

LICENCE AGREEMENT

THIS LICENCE AGREEMENT (this “**Agreement**”) is made as of _____
(the “**Effective Date**”),

BETWEEN:

- (1) **THE MEDICINES PATENT POOL FOUNDATION**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Varembe 7, CH-1202 Geneva (the “**Licensor**”); and
- (2) a company incorporated under the laws of _____ and having its registered office at _____ (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, as are identified in Appendix A, which relate to the compound known as abacavir for paediatric 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 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 “**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.
- 1.2 “**Agreement Quarter**” shall mean any period of three months ending on the last day of March or June or September or December.
- 1.3 “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.
- 1.4 “**Compound**” shall mean the chemical compound known generically as abacavir, whose more specific chemical name is set out in Appendix B.
- 1.5 “**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.

- 1.6 “**Event of Force Majeure**” has the meaning given in Clause 14.
- 1.7 “**HSR**” has the meaning given in Clause 6.
- 1.8 “**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 or incorporate or are based on the Patents.
- 1.9 “**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.
- 1.10 “**Non-Territory Patents**” shall mean any patents relating to the Products owned by ViiV or its Affiliates which have been granted by a country which is outside of the Territory.
- 1.11 “**Patents**” shall mean those patents and patent applications owned by ViiV as are set out in Appendix A.
- 1.12 “**Products**” shall mean pharmaceutical combinations and compositions for paediatric use produced under this Agreement that have been prepared and are in a form ready for administration for antiretroviral therapy for HIV/AIDS which contain the Compound.
- 1.13 “**Raw Materials**” shall mean, as the context admits and requires, the active ingredients which are protected by the Patents and which are required to prepare the Products in final consumer package form as envisaged under the licences granted under Clauses 2.1 and 2.2.
- 1.14 “**Territory**” shall mean all those countries as are set out in Appendix C.
- 1.15 “**Third Party(ies)**” shall mean any party other than a party to this Agreement.
- 1.16 “**ViiV**” means ViiV Healthcare UK Limited and/or its Affiliates, as the context admits.
- 1.17 References to “this Agreement” shall mean this licence agreement and shall include the Appendices.
- 1.18 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.
- 1.19 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.
- 1.20 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.

- 1.21 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 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-free, 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 in the Territory solely for use in antiretroviral for HIV / AIDS; and
- (b) manufacture, have manufactured, use, sell, supply, import or export Products in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS.

- 2.2 Subject to the terms and conditions of this Agreement and to the extent to which the Licensor has the right to grant a licence in respect of the Non-Territory Patents, the Licensor hereby grants to the Licensee a non-exclusive, royalty-free, non-sublicensable, non-transferable licence under the Non-Territory Patents to:

- (a) Manufacture, have manufactured, use, sell, supply, import or export outside the Territory Products exclusively for use, sale, supply, import or export of such Products in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS;
- (b) manufacture, have manufactured, use, sell, supply, import or export outside the Territory Raw Materials exclusively for supplying to the Territory for use in the manufacture of Products to be supplied in the Territory and solely for use in antiretroviral therapy for HIV / AIDS; 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, supply, import or export in each case in the Territory and solely for use in antiretroviral therapy for HIV / AIDS.

- 2.3 Notwithstanding anything contained in this Agreement, nothing in this Agreement shall be construed to 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.

- 2.4 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.

For the avoidance of doubt, 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 not be construed as a right to sublicense manufacture for supply to any Third Party. The Licensee shall procure that any Third Party manufacturer 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.

- 2.5 Save for the right to have manufactured Raw Materials and Products in accordance with Clauses 2.1 and 2.2, this Agreement confers no rights on the Licensee to sublicense its rights hereunder, which is expressly prohibited.
- 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.
- 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 to perform any acts or omissions which infringe:
 - (a) 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; and/or
 - (b) any rights of any Third Party (including, without limitation, ViiV and their Affiliates) inside or outside the Territory.

3 DEVELOPMENT AND REGISTRATION

- 3.1 As of the Effective Date and subject always to ViiV's retained rights to the Patents, 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.
- 3.2 Licensee agrees that it will manufacture Raw Materials and Product in a manner consistent with (i) World Health Organization ("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.
- 3.3 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.
- 3.4 If the Licensee sells, supplies or otherwise disposes of any Product in the Territory but has not obtained the necessary approvals pursuant to Clauses 3.2 and 3.3, the Licensor shall be entitled to immediately terminate this Agreement by providing written notice to the Licensee.

- 3.5 Licensee shall provide Licensor with a quarterly written report setting forth (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 within the Territory for which such regulatory approvals or authorizations have been obtained for any Product. The Parties agree to confer on a quarterly basis regarding such reports. For avoidance of doubt, ViiV and the Licensor agree that information contained in quarterly and other such reports shall be treated as Confidential Information.
- 3.6 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 SUPPLY, DISTRIBUTION AND LABELLING

- 4.1 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.
- 4.2 The Licensee shall be solely responsible for the distribution in the Territory of all Products to be sold in the Territory under this Agreement.

5 EXCHANGE OF INFORMATION, CONFIDENTIALITY AND ADVERSE EXPERIENCE REPORTING

- 5.1 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; or
 - (d) is subsequently and independently developed by employees of the receiving party or its Affiliates who had no knowledge of the Confidential Information disclosed;
 - (e) in the case of the Licensor, is required to be disclosed to ViiV under the terms of the Licensor's agreement with ViiV.

- 5.2 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.
- 5.3 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.
- 5.4 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.
- 5.5 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 in to account ViiV's reasonable comments in connection therewith.
- 5.6 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.
- 5.7 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.

6 HYPERSENSITIVITY REACTION

The Licensee acknowledges that the appropriate use of certain abacavir-containing products is complicated by the occurrence of a potentially fatal hypersensitivity reaction (“HSR”) to abacavir and that, overall, in clinical studies conducted before the introduction of screening for the human leukocyte antigen (HLA)-B*5701 allele, approximately five per cent. of subjects receiving abacavir developed a HSR. The Licensee further acknowledges that it is ViiV's policy that HSR education initiatives and a stock release programme be developed prior to the release of abacavir-containing products into any new markets, to manage the issue of HSR, further details of which are set out in Appendix D (as may be updated by ViiV from time to time by providing an update to the Licensee).

7 NON-DIVERSION

- 7.1 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;
 - (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; and/or
 - (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.
- 7.2 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 7 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 7 and will assist the Licensor and ViiV in securing compliance with this Clause 7.

8 INTELLECTUAL PROPERTY

- 8.1 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.
- 8.2 Licensee shall grant to Licensor and ViiV a perpetual, irrevocable, worldwide, royalty free, non-exclusive licence to use any Improvement, Improvement Patent and related know-how. 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:
- 8.2.1 Affiliates; or
 - 8.2.2 contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercialising ViiV products.
- 8.3 The Licensee shall have no rights in relation to, the conduct of any matter relating to the Patents, including the filing, prosecution and maintenance thereof.

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 anywhere in the Territory, 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.

- 8.4 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.

9 TRADE MARKS AND NON-PROPRIETARY NAMES

- 9.1 Subject always to Clauses 9.2 and 9.3, 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.
- 9.2 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.
- 9.3 The Licensee shall obtain the prior written approval, such approval not to be unreasonably withheld, 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 offering to sell, selling or otherwise disposing of any Products, and before applying for government or relevant regulatory authorisation to do so. Such consent shall be understood as provided unless otherwise notified to Licensee within 30 days of Licensee's initial request. For clarity, ViiV's consent under this Clause shall be deemed to indicate Licensee's compliance with Clause 9.2

10 STATEMENTS AND REMITTANCES

- 10.1 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 10.2. The Licensor and ViiV shall 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 and sales 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 under 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; and

- (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 7; 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.

10.2 Within 45 days after the close of each Agreement Quarter, the Licensee shall deliver to such persons as the Licensor and ViiV (respectively) may nominate a statement accounting for all Products (volumes of tablets and packs for each formulation, including syrups) sold or supplied by the Licensee under this Agreement during such Agreement Quarter. Such accounting (if applicable) shall show units and value sales on a Product-by-Product, country-by-country and purchaser-by-purchaser basis.

11 TERM AND TERMINATION

11.1 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 11.

11.2 Unless otherwise terminated, this Agreement shall expire upon the later of the expiration, lapse or invalidation of the last remaining Patent in the Territory.

11.3 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.

11.4 If:

11.2.1 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

11.2.2 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 11.5), 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 13.5) 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.

- 11.5 If:
- (a) the Licensee breaches any of the provisions of Clause 7;
 - (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; and/or
 - (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,

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.

- 11.6 The provisions of Clause 11.5(a) 11.5(b) and 11.5 (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 damage or loss under clause 11.5(a), (b) and/or (d) the Licensee hereby agrees to indemnify the Licensor and ViiV subject to (i) 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, and (ii) the provisions of 27.3.
- 11.7 Any party may terminate this Agreement with immediate effect by providing a written termination notice to the other parties if, at any time, any of the other parties 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.
- 11.8 Any change in the legal or beneficial ownership or control of the Licensee and/or any of its Affiliates shall be immediately notified in writing to the Licensor and ViiV by the Licensee. For the purposes of this Clause 11.8, "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.
- 11.9 If, in the reasonable opinion of the Licensor, the Licensee fails to promote access to

the Products in the Territory, the Licensor shall give notice to the Licensee requiring it cure such failure to promote. 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 11.8, 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 3.2 and 3.3, normal development lead time for the Products, and progress reported by Licensee in its quarterly reports provided under Clause 3.5.

- 11.10 Unless notice to the contrary is given by ViiV, this Agreement shall terminate immediately in the event that the Licensor's agreement with ViiV dated [*insert date*] under which its right to licence the Patents is derived 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.
- 11.11 Licensee may terminate this Agreement at any time by providing 30 days written notice to Licensor.

12 RIGHTS AND DUTIES UPON TERMINATION OR EXPIRY

- 12.1 Upon termination or expiry of this Agreement, in accordance with Clauses 11.7, 11.8, 11.9, 11.10 and/or 11.11, 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.
- 12.2 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 5, 10, 13.5, 13.6 and 13.7 and the relevant provisions of this Clause 12. 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.
- 12.3 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.

13 WARRANTIES AND INDEMNITIES

- 13.1 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.
- 13.2 Nothing in this Agreement shall be construed as a warranty that any of the Patents are

valid or enforceable or that their exercise does not infringe any patent rights of any Third Parties.

- 13.3 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.
- 13.4 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, whether as single compounds or in combination with each other, or whether in combination with other compounds.
- 13.5 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 8.4 and 11.6, 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.
- 13.6 Clause 13.5 may be enforced, by each Indemnified Person against the Licensee under the Contracts (Rights of Third Parties) Act 1999.
- 13.7 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.

14 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.

15 RIGHT OF SET OFF

- 15.1 All amounts due by the Licensee under this Agreement shall be paid in full in Pound Sterling 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.
- 15.2 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 12), 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 15.2 shall be without prejudice to any other rights or remedies available to the Licensor or ViiV under this Agreement.

16 THIRD PARTY RIGHTS

- 16.1 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.
- 16.2 ViiV and/or any of their 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.
- 16.3 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.

17 SEVERABILITY

- 17.1 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.
- 17.2 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.

- 17.3 In the event that the terms and conditions of this Agreement are materially altered as a result of Clauses 17.1 or 17.2, 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 27.3 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.

18 ENTIRE AGREEMENT

- 18.1 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.
- 18.2 Subject to Clause 18.3, 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.
- 18.3 Nothing in this Clause 18 limits or excludes any liability for fraud.

19 NOTICES

- 19.1 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;
 - (iv) sent by fax; or
 - (v) sent by airmail, requiring signature on delivery.
- 19.2 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:

fax number: _____

marked for the attention of _____

(c) to ViiV at:

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

fax number: +44 208 380 6201,

marked for the attention of Director, Legal Operations.

19.3 If a notice or other communication has been properly sent or delivered in accordance with this Clause 19, 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;
- (d) if sent by fax, at the time of transmission; or
- (e) if sent by airmail, 9.00 a.m. on the fifth Business Day after posting.

19.4 The provisions of this Clause 19 shall not apply to the service of any proceedings or other documents in any legal action.

19.5 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.

20 ASSIGNMENT AND SUB-CONTRACTING

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

20.2 Save as expressly set out in Clauses 2.1, 2.2 or 2.4, 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.

21 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.

22 COSTS

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

23 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.

24 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.

25 NO PARTNERSHIP OR AGENCY

Nothing in this Agreement shall be deemed to constitute a partnership between the parties, nor constitute any party as the agent of any of the other parties.

26 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.

27 GOVERNING LAW AND JURISDICTION

- 27.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by English law.
- 27.2 Subject to Clause 27.3, 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
- 27.3 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.
- 27.4 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.
- 27.5 Without prejudice to the foregoing in relation to the Licensee, nothing in this Clause 27 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

ABACAVIR PATENTS

For OAPI, the relevant countries are:

Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal, Togo.

PB1198 – abacavir enantiomer

Country	Application Number	Application Date	Status	Patent Number	Expiry date
Jamaica	18.1.3972	05-Jan-2000	Granted	3278	22-Jan-2016

PG3176:- Abacavir Hemisulfate Salt

Country	Application Number	Application Date	Status	Patent Number	Expiry date
Algeria	980103	17-May-1998	Granted	2493	17-May-2018
Angola	258	15-May-1998	Granted	113	15-May-2013
Argentina	P070100006	02-Jan-2007	Granted	AR059120B2	14-May-2018
Argentina	P980102251	14-May-1998	Granted	AR015668B1	14-May-2018
A.R.I.P.O.	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Armenia	EA1999.00944	14-May-1998	Granted	EA001809	14-May-2018
Azerbaijan	EA1999.00944	14-May-1998	Granted	EA001809	14-May-2018
Bangladesh	59.98	28-Apr-1998	Granted	1003083	17-May-2013
Bolivia	06315	14-May-1998	Inactive		14-May-2018
Chile	1998.999	07-May-1998	Granted	42.213	21-Jul-2019
Colombia	98.027.044	14-May-1998	Inactive		14-May-2018
Ecuador	SP98.2505	14-May-1998	Granted	PI08-1913	14-May-2018
Egypt	526.98	14-May-1998	Granted	23836	13-May-2018
Gambia	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Georgia	AP1998.003738	14-May-1998	Granted	P2680	14-May-2018
Ghana	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Guatemala	PI980069	20-May-1998	Granted	4700	20-May-2018
Honduras	PI.GB98.71	14-May-1998	Granted	3777	14-May-2018
India	872/CAL/1998	14-May-1998	Inactive		14-May-2012
Indonesia	W.991393	14-May-1998	Granted	ID0011367	14-May-2018
Jamaica	18.1.4081	06-Feb-2001	Inactive		

Jamaica	18.1.4167	15-Mar-2002	Granted	3575	18-Sep-2017
Kenya	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Lebanon	96.01.0149359	09-May-1998	Granted	5955	09-May-2018
Lesotho	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Libya	509.98	16-May-1998	Inactive	509-1998	16-May-2008
Malawi	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Malaysia	PI98002147	14-May-1998	Granted	MY-120151-A	30-Sep-2020
Mauritius	1157.652	11-May-1998	Granted	00024/2012	11-May-2018
Moldova	EA1999.00944	14-May-1998	Granted	EA001809	14-May-2018
Morocco	PV25078	15-May-1998	Granted	26498	15-May-2018
Nicaragua	98.0060	14-May-1998	Granted	1197RPI	14-May-2018
Nigeria	164.98	15-May-1998	Granted	RP.13708	15-May-2018
O.A.P.I	9900249	14-May-1998	Granted	11304	14-May-2018
Pakistan	467.98	13-May-1998	Granted	141284	17-May-2017
Panama	PI.PA98.084513	14-May-1998	Granted	84513-01	14-May-2018
Philippines	01172	15-May-1998	Granted	1-1998-01172	15-May-2018
Seychelles	TBN	14-May-1998	Granted	2340491	14-May-2018
Sierra Leone	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
South Africa	984085	14-May-1998	Granted	98.4085	14-May-2018
Sri Lanka	4.11897	14-May-1998	Granted	11897	15-Mar-2015
Sudan	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Swaziland	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Syria	5228	14-May-1998	Granted	5330	14-May-2013
Tajikistan	EA1999.00944	14-May-1998	Granted	EA001809	14-May-2018
Thailand	043847	14-May-1998	Filed		14-May-2018
Tunisia	SN98065	15-May-1998	Granted	18129	15-May-2018
Turkmenistan	EA1999.00944	14-May-1998	Granted	EA001809	14-May-2018
Uganda	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018
Zimbabwe	AP.P.99.01688	14-May-1998	Granted	AP2009	14-May-2018

ARIPO:- Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra Leone, Sudan, Swaziland, Uganda, Zimbabwe.

PU3347 : Abacavir Oral Solution

Country	Application Number	Application Date	Status	Patent Number	Expiry date
Argentina	P990100439	03-Feb-1999	Granted	AR017455B1	03-Feb-2019
A.R.I.P.O.	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Armenia	EA200000736	04-Feb-1999	Granted	002916	04-Feb-2019
Azerbaijan	EA200000736	04-Feb-1999	Granted	002916	04-Feb-2019
Chile	1999.178	03-Feb-1999	Granted	44.020	30-Sep-2023

Colombia	99.006.407	04-Feb-1999	Granted	28448	04-Feb-2019
Ecuador	SP.99.2846	02-Feb-1999	Inactive		02-Feb-2019
Egypt	106.99	04-Feb-1999	Filed		
Gambia	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Ghana	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
India	2000/00193/KOL	04-Feb-1999	Granted	212734	04-Feb-2019
Indonesia	W.20001507	04-Feb-1999	Granted	ID0011128	04-Feb-2019
Kenya	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Lesotho	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Malawi	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Malaysia	PI99000389	04-Feb-1999	Granted	MY-121043-A	30-Dec-2020
Morocco	PV25452	04-Feb-1999	Granted	26604	04-Feb-2019
Mozambique	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Pakistan	72.99	03-Feb-1999	Inactive	139521	06-Feb-2018
Philippines	I.1999.00225	04-Feb-1999	Granted	1-1999-00225	04-Feb-2019
Sierra Leone	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
South Africa	99.0890	04-Feb-1999	Granted	99.0890	04-Feb-2019
Sri Lanka	12147	04-Feb-1999	Granted	12147	29-Aug-2018
Sudan	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Swaziland	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Tajikistan	EA200000736	04-Feb-1999	Granted	002916	04-Feb-2019
Thailand	048503	03-Feb-1999	Filed		03-Feb-2019
Turkmenistan	EA200000736	04-Feb-1999	Granted	002916	04-Feb-2019
Uganda	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019
Zimbabwe	AP.P.00.01878	04-Feb-1999	Granted	AP1212	04-Feb-2019

ARIPO:- Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierra Leone, Sudan, Swaziland, Uganda, Zimbabwe.

PB1618 : Abacavir in Combination

Country	Application Number	Application Date	Status	Patent Number	Expiry date
A.R.I.P.O.	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Armenia	97.0203	28-Mar-1996	Granted	000626	28-Mar-2016
Azerbaijan	97.0203	28-Mar-1996	Granted	000626	28-Mar-2016
Chile	1999.3149	28-Dec-1999	Filed		28-Mar-2016
Chile	2006-1968	27-Jul-2006	Filed		
Georgia	002816	28-Mar-1996	Granted	P2647	28-Mar-2016
Ghana	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Jamaica	18.1.4062	03-Nov-2000	Granted	3402	02-Aug-2016
Kenya	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Kyrgyzstan	97.0203	28-Mar-1996	Granted	000626	28-Mar-2016

Lesotho	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Malawi	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Malaysia	PI96001152	27-Mar-1996	Granted	MY-115461-A	30-Jun-2018
Moldova	97.0203	28-Mar-1996	Granted	000626	28-Mar-2016
O.A.P.I	PV70075	28-Mar-1996	Granted	10616	28-Mar-2016
Pakistan	108.98	03-Feb-1998	Granted	141204	30-Mar-2015
Pakistan	169/2011	11-Mar-2011	Granted	141205	30-Mar-2015
Philippines	52732	28-Mar-1996	Granted	1-1996-52732	21-Jan-2021
South Africa	96.2477	28-Mar-1996	Granted	96.2477	28-Mar-2016
Sri Lanka	11281	28-Mar-1996	Filed		
Sudan	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Swaziland	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Tajikistan	97.0203	28-Mar-1996	Granted	000626	28-Mar-2016
Turkmenistan	97.0203	28-Mar-1996	Granted	000626	28-Mar-2016
Uganda	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016
Uzbekistan	UZI HAP9700793.2	28-Mar-1996	Granted	IAP02391	28-Mar-2016
Zimbabwe	AP.P.97.01089	28-Mar-1996	Granted	AP652	28-Mar-2016

ARIPO:- Ghana, Kenya, Lesotho, Malawi, Sudan, Swaziland, Uganda, Zimbabwe.

PG3273 : Manufacturing Process

Country	Application Number	Application Date	Status	Patent Number	Expiry date
Algeria	990067	13-Apr-1999	Granted	2767	13-Apr-2019
Angola	621	02-Jul-1999	Filed		02-Jul-2014
Argentina	P980105097	13-Oct-1998	Granted	AR014921B1	13-Oct-2018
A.R.I.P.O.	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Armenia	EA200000318	14-Oct-1998	Granted	003183	14-Oct-2018
Azerbaijan	EA200000318	14-Oct-1998	Granted	003183	14-Oct-2018
Bangladesh	57.99	11-Apr-1999	Granted	1003212	11-Apr-2015
Bolivia	4452	21-Apr-1999	Inactive		21-Apr-2019
Colombia	98.059323	13-Oct-1998	Inactive		13-Oct-2018
Ecuador	SP98.2692	12-Oct-1998	Inactive		
Egypt	1240.98	13-Oct-1998	Inactive		
El Salvador	E.40.99	13-Apr-1999	Filed		
Gambia	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Georgia	1998.003907	14-Oct-1998	Granted	GEP2679	14-Oct-2018
Ghana	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Guatemala	PI.990052	13-Apr-1999	Granted	4978	13-Apr-2019

Honduras	PI.GB99.48	14-Apr-1999	Granted	3785	14-Apr-2019
India	1821.CAL.98	13-Oct-1998	Granted	184590	13-Oct-2018
Indonesia	W.20000707	14-Oct-1998	Granted	ID0009275	14-Oct-2018
Kenya	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Lebanon	6060	13-Apr-1999	Granted	6040	13-Apr-2019
Lesotho	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Libya	549.99	13-Apr-1999	Inactive		
Malawi	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Malaysia	PI98004673	13-Oct-1998	Granted	MY-127470-A	29-Dec-2021
Mauritius	1157.669	06-Apr-1999	Filed		
Mexico	3379	14-Oct-1998	Granted	220762	14-Oct-2018
Morocco	PV25292	13-Oct-1998	Granted	24676	13-Oct-2018
Nicaragua	99.0036	14-Apr-1999	Granted	1580 R.P.I.	14-Apr-2019
Nigeria			Docketed		14-Oct-2018
O.A.P.I	1200000101	14-Oct-1998	Granted	11370	14-Oct-2018
Pakistan	1045.98	13-Oct-1998	Granted	136516	14-Oct-2013
Panama	PA99.84706	13-Apr-1999	Granted	84706-01	13-Apr-2019
Philippines	2655	14-Oct-1998	Granted	1-1998-02655	14-Oct-2018
Sierra Leone	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
South Africa	989338	13-Oct-1998	Granted	98.9338	13-Oct-2018
Sri Lanka	12054	14-Oct-1998	Granted	12054	18-Dec-2015
Sudan	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Swaziland	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Tajikistan	EA200000318	14-Oct-1998	Granted	003183	14-Oct-2018
Thailand	46490	14-Oct-1998	Inactive		14-Oct-2018
Tunisia	SN99060	13-Apr-1999	Granted	18233	13-Apr-2019
Turkmenistan	EA200000318	14-Oct-1998	Granted	003183	14-Oct-2018
Uganda	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018
Zimbabwe	AP.P.00.01790	14-Oct-1998	Granted	AP1182	14-Oct-2018

ARIPO:- Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra Leone, Sudan, Swaziland, Uganda, Zimbabwe.

PB1563 : Abacavir Succinate Salt

Country	Application Number	Application Date	Status	Patent Number	Expiry date
South Africa	95.7166	25-Aug-1995	Granted	95.7166	25-Aug-2015

PB1517 : Improved Process

Country	Application Number	Application Date	Status	Patent Number	Expiry date
Philippines	1-2003-000078	10-Feb-2003	Granted	1-2003-00078	08-Nov-2022
Philippines	1-2004-000513	16-Nov-2004	Inactive		
Philippines	1-2007-000362	14-Sep-2007	Inactive		
Philippines	49893	03-Feb-1995	Granted	1-1995-49893	05-May-2022
South Africa	95.0884	03-Feb-1995	Granted	95.0884	03-Feb-2015
Thailand	025337	03-Feb-1995	Granted	14384	02-Feb-2015

PG3220 : Enzyme for Intermediate Process

Country	Application Number	Application Date	Status	Patent Number	Expiry date
A.R.I.P.O.	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Armenia	EA199901059	20-Aug-1998	Granted	001964	20-Aug-2018
Azerbaijan	EA199901059	20-Aug-1998	Granted	001964	20-Aug-2018
Gambia	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Ghana	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
India	1499.CAL.98	21-Aug-1998	Granted	183908	21-Aug-2018
Indonesia	W.991671	20-Aug-1998	Granted	ID0010055	20-Aug-2018
Kenya	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Lesotho	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Malawi	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Pakistan	856.98	20-Aug-1998	Granted	136497	22-Aug-2017
Philippines	2169	21-Aug-1998	Granted	1-1998-02169	21-Aug-2018
Sierra Leone	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Sri Lanka	4.11955	20-Aug-1998	Granted	11955	23-May-2015
Sudan	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Swaziland	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Tajikistan	EA199901059	20-Aug-1998	Granted	001964	20-Aug-2018
Thailand	45604	17-Aug-1998	Inactive		17-Aug-2018
Turkmenistan	EA199901059	20-Aug-1998	Granted	001964	20-Aug-2018
Uganda	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018
Zimbabwe	AP.P.99.01721	20-Aug-1998	Granted	AP1104	20-Aug-2018

ARIPO:- Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra Leone, Sudan, Swaziland, Uganda, Zimbabwe.

APPENDIX B

SPECIFIC CHEMICAL NAME OF THE 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 C
LIST OF COUNTRIES
FORMING THE TERRITORY

1. Afghanistan
2. Algeria
3. Angola
4. Argentina
5. Armenia
6. Azerbaijan
7. Bangladesh
8. Belize
9. Benin
10. Bhutan
11. Bolivia
12. Botswana
13. Burkina Faso
14. Burundi
15. Cambodia
16. Cameroon
17. Cape Verde
18. Central African Republic
19. Chad
20. Chile
21. Colombia
22. Comoros
23. Congo, Dem. Rep. Of The
24. Congo, Rep
25. Costa Rica
26. Côte d'Ivoire
27. Cuba
28. Djibouti
29. Dominican Republic
30. E.Timor
31. Ecuador
32. Egypt
33. El Salvador
34. Equatorial Guinea
35. Eritrea
36. Ethiopia
37. Fiji
38. Gabon
39. Gambia
40. Georgia
41. Ghana
42. Guatemala
43. Guinea
44. Guinea-Bissau
45. Guyana
46. Haiti
47. Honduras
48. India
49. Indonesia
50. Iran
51. Iraq
52. Jamaica
53. Kenya
54. Kiribati
55. Kosovo
56. Lao, People's Dem. Rep.
57. Lebanon
58. Lesotho
59. Liberia
60. Libya
61. Madagascar
62. Malawi
63. Malaysia
64. Maldives
65. Mali
66. Marshall Islands
67. Mauritania
68. Mauritius
69. Micronesia
70. Moldova, Rep. of
71. Mongolia
72. Morocco
73. Mozambique
74. Myanmar
75. Namibia
76. Nauru
77. Nepal
78. Nicaragua
79. Niger
80. Nigeria
81. Pakistan
82. Palau
83. Papua New Guinea
84. Panama
85. Paraguay
86. Peru
87. Philippines
88. Republic Kyrgyz
89. Democratic People's Republic of Korea
90. Rwanda
91. Samoa
92. São Tomé and Príncipe
93. Sénégal
94. Seychelles
95. Sierra Leone
96. Solomon Islands
97. Somalia
98. South Africa
99. South Sudan
100. Sri Lanka
101. Sudan
102. Swaziland
103. Syrian Arab Republic
104. Tajikistan
105. Tanzania, U. Rep. of
106. Thailand
107. Togo
108. Tonga
109. Tunisia
110. Turkmenistan
111. Tuvalu
112. Uganda
113. Ukraine
114. Uzbekistan
115. Vanuatu
116. Venezuela
117. Vietnam
118. West Bank and Gaza
119. Yemen
120. Zambia
121. Zimbabwe

APPENDIX D

ABACAVIR HYPERSENSITIVITY REACTION

1. Objectives of the Abacavir HSR Education Initiatives

Abacavir HSR education initiatives in each local market must satisfy the following communication objectives with patients receiving abacavir-containing products and their healthcare providers:

- Awareness:
 - of the possibility of a generalised HSR to abacavir;
 - that the risk of a HSR is increased if patients are *HLA-B*5701* positive; however, *HLA-B*5701* negative patients can also experience abacavir HSR;
 - that abacavir is contained in certain specific products.
- Clinicians should consider screening for carriage of the *HLA B*5701* allele in any HIV infected patient without prior exposure to abacavir. Screening is also recommended prior to re-initiation of abacavir in patients of unknown *HLA-B*5701* status who have previously tolerated abacavir.
- Use of abacavir in patients known to carry the *HLA B*5701* allele is not recommended and should be considered only under exceptional circumstances where potential benefit outweighs the risk and with close medical supervision.
- *HLA-B*5701* screening must never substitute for clinical vigilance in the management of clinically suspected abacavir HSR.
- *HLA-B*5701* status must never be used to exclude a past HSR diagnosis or to justify re-challenge decisions in the clinic.
- Ability to recognise signs and symptoms of the clinically suspected HSR, regardless of a patient's *HLA-B*5701* status.
- Understanding of necessary actions to be taken in the event of a clinically suspected HSR, regardless of a patient's *HLA-B*5701* status.
- Prevention of rechallenge:
 - patients who have had therapy using abacavir-containing products discontinued as a result of a known or suspected HSR to abacavir should never be rechallenged with an abacavir-containing drug, regardless of a patient's *HLA-B*5701* status;

- there have been infrequent reports of HSR following reintroduction of abacavir, where the interruption was preceded by a single key symptom of HSR (rash, fever, malaise/fatigue, gastrointestinal symptoms or a respiratory symptom). If a decision is made to restart abacavir in these patients, this should be done only under direct medical supervision;
- on very rare occasions HSRs have been reported in patients who have re-started abacavir therapy, and who had no preceding symptoms of a HSR (i.e. patients who were previously considered to be abacavir tolerant). If a decision is made to re-start abacavir, this must be done only if medical care can be accessed readily by the patient or others;
- patients who have stopped abacavir for any reason, and particularly due to possible adverse reactions or illness, must be advised to contact their doctor before restarting.

At a minimum, these programmes must incorporate the following:

1. An alert card (or similar HSR information device subject to local regulatory approval) must be distributed with each pack of abacavir-containing products. The wording of the alert card cannot be edited (other than translation into appropriate language to the market) without appropriate central approval. Details of the approved wording for use in the data sheet, patient information leaflet and alert card are provided to local regulatory staff.
2. Each country must have a comprehensive abacavir HSR educational programme in place at the time of the launch of an abacavir-containing product. This plan is reviewed by the local Medical Director, Product Manager/Commercial Director and/or General Manager of ViiV to assure that it achieves the necessary educational objectives (detailed above) with patients and healthcare providers in the given market.

2. The Abacavir Stock Release Programme

ViiV have the following process in place to ensure that abacavir-containing products cannot be supplied for launch to take place in any new markets, or to any Non-Governmental Organisations (NGO), until the responsible company contact(s) has/have received confirmation that the market/NGO programme have sufficient abacavir HSR education measures in place (as detailed above).

1. The Local Operating Company (LOC) commercial representatives complete the abacavir-containing product Launch Stock Release Form.
2. The LOC Medical Director and Commercial Director sign off the form.
3. The LOC sends the form, together with a copy of each abacavir HSR educational material listed on the form, to the central abacavir HSR Task Force Leader.
4. Appropriate approval from the abacavir HSR Task Force Leader is required prior to release of stock.

SIGNATORIES

For and on behalf of THE MEDICINES PATENT POOL FOUNDATION

Signature:

Name (Printed):

Position:

Date:

For and on behalf of _____

Signature:

Name (Printed):

Position:

Date: