensed Mono Product if sold in such country in the relevant Agreement Quarter, and C is the mean average invoice price of the Licensed Combination Product invoiced by the Licensee in the relevant Agreement Quarter; or
- 3.3.3 if, on a country-by-country basis, and Agreement Quarter-by-Agreement Quarter basis, Licensed Mono Product is not sold by the Licensee in such country, the Net Sales Value for the purposes of determining royalties due to Licensor for the Licensed Combination Product will be  $D/(D+E)$ , where D is the fair market value of the portion of the Licensed Combination Products that contains the DTG Compound, and E is the fair market value of the portion of the Licensed Combination Product containing the other active pharmaceutical ingredient(s) or delivery device included in such Licensed Combination Product, as such fair



market values are provided (where applicable) in a statement by the Licensor on an annual basis and based on the average generic cost of the components of the Products.

- 3.4 When providing the information specified in Clause 11.2, the Licensee shall also provide to Licensor (or its nominee) its calculation of royalties payable to Licensor pursuant to this Clause 3 in relation to the relevant Agreement Quarter.
- 3.5 The Licensee shall, on or before the sixtieth calendar day following the end of each Agreement Quarter, pay to ViiV (or to such other person as ViiV may nominate in writing) in US dollars, by way of telegraphic transfer to such bank account as Licensor shall nominate, an amount equal to the royalties payable pursuant to this Agreement for the immediately preceding Agreement Quarter. All foreign currencies shall be converted into US dollars at the exchange rate published in the Financial Times in London on the last Business Day of the relevant Agreement Quarter.
- 3.6 In the event of any delay in the Licensee paying to ViiV any sum due under this Clause 3 on the relevant due date, the Licensee shall pay to ViiV 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 as reported by The Financial Times (London edition) 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.
- 3.7 If an inspection pursuant to Clause 11 reveals an underpayment by Licensee, Licensee shall promptly, and in any event within 60 days of the determination of such shortfall, pay to ViiV the amount of such shortfall (including any interest payable pursuant to Clause 3.6 hereof) together with all costs incurred by ViiV and/or Licensor in carrying out the inspection.
- 3.8 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, as 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.

#### **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 that 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 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 ("SRA"), defined as regulatory authorities which are members, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time. Where such approvals 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 will obtain from the relevant authorities in the Territory and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorisations relating to the importation, manufacture and sale of the Products which are necessary to enable the Products to be sold or supplied in the Territory in accordance with this Agreement. Licensee shall file for regulatory approval before at least one Relevant Regulatory Authority (including, but not limited to the WHO pre-qualification programme) not later than 30 months from the Effective Date in respect to the DTG Compound and not later than 36 months from the Effective Date in respect to at least one of the Products. Licensee shall also, upon Licensor's reasonable request, file for regulatory approval before the Relevant Regulatory Authority for any subsequent Products within a reasonable time.
- 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 the status of development of the Compound and any regulatory filing regarding the Products in relation to that Agreement Quarter. Such reporting shall be made in accordance with the Reporting Guidance issued by the Licensor and should cover (a) Products in its development pipeline, (b) status of development of each Product in development, (c) regulatory filing plan for each Product, and (d) a list of countries for which such regulatory approvals or authorizations have been filed and/or obtained for any Product. The Parties agree to confer on a quarterly basis regarding such reports and also review development and 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, Licensee shall:
- 4.7.1 provide Licensor and ViiV with not less than one (1) month written notice of its intention to carry out such Development Activity;
- 4.7.2 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
- 4.7.3 comply with the Licensor's and ViiV's reasonable requests in relation to the design and conduct of such Development Activity.

#### **4A SELECTIVE WAIVER LETTERS**

- 4A.1 The Parties acknowledge that, in order for the Licensee to be able to supply a Product to applicable countries in the Territory under the United States President's Emergency Plan for AIDS Relief ("PEPFAR"), it may be necessary for the Licensee to obtain tentative approval for that Product from the FDA under section 505(b)(2) or 505(j) of



the U.S. Food, Drugs and Cosmetics Act (the “Act”).

4A.2 In the event that the Licensee wishes to obtain tentative approval from the FDA for a Product in circumstances where:

- (i) the purpose of obtaining such tentative approval from the FDA is solely to enable the Licensee to supply that Product to countries in the Territory under PEPFAR;
- (ii) the FDA’s tentative approval is sought in respect of a Relevant ANDA or Relevant NDA (as applicable);
- (iii) the NCE Exclusivity Period has not expired; and
- (iv) the Licensee has complied with, and continues to comply with, the requirements of this Clause 4A,

the Licensor shall, following a written request to do so from the Licensee, procure that ViiV submits to the FDA a Selective Waiver Letter in respect of the Licensee’s Relevant ANDA or Relevant NDA (as applicable). The Licensee shall provide to the Licensor such information in respect of its Relevant ANDA or Relevant NDA as the Licensor or ViiV may reasonably require in connection with the preparation of such a Selective Waiver Letter and/or in order to assess the Licensee’s compliance with the requirements of this Clause 4A.

4A.3 For the avoidance of doubt, each of the Licensor and the Licensee acknowledge that:

- (i) the form and content of any Selective Waiver Letter shall be determined by ViiV in its sole discretion, provided that the form and content of such Selective Waiver Letter is consistent with the terms of this Clause 4A;
- (ii) any Selective Waiver Letter will be submitted by ViiV to the FDA and a copy provided to the Licensor following submission; and
- (iii) ViiV shall remain entitled at any time to revoke a Selective Waiver Letter and/or any consent or waiver contained therein if the Licensee fails to comply with any of the requirements of this Clause 4A and/or if the Licensee submits a Paragraph IV Certification in relation to any Relevant ANDA or Relevant NDA.

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

4A.4 The Licensee undertakes, in respect of any Relevant ANDA or Relevant NDA for which a Selective Waiver Letter is requested, to:

- (i) identify TIVICAY® NDA 204790 as the or a (as applicable) “listed drug” (as that term is used and defined in section 505 of the Act and related regulations) in such Relevant ANDA or Relevant NDA;



- (ii) include with Relevant ANDA or Relevant NDA (as applicable) a Paragraph III Certification in respect of each Listed Patent; and
- (iii) maintain that Paragraph III Certification until the expiration of the period described in sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Act, as extended by any applicable paediatric exclusivity describe in section 505A(c)(1)(A)(i)(I) of the Act; and
- (iv) submit any Relevant ANDA or Relevant NDA (as applicable) within 90 days of the date of the Selective Waiver Letter.

4A.5 Nothing in this Agreement or any Selective Waiver Letter that may be issued by ViiV pursuant to this Clause 4A shall:

- (i) be read, interpreted or otherwise considered to be a waiver of any other rights which extend to ViiV under section 505 of the Act, including (without limitation) the right to receive notice of any Paragraph IV Certification, to bring suit within 45 days of receiving such a notice and, to prevent the approval of an application during the applicable periods set forth in sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Act, as extended by any applicable paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the Act (the Licensee acknowledges that nothing in this Agreement or any Selective Waiver Letter shall relieve the Licensee of any obligations in respect of a Paragraph IV Certification that may be imposed by the Act); or
- (ii) authorise the Licensee to obtain final approval for a Relevant ANDA or Relevant NDA prior the expiration of the NCE Exclusivity Period and any other applicable periods set forth in sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Act, as extended by any applicable paediatric exclusivity described in section 505A(c)(1)(A)(i)(I) of the Act; or
- (iii) authorise the Licensee to do (or permit any Third Party to do) anything that infringes a Non-Territory Patent or Listed Patent.

4A.6 The provisions of this Clause 4A apply solely in respect of a Relevant ANDA or Relevant NDA submitted by the Licensee for the purposes specified in Clause 4A.1 and, for the avoidance of doubt and without limitation, the provisions of this Clause 4A do not apply in respect of:

- (i) any Abbreviated New Drug Application or New Drug Application submitted to the FDA:
  - (a) that is not, in respect of the Product concerned, a First US Application; and/or
  - (b) in connection with which the Licensee submits a Paragraph IV Certification; or
- (ii) any application for a marketing authorisation or equivalent licence in respect of any product (including any Product) in any country other than the United States.





- 4A.7 In the event of breach by the Licensee of this Clause 4A, the Licensor shall have the right to immediately terminate this Agreement, without notice and with immediate effect.

## **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.

## **6 EXCHANGE OF INFORMATION AND CONFIDENTIALITY**

- 6.1 During the term of this Agreement and for five years thereafter, the Parties shall not, use, reveal or disclose to any Third Party, or to any of its Affiliates, save for those of its Affiliates who need to know such information to exercise the Party's rights under this Agreement, any Confidential Information received from the other Party or ViiV and/or any of their Affiliates or otherwise developed by any party in the performance of activities in furtherance of this Agreement, except as may be otherwise provided herein or as may be required for the purposes of securing essential authorisations in respect of the performance of this Agreement from governmental agencies in the Territory, or as may be required to be disclosed under law or regulation in the Territory. This confidentiality obligation shall not apply to such information which:
- (a) the receiving party can prove, by written records and to the reasonable satisfaction of the disclosing party, is or has become a matter of public knowledge other than through any breach by or at the instigation of the receiving party, or any of its Affiliates, of this Agreement;
  - (b) is already legitimately in the possession of the receiving party;
  - (c) is disclosed to the receiving party by a Third Party (other than the disclosing party or ViiV and/or its Affiliates) having the right to do so;
  - (d) is subsequently and independently developed by employees of the receiving party or its Affiliates who had no knowledge of the Confidential Information disclosed; or
  - (e) in the case of the Licensor, is required to be disclosed to ViiV under the terms of the Licensor's agreement with ViiV.
- 6.2 The Parties shall ensure that no unauthorised use or disclosure is made by others to whom access to such Confidential Information is granted, by binding such persons on like terms to this Agreement which are enforceable by each of the Licensor and ViiV.
- 6.3 All Confidential Information shall remain the property of the disclosing party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a party to this Agreement, based on the insolvency or bankruptcy of such party (or based on any other analogous or similar status of that party



under foreign laws), the bankrupt or insolvent party shall promptly notify the court or other tribunal:

- (a) that Confidential Information remains the property of the disclosing party; and
- (b) of the confidentiality obligations under this Agreement.

- 6.4 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.
- 6.5 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.
- 6.6 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.

## **7 ADVERSE EXPERIENCE REPORTING**

- 7.1 The responsibilities of the Parties for reporting of adverse drug experiences related to the Products to regulatory authorities in the Territory shall be performed in accordance with local laws and regulations. The responsibilities of the Parties for safety related or Product related inquiries shall be performed in accordance with local laws and regulations.
- 7.2 Without prejudice to Clause 7.1:
- 7.2.1 Licensee undertakes that it will maintain until the termination of this Agreement (or, as applicable, until the rights and obligations intended to survive termination of this Agreement have been fulfilled) pharmacovigilance and risk management systems, procedures and documentation needed to perform and comply with its regulatory obligations and its related obligations under this Agreement.
- 7.2.2 Licensee undertakes that it will ensure that it will comply with all applicable laws and regulations regarding the Products in the Territory including without limitation those laws and regulations relating to risk management, drug safety and pharmacovigilance.
- 7.2.3 Licensee will hold and maintain a safety database regarding the Products in the Territory.
- 7.2.4 Licensee will be responsible for fulfilling all Pharmacovigilance activities as per the local regulations and requirements for the Products in the Territory (this includes but is not limited to collating AE, and Pregnancy Reports, expedited and periodic reporting to regulatory agencies in the Territory, literature review, performing safety evaluation and signal detection on all available AE and Pregnancy data etc).



7.2.5 Licensee shall provide Licensor and ViiV with a report containing information regarding AEs and Pregnancy Reports which are associated with the Products and which have been received by Licensee, from both spontaneous reporting and clinical trial sources. Such report shall be provided annually and otherwise on reasonable request by the Licensor and/or ViiV.

7.2.6 Licensee shall notify the Licensor and ViiV forthwith of the receipt of an enquiry from a regulatory authority in the Territory relating to the Product that concerns any safety issue. If 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 Licensor and ViiV in writing (including, but not limited to email communications) with available details regarding the same.

7.2.7 On conclusion of any clinical research relating to the Products, Licensee undertakes to submit to Licensor and ViiV copies of the clinical trial reports generated by or on behalf of Licensee relating to such clinical research.

7.2.8 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: [nassrin.x.payvandi@viiivhealthcare.com](mailto:nassrin.x.payvandi@viiivhealthcare.com)

or such person as shall be nominated by him in writing from time to time.

## 8 NON-DIVERSION

8.1 Save as provided under this Agreement, 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 to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Raw Materials other than in the Territory where there is a Non-Territory Patent, for the duration of the relevant Non-Territory Patent;
- (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 Royalty Countries, 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 Royalty Countries; 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 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 type that:
- (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, provided however that this obligation shall only apply in relation to a Product in Royalty Countries with Jurisdiction-Specific Packaging; and
  - (c) any other use is not authorised.

These obligations are further elaborated in the Trade Dress Guidance.

- 8.3 The Licensee agrees that the Products sold pursuant to this Agreement will be visually differentiated from Products sold by ViiV in a manner further elaborated under the Trade Dress Guidance. Licensee will submit samples of the Products 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 Products pursuant to this Agreement until the Licensor and ViiV have approved the colour and shape of the trial batches, such approval will not be unreasonably withheld, delayed or conditioned. Once Licensor and ViiV have approved the colour and shape 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 Products that conform to the colour and shape of the trial batch approved by the Licensor and ViiV pursuant to this clause 8.3.
- 8.4A For the avoidance of any doubt, any Product, packaging (whether external, intermediate or internal), data sheets and promotional materials for the Products approved by the Licensor and ViiV before the Effective Amendment Date will be considered as already approved, and ViiV and Licensor will not request the Licensee to make any additional changes except as provided in Clause 8.4 below.
- 8.4 Without prejudice to Clause 8.3, Licensee agrees to comply with such additional requirements for differentiation of the packaging of Products as ViiV may request and agrees to use its reasonable endeavours to ensure timely registration of the variation with all Relevant Regulatory Authorities as they may require, provided that:



8.4.1 ViiV shall only be entitled to request such additional differentiation once during the Term of this Agreement;

8.4.2 ViiV shall not request such additional differentiation earlier than the third (3<sup>rd</sup>) anniversary of the Effective Date of this Agreement; and

8.4.3 Licensee may continue to sell the Products of the original packaging:

8.4.3.1. in all countries in the relevant Territory until the total number of countries which have approved the revised packaging when added to the number of countries for which such approval is not required equates to ten (10) countries (unless the Licensee can demonstrate to the reasonable satisfaction of the Licensor and ViiV that the volume requirements in those 10 countries do not equate to one batch of Products (the “**Volume Threshold**”), in which case Licensee shall not be obliged to sell the newly differentiated Product until such additional approvals as are necessary to meet the Volume Threshold are obtained); and

8.4.3.2. thereafter on a country-by-country basis until such time as the variation for the differentiated packaging is approved for sale in that country.

8.5 The Licensee shall give written notice, prior to any sale of Products, to any Third Party to which it sells Products of the restrictions contained in this Clause 8 and the Licensee shall use its best endeavours, without prejudice to any other provision of this Agreement, to ensure that such Third Parties will undertake to abide by the restrictions contained in this Clause 8 and will assist the Licensor and ViiV in securing compliance with this Clause 8 and the restrictions which it contemplates.

## 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 Licensor and ViiV in full together with all available information concerning the mode of working and using the same. Licensor and ViiV shall treat this information as Confidential Information.

9.2 Licensee hereby grants to 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). Licensor shall not sub-license such rights to any Third Party, provided, however, that should Licensor desire to sub-license any such rights, Licensee and Licensor agree to enter in good-faith negotiations regarding such sub-licence. ViiV shall be entitled to grant sub-licences (without further right to sub-licence) under such licence only to its:

9.2.1 Affiliates; and/or

9.2.2 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 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 Clause 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 the previous two years (or for the period from the Effective Date to the then current date if such period is less than two years) of all quantities of Raw Materials and Products manufactured and/or sold under the licences granted by this Agreement, together with that information contemplated by Clause 11.2 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), at its expense, through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the term of this Agreement and for six months after its termination or expiry; provided, however, that such examination shall not take place more often than twice in any calendar year and shall not cover such records for more than the preceding two calendar years and provided further that such accountant or like person shall report to 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 Agreement Quarter, the Licensee shall provide the Licensor with a quarterly 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 Agreement Quarter. Such accounting shall be made in accordance with the Reporting Guidance issued by the Licensor and show smallest unit, pack size, gross sales and Net Sales Value in US Dollars on a Product-by-Product, country-by-country, month-by-month and purchaser-by-purchaser basis. Such a statement shall include copies of the relevant Public Market procurement documentation in relation to which Approved Public Market Procurement the relevant Products were supplied.



## 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 Licensor and ViiV that (a) neither the Licensee nor, to the knowledge of the Licensee, any Affiliate, director, officer, 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 MPPF, 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 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 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 (i) is material and incapable of correction; or (ii) is capable of correction but is not corrected within 60 days after receiving 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.

13.4 If:

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

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

Licensor shall (and ViiV shall be entitled to) notify the Licensee in writing, detailing the nature of such claim or challenge. 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 Licensor and ViiV against any Losses (as defined in Clause 15.5) incurred by Licensor and/or ViiV in connection with Licensee's continued use of such Patent pursuant to this Licence.

If Licensee does not so notify Licensor within ten (10) Business Days of Licensor'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 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;
- (f) Licensee repeatedly fails to comply with or to timely provide Licensor with any report or statement such as those contained in Clause 11.2 of this



Agreement;

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 Any Party may terminate this Agreement with immediate effect by providing a written termination notice to the other Parties 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 Licensee fails to file for regulatory approval before at least one Relevant Regulatory Authority (including, but not limited to the WHO pre-qualification programme) within 30 months from the Effective Date in respect to the DTG Compound and within 36 months in respect to at least one of the Products, or fails to respond to Licensor's reasonable request for any subsequent Products, Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.
- 13.10 If, in the reasonable opinion of the Licensor, the Licensee fails to promote access to the Products in the Territory in accordance with this Agreement, the Licensor shall give notice to the Licensee requiring it cure such failure. If in the opinion of the Licensor, the Licensee fails to report reasonable progress within 180 days after receiving written notice with respect to the default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee. Without limitation to the generality of this Clause 13.10 in exercising its reasonable opinion, the Licensor shall take into account the period within which the relevant authorities provide the necessary approvals as referred to in Clauses 4.2 and 4.3, normal development lead time for the Products, and progress reported by Licensee in its quarterly reports provided under Clause 4.5.
- 13.11 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 Sublicence Agreement shall be converted into a licence between ViiV and the



Sublicensee, provided that Sublicensee is not in breach of this Agreement and that ViiV has notified both the Licensor and Licensee of such conversion.

- 13.12 Licensee may terminate this Agreement at any time by providing 30 days written notice to Licensor.

#### **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, 13.11 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 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 expressed or intended to survive the termination or expiration of this Agreement in particular, but without limitation, Clauses 6, 11, 15.5, 15.6 and 15.7 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.
- 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.

#### **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 D or Appendix E 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 Product), 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, judgements, 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 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 Licensee with prompt written notice of such claims. Subject to Clauses 9.4 and 13.6, the Indemnified Person and 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 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.

## 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 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, document or other communication required to be given or served under, or in connection with, this Agreement:

- (a) shall be in writing;
- (b) shall be in the English language; and
- (c) shall be:
  - (i) delivered personally;
  - (ii) sent by commercial courier;
  - (iii) sent by pre-paid post; or
  - (iv) sent by airmail, requiring signature on delivery.

21.2 The addresses for delivery of a notice or other communication are as follows:

- (a) to the Licensor at:

Rue de Varembe 7  
CH-1202 Geneva  
Switzerland,  
e-mail: office@medicinespatentpool.org,

marked for the attention of General Counsel,

- (b) to the Licensee at:

Cipla House, Peninsula Business Park  
Ganpatrao Kadam Marg, Lower Parel  
Mumbai – 400013, Maharashtra, India

marked for the attention of Chief Legal Officer,

- (c) to ViiV at:

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



marked for the attention of General Counsel.

- 21.3 If a notice or other communication has been properly sent or delivered in accordance with this Clause 21, it will be deemed to have been received as follows:
- (a) if delivered personally, at the time of delivery;
  - (b) if sent by commercial courier, on the date and at the time of signature of the courier's delivery receipt;
  - (c) if sent by pre-paid post, 9.00 a.m. on the second Business Day after posting; or
  - (d) if sent by airmail, 9.00 a.m. on the fifth Business Day after posting.
- 21.4 The provisions of this Clause 21 shall not apply to the service of any proceedings or other documents in any legal action.
- 21.5 Any notice, document or other communication required to be given or served under, or in connection with, this Agreement shall not be validly given if sent by e-mail.

## **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 or 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 D and Appendix E of this Agreement at any time without the Licensee's consent in order to include additional patents in those appendices.

## **26 WAIVER**

The rights of each Party 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 English law.
- 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 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-difluorobenzamide

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

Countries forming the Territory are Royalty-Free Countries except for those designated with an asterisk (\*) which are Royalty-Countries.

- |                              |   |
|------------------------------|---|
| 1. Afghanistan               | 51. Moldova*                                    |
| 2. Angola                    | 52. Mongolia*                                   |
| 3. Armenia*                  | 53. Morocco*                                    |
| 4. Bangladesh                | 54. Mozambique                                  |
| 5. Benin                     | 55. Myanmar                                     |
| 6. Bhutan                    | 56. Namibia                                     |
| 7. Bolivia                   | 57. Nepal                                       |
| 8. Botswana                  | 58. Nicaragua                                   |
| 9. Burkina Faso              | 59. Niger                                       |
| 10. Burundi                  | 60. Nigeria                                     |
| 11. Cambodia                 | 61. Democratic People's Republic of North Korea |
| 12. Cameroon                 | 62. Pakistan                                    |
| 13. Cape Verde               | 63. Papua New Guinea                            |
| 14. Central African Republic | 64. Philippines*                                |
| 15. Chad                     | 65. Republic Kyrgyz                             |
| 16. Comoros                  | 66. Rwanda                                      |
| 17. Congo                    | 67. Samoa                                       |
| 18. Cote d'Ivoire            | 68. Sao Tome and Principe                       |
| 19. Djibouti                 | 69. Senegal                                     |
| 20. DR Congo (Zaire)         | 70. Seychelles                                  |
| 21. East Timor               | 71. Sierra Leone                                |
| 22. Egypt*                   | 72. Solomon Islands                             |
| 23. El Salvador              | 73. Somalia                                     |
| 24. Equatorial Guinea        | 74. South Africa                                |
| 25. Eritrea                  | 75. South Sudan                                 |
| 26. Ethiopia                 | 76. Sri Lanka                                   |
| 27. Gabon                    | 77. Sudan                                       |
| 28. Ghana                    | 78. Syria                                       |
| 29. Gambia                   | 79. Swaziland                                   |
| 30. Georgia                  | 80. Tanzania                                    |
| 31. Guatemala                | 81. Tajikistan                                  |
| 32. Guinea                   | 82. Togo  |
| 33. Guinea Bissau            | 83. Tunisia*                                    |
| 34. Guyana                   | 84. Turkmenistan*                               |
| 35. Haiti                    | 85. Tuvalu                                      |
| 36. India*                   | 86. Uganda                                      |
| 37. Indonesia*               | 87. Ukraine*                                    |
| 38. Honduras                 | 88. Uzbekistan                                  |
| 39. Kenya                    | 89. Vanuatu                                     |
| 40. Kiribati                 | 90. Vietnam*                                    |
| 41. Kosovo                   | 91. West Bank and Gaza                          |
| 42. Lao People's DR          | 92. Yemen                                       |
| 43. Lesotho                  | 93. Zambia                                      |
| 44. Liberia                  | 94. Zimbabwe                                    |
| 45. Madagascar               |   |
| 46. Malawi                   |   |
| 47. Mali                     |   |
| 48. Mauritania               |   |
| 49. Mauritius                |   |
| 50. Micronesia               |   |

#### Tiers for Royalty Countries:

<b>Tier 1</b>	India, Vietnam, Philippines, Moldova
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<b>Tier 2</b>	Indonesia, Egypt, Morocco, Armenia, Ukraine, Mongolia, Tunisia
<b>Tier 3</b>	Turkmenistan



## APPENDIX C

### LOW AND MIDDLE INCOME JURISDICTIONS

#### LIC

Afghanistan  
Benin  
Burkina Faso  
Burundi  
Cambodia  
Central African Republic  
Chad  
Comoros  
Congo, Dem. Rep.  
Eritrea  
Ethiopia

Gambia, The  
Guinea  
Guinea-Bissau  
Haiti  
Korea, Dem Rep.  
Liberia  
Madagascar  
Malawi  
Mali  
Mozambique

Nepal  
Niger  
Rwanda  
Sierra Leone  
Somalia  
South Sudan  
Tanzania  
Togo  
Uganda  
Zimbabwe

#### LMIC

Armenia  
Bangladesh  
Bhutan  
Bolivia  
Cameroon  
Cape Verde  
Congo, Rep.  
Côte d'Ivoire  
Djibouti  
Egypt, Arab Rep.  
El Salvador  
Georgia

India  
Kenya  
Kiribati  
Kosovo  
Kyrgyz Republic  
Lao PDR  
Lesotho  
Mauritania  
Micronesia, Fed. Sts.  
Moldova  
Mongolia  
Morocco  
Myanmar

Samoa  
São Tomé and Príncipe  
Senegal  
Solomon Islands  
Sri Lanka  
Sudan  
Swaziland  
Syrian Arab Republic  
Tajikistan  
Timor-Leste  
Tunisia  
Ukraine  
Uzbekistan



Ghana	Nicaragua	Vanuatu
Guatemala	Nigeria	Vietnam
Guyana	Pakistan	West Bank and Gaza
Honduras	Papua New Guinea	Yemen, Rep.
Indonesia	Philippines	Zambia
UMIC		
Angola	Fiji	Namibia
Albania	Gabon	Palau
Algeria	Grenada	Panama
American Samoa	Iran, Islamic Rep.	Paraguay
Azerbaijan	Iraq	Peru
Belarus	Jamaica	Romania
Belize	Jordan	Serbia
Bosnia and Herzegovina	Kazakhstan	South Africa
Botswana	Lebanon	St. Lucia
Brazil	Libya	St. Vincent and the Grenadines
Bulgaria	Macedonia, FYR	Suriname
China	Malaysia	Thailand
Colombia	Maldives	Tonga
Costa Rica	Marshall Islands	Turkey
Cuba	Mauritius	Turkmenistan
Dominica	Mexico	Tuvalu
Dominican Republic	Montenegro	
Ecuador		



**APPENDIX D**

**THE PATENTS**

Appendix D, Part A: ABC Patents:



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



**APPENDIX E**

**THE NON-TERRITORY PATENTS**

**Appendix E, Part A:** Non-Territory Patents in respect of the ABC Compound registered in countries which fall within Appendix C but do not fall within Appendix B (Territory):





**Appendix E, Part B: Non-Territory Patents in respect of the DTG Compound registered in countries which fall within Appendix C but do not fall within Appendix B (Territory):**



**SIGNATORIES**

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

Signature: *Charles Gore*

Name (Printed): CHARLES GORE

Position: EXECUTIVE DIRECTOR

Date: 22.11.2018



Medicines Patent Pool  
Rue de Varembe 7  
1202 Geneva  
Switzerland

**For and on behalf of Cipla Limited**

Signature: *Anant Atal*

Name (Printed): ANANT ATAL

Position: VICE PRESIDENT

Date: 13.11.2018



**For and on behalf of Cipla Limited**

Signature: *Shree Nidhee Vartak*

Name (Printed): SHREE NIDHEE VARTAK

Position: DIRECTOR FINANCE

Date: 13/11/2018

**A.R.I.P.O.:** Botswana, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

**O.A.P.I.:** Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal and Togo.

Country	Application Number	Application Date	Patent Number
A.R.I.P.O.	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104
Armenia	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	EA200000318	14-Oct-1998	003183
	EA199901059	20-Aug-1998	001964
Egypt	526.98	14-May-1998	23836
El Salvador	E-0057/1998	15-May-1998	188Book3
Gambia	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104
Georgia	AP1998.003738	14-May-1998	P2680
	1998.003907	14-Oct-1998	GEP2679
Ghana	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182



Country	Application Number	Application Date	Patent Number
	AP.P.99.01721	20-Aug-1998	AP1104
Guatemala	PI980069	20-May-1998	4700
	PI.990052	13-Apr-1999	4978
Honduras	PI.GB98.71	14-May-1998	3777
	PI.GB99.48	14-Apr-1999	3785
India	2000/00193/KOL	04-Feb-1999	212734
	1821.CAL.98	13-Oct-1998	184590
	1499.CAL.98	21-Aug-1998	183908
Indonesia	W.991393	14-May-1998	ID0011367
	W.20001507	04-Feb-1999	ID0011128
	W.20000707	14-Oct-1998	ID0009275
	W.991671	20-Aug-1998	ID0010055
Kenya	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104
Kyrgyzstan	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	EA200000318	14-Oct-1998	003183
	EA199901059	20-Aug-1998	001964
Lesotho	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104



Country	Application Number	Application Date	Patent Number
Malawi	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104
Mauritius	1157.652	11-May-1998	00024/2012
Moldova	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	EA200000318	14-Oct-1998	003183
	EA199901059	20-Aug-1998	001964
Morocco	PV25078	15-May-1998	26498
	PV25452	04-Feb-1999	26604
	PV25292	13-Oct-1998	24676
Mozambique	AP.P.00.01878	04-Feb-1999	AP1212
Nicaragua	98.0060	14-May-1998	1197RPI
	99.0036	14-Apr-1999	1580 R.P.I.
Nigeria	164.98	15-May-1998	RP.13708
O.A.P.I	9900249	14-May-1998	11304
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Pakistan	467.98	13-May-1998	141284
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Philippines	01172	15-May-1998	1-1998-01172
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	2169	21-Aug-1998	1-1998-02169
Seychelles	TBN	14-May-1998	2340491
Sierra Leone	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
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South Africa	984085	14-May-1998	98.4085
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Sri Lanka	4.11897	14-May-1998	11897
	12147	04-Feb-1999	12147
	4.11955	20-Aug-1998	11955
Sudan	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104
Swaziland	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
	AP.P.99.01721	20-Aug-1998	AP1104
Tajikistan	EA1999.00944	14-May-1998	EA001809
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	EA199901059	20-Aug-1998	001964
Turkmenistan	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	EA200000318	14-Oct-1998	003183
	EA199901059	20-Aug-1998	001964
Uganda	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
	AP.P.00.01790	14-Oct-1998	AP1182
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Ukraine	UA99116246.M	14-May-1998	56231
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Zimbabwe	AP.P.99.01688	14-May-1998	AP2009
	AP.P.00.01878	04-Feb-1999	AP1212
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A.R.I.P.O.: Botswana, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

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Egypt	1167/2007	28-Apr-2006	
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India	3865/KOLNP/2007	28-Apr-2006	
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	1971/KOLNP/2011	9-Dec-2009	
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Indonesia	W-00200703559	28-Apr-2006	ID0025669
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	W-00201102355	8-Dec-2009	
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Kyrgyzstan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Moldova	200702080	28-Apr-2006	14162
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Morocco	PV/30388	28-Apr-2006	29460
	35145	24-Jan-2011	34002
Nigeria	2007/12/473/LOS/IP	28-Apr-2006	



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South Africa	2007/08970	28-Apr-2006	2007/08970
	2012/05586	24-Jan-2011	2012/05586
Tajikistan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Turkmenistan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Ukraine	200711345	28-Apr-2006	96568
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Vietnam	1-2007-02531	28-Apr-2006	12249
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Azerbaijan	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	EA200000318	14-Oct-1998	003183
	EA199901059	20-Aug-1998	001964
Belarus	EA001809	29-Jul-2011	EA001809
	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	000626	21-Jul-2011	000626
	97.0203	28-Mar-1996	000626
	EA200000318	14-Oct-1998	003183
	EA199901059	20-Aug-1998	001964
Brazil	PI9607851.0	28-Mar-1996	PI9607851-0
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Bulgaria	103959	14-May-1998	64390
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China P.R.	03102921.3	20-Jan-2003	ZL03102921.3
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Colombia	99.006.407	04-Feb-1999	28448
Ecuador	SP98.2505	14-May-1998	PI08-1913



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Jordan	2032	16-May-1998	2032
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Kazakhstan	97.0203	28-Mar-1996	000626
	EA1999.00944	14-May-1998	EA001809
	EA200000736	04-Feb-1999	002916
	EA200000318	14-Oct-1998	003183
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Lebanon	96.01.0149359	09-May-1998	5955
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Malaysia	PI98002147	14-May-1998	MY-120151-A
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Mexico	9910373	14-May-1998	219275
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Panama	PI.PA98.084513	14-May-1998	84513-01
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Peru	000374.1998	14-May-1998	2472
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Romania	99907477.6	04-Feb-1999	EP1051156
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Thailand	9801001741	14-May-1998	46105
Tunisia	SN98065	15-May-1998	18129
	SN99060	13-Apr-1999	18233
Turkey	1999.02810	14-May-1998	TR199902810B
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Algeria	70738	28-Apr-2006	5531
	120523	24-Jan-2011	
Azerbaijan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Belarus	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Bosnia and Herzegovina	11737484.3	24-Jan-2011	EP2531027
Brazil	PI0610030-9	28-Apr-2006	
	PI0923217-6	8-Dec-2009	
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Bulgaria	6758843.4	28-Apr-2006	1874117
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China P.R.	2.00680022891.4	28-Apr-2006	ZL200680022891.4
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Colombia	07-115501	28-Apr-2006	1886
	12-125.933	24-Jan-2011	5085
Costa Rica	2012-423	24-Jan-2011	



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Ecuador	SP-12-12106	24-Jan-2011	
Kazakhstan	200702080	28-Apr-2006	14162
	201290583	24-Jan-2011	
Macedonia	MK/P/2015/352	24-Jan-2011	EP2531027
Malaysia	PI20071883	31-Oct-2007	MY-149571-A
	PI2012003346	24-Jan-2011	
Mexico	MX/a/2007/013351	28-Apr-2006	302718
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	MX/a/2013/008013	9-Jul-2013	
	MX/a/2012/008774	24-Jan-2011	325889
Mongolia	4889	24-Jan-2011	3887
Montenegro	P-2015/106	24-Jan-2011	EP2531027
Peru	001082-2012/DIN	24-Jan-2011	
Romania	6758843.4	28-Apr-2006	1874117
	11737484.3	24-Jan-2011	EP2531027
Serbia	P-462/15	24-Jan-2011	54123
Thailand	1201003753	24-Jan-2011	
Tunisia	TN2012/0376	24-Jan-2011	22965
Turkey	2013/11091	28-Apr-2006	2013/11091
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