

AGREEMENT

This agreement (the "Agreement") dated 5 August 2013 ("Effective Date"), is made between F. Hoffmann-La Roche Ltd, having an office and place of business at Grenzacherstrasse 124, CH-4070 Basel, Switzerland, ("Roche") and the Medicines Patent Pool Foundation, having an office and place of business at Chemin Louis Dunant 17, 1202 Geneva, Switzerland ("MPP").

WHEREAS, there is a latent unmet need in developing countries for preventing and treating HIV-related cytomegalovirus infections ("CMV");

WHEREAS, *valganciclovir* is an effective and easy-to-administer treatment for HIV-related CMV;

WHEREAS, the absence of quality-assured, affordable sources of *valganciclovir* has contributed to the lack of screening, diagnosis and treatment of HIV-related CMV in developing countries;

WHEREAS, Roche is willing to supply its quality-assured *valganciclovir* at a discounted price in an effort to scale-up the screening, diagnosis and treatment of HIV-related CMV in certain developing countries;

WHEREAS, Roche is willing to explore opportunities for technology transfer in order to ensure access to quality-assured, affordable generic sources of *valganciclovir*;

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

WHEREAS, MPP and Roche desire to improve access to quality-assured, affordable *valganciclovir* for the treatment of HIV-related CMV in developing countries, and Roche desires for MPP to provide assistance towards that end;

WHEREAS, this Agreement sets forth the terms and conditions under which Roche agrees to sell and deliver *valganciclovir* manufactured by Roche;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

1. Definitions

"Adverse Event" is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

"Adverse Reaction" is a response to a medicinal product which is noxious and unintended. This includes adverse reactions which arise from:

- the use of a medicinal product within the terms of the marketing authorisation;
- the use outside the terms of the marketing authorisation, including these Special Situations:
 - o overdose - This refers to the administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended



dose according to the authorised product information. Clinical judgment should always be applied.

- o off-label use- This relates to situations where the medicinal product is intentionally used for a medical purpose not in accordance with the authorised product information.
- o misuse - This refers to situations where the medicinal product is intentionally and inappropriately used not in accordance with the authorised product information.
- o abuse - This corresponds to the persistent or sporadic, intentional excessive use of a medicinal product, which is accompanied by harmful physical or psychological effects.
- o medication errors - This refers to any unintentional error in the prescribing, dispensing, or administration of a medicinal product while in the control of the healthcare professional, patient or consumer.
- o occupational exposure - This refers to the exposure to a medicinal product as a result of one's professional or non-professional occupation.

In addition, the following Reports considered as Special Situations (referred hereinafter to as "Special Situation Reports") should be collected and transmitted to Roche as the Market Authorisation Holder:

- Data related to product usage in paediatric population
- Data related to suspected transmission via a medicinal product of an infectious agent
- Suspected Adverse Reaction related to quality defect or falsified medicinal products (whether suspected or confirmed)
- Reports from class action lawsuits

Please note that the following Special Situations Reports should be collected and transmitted to Roche even in the absence of an Adverse Event:

- Data related to product usage during pregnancy or breastfeeding
- Data related to overdose, abuse, misuse, medication error or occupational exposure
- Lack of therapeutic efficacy.

"Affiliates" shall mean a) an organisation, which directly or indirectly controls a Party to this Agreement; b) an organisation, which is directly or indirectly controlled by a Party to this Agreement; c) an organisation, which is controlled, directly or indirectly, by the ultimate parent company of a Party to this Agreement. The term "control" as per a) to c) is defined as owning more than fifty percent (50%) of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization. With respect to Roche the term "Affiliate" shall not include Chugai Pharmaceutical Co., Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan ("Chugai"), unless Roche opts for such inclusion of Chugai by giving written notice to MPP.

"Organisations" shall mean the not-for-profit HIV treatment organisations, including those financed by national governments, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States Presidents Emergency Plan for AIDS Relief, UNITAID, Médecins Sans Frontières, and any other similar organisations identified by MPP and accepted by Roche (such acceptance not to be unreasonably withheld) as the Parties may agree to from time to time.

"Individual Case Safety Report (ICSR)" shall mean the format and content for the reporting of one or several suspected Adverse Reactions to a Product that occur in a single patient at a specific point of time.



"Indication" shall mean Cytomegalovirus ("CMV") infection (including prevention) in relation to HIV therapy.

"Product" shall mean formulated *valganciclovir* manufactured and supplied by Roche under this Agreement.

"Territory" shall mean the developing countries as set forth in Exhibit B.

2. Supply, Distribution and Use of the Product

- 2.1 Roche shall supply Organisations with the Product directly or through a non-profit procurement organisation mutually agreed by the Parties.
- 2.2 Roche has existing or future distribution agreements with third parties in certain countries of the Territory ("Third Party Distribution Countries") relating to the Product. The supply of the Product in the Third Party Distribution Countries is subject to agreement of the distributor to supply the Product to the Organisations for such countries. In such cases, Roche shall use commercially reasonable efforts to (i) procure the agreement of the distributor to allow supply of the Product by Roche to the Organisation directly or (ii) ensure other ways of supply of the Product in their respective Third Party Distribution Country (ies).
- 2.3 The Organisations shall use the Product only
(i) for administration directly to the patient;
(ii) in the Indication;
(iii) as per Product Information/package leaflet delivered to the Organisations; and
(iv) in the Territory.
- 2.4 Upon request of MPP, and if MPP can demonstrate unmet treatment needs in countries of the world outside the Territory, then Roche and MPP will discuss in good faith potential future expansion of the Territory to such countries outside the Territory.
- 2.5 The following function at Roche shall be the contacted:

Sandra Torriani
Demand Manager International Customers
F. Hoffmann-La Roche Ltd, Basel
Building 237/2.17
CH 4303 Switzerland
Phone +41 61 688 9390
Fax +41 61 687 1815
email: Sandra.torriani_cazzato@roche.com

3. Licence to *Saquinavir*

Roche offers to enter into good-faith negotiations with MPP on the licensing of *saquinavir* for use in developing countries. Should MPP identify a significant medical need for *saquinavir*, Roche and MPP shall enter into such negotiations.

4. Quantity

- 4.1 The Organisations will place orders with Roche or a third party distributor designated by Roche, with a copy to MPP, pursuant to this Agreement and Appendix A. The



maximum lead time for each order is three (3) months from the date the order is placed to the date of receipt of the order by the Organisations. For clarity, nothing contained in this Agreement shall be construed as placing an obligation on Organisations to purchase *valganciclovir* exclusively from Roche.

- 4.2 The Parties agree to closely monitor sales volumes in the Territory, and upon such volumes exceeding 500 packs per quarter, the Parties will agree on a rolling 36-month order forecast.

5. Delivery

- 5.1 Unless otherwise specified in writing by an Organisation, Roche may use its reasonable discretion in determining the means of shipment for Products to such Organisation location. Any delivery date quoted for shipment hereunder is intended to be an estimate only.

- 5.2 Roche shall deliver Product to the Organisation CIP (final destination), Incoterms® 2010 (FCA pack price as per Exhibit A + Freight charges + Insurance premium), excluding VAT.

- 5.3 The Organisations shall be exclusively responsible for (i) obtaining necessary import and other licenses, (ii) paying all import and sales taxes (including VAT), insurances, duties and levies under this Agreement and/or (iii) providing documentation, as applicable, that the Organisation is exempt from any such obligations.

6. Permitted Sales

MPP shall ensure that the Organisations have agreed to be bound by the terms of this Agreement. Roche and MPP shall discuss and agree in good faith the addition of further Organisations.

7. Price

Roche shall invoice the Organisation, and the Organisation shall pay Roche the respective unit price for each Product purchased hereunder as set forth on Exhibit A. All invoices shall be payable by Organisation thirty (30) days from receipt of Roche's invoice.

8. Technology Transfer

- 8.1 One (1) year after the Effective Date, Roche and MPP will review the extent of the scale-up of the use of the Product for the Indication within the Territory. At such time, Roche and MPP will enter into good faith negotiations regarding licensing and technology transfer to suitable appropriate third parties in the Territory to ensure supply of low-cost generic *valganciclovir*.

- 8.2 One (1) year after the Effective Date and upon request of MPP, Roche and MPP will enter into good faith negotiations regarding licensing and technology transfer to suitable appropriate third parties in developing countries other than the Territory to ensure supply of low-cost generic *valganciclovir*.



9. Warranty

- 9.1 Roche warrants that it is the owner of the Product without violating or infringing any law, rule, regulation, copyright, patent, trade secret or other proprietary right of any third party. Roche further warrants that Organisations shall obtain good and clear title to the Product, free and clear of all liens, claims, security interests and encumbrances.
- 9.2 Roche further warrants that Product shall be manufactured, sold and packaged in accordance with current Good Manufacturing Practice for Pharmaceutical Products- as specified in the Code of Federal Regulations 21 of the Food and Drug Administration of the U.S.A., and according to the current EU Good Manufacturing Practice of Pharmaceutical Products, or other applicable regulations. Roche further warrants that the Product will conform to the specifications as approved by the U.S. Food and Drug Administration, the European Medicines Agency, or other stringent regulatory authority (defined as members, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use).

In the event any Product delivered to Organisations hereunder does not conform to the above referenced warranties, Roche shall, at Organisations' discretion, either (a) replace such nonconforming product with Product that is conforming, at no additional cost to such Organisation; or (b) refund Organisation the amount paid by Organisation or invoiced to Organisation for such nonconforming product.

10. Disclaimer of Further Warranties

EXCEPT AS SET FORTH IN PARAGRAPH 9, ROCHE PROVIDES NO FURTHER OR ADDITIONAL WARRANTY, REPRESENTATION OR CONDITION OF ANY KIND, EXPRESS OR IMPLIED, BY FACT OR LAW, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

11. Indemnification and Limitation of Liability

- 11.1 Roche shall indemnify and hold MPP, the Organisations and its employees, servants and agents harmless from and against any and all liabilities, claims, demands, actions, suits, losses, damages, costs and expenses (including reasonable attorney's fees and disbursements), based upon any death, actual bodily injury or physical property damage (a) resulting from Roche's manufacture and packaging of Product, or (b) otherwise resulting from Roche's negligence, willful act or omission or material breach of this Agreement; except to the extent caused by MPP' negligence or willful act or omission or its material breach of this Agreement.
- 11.2 MPP shall indemnify and hold Roche and its Affiliates, employees, servants and agents harmless from and against any and all liabilities, claims, demands, actions, suits, losses, damages, costs and expenses (including reasonable attorney's fees and disbursements), based upon any death, actual bodily injury or physical property damage (a) resulting from MPP' handling, storing, use, distribution or sale of the Products, including resulting from MPP' activities for the purpose of which MPP intends to purchase Products, or (b) otherwise resulting from MPP' negligence, willful act or omission or material breach of this Agreement; except to the extent caused by Roche's negligence or willful act or omission or its material breach of this Agreement.



- 11.3 Except for willful misconduct, gross negligence, breach of confidentiality and indemnification obligations as provided hereunder, neither Party shall be liable to the other for any special, indirect or consequential damages whatsoever, however arising, including but not limited to, lost revenue or lost profits hereunder, even if advised of the possibility thereof.
- 11.4 THE MAXIMUM AGGREGATE CUMULATIVE LIABILITY OF ROCHE UNDER THIS AGREEMENT IN RESPECT OF ANY INDEMNIFICATION OR LIABILITY OBLIGATIONS IS EURO FIVE HUNDRED THOUSAND (500'000).
- 11.5 MPP AND ROCHE SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

12. Confidentiality and Publication

- 12.1 In the event that Confidential Information is exchanged under this Agreement, each Party shall keep confidential and secret any and all such Confidential Information of the other Party. "Confidential Information" shall consist of products, trade secrets, know-how, proprietary information, formula, processes, techniques and information relating to a Party's past, present and future marketing and research and development activities that are disclosed by a Party or Affiliates to the other Party or its Affiliates. Notwithstanding the foregoing, Confidential Information shall not include:
- i. Information that is now in the public domain or subsequently enters the public domain through no fault of the receiving Party;
 - ii. Information that is presently known or becomes known to the receiving Party from its own independent sources as evidenced by its written records;
 - iii. Information that is received from any third party not under any obligation to keep such information confidential; or
 - iv. Information independently developed by or for a Party hereto by persons who did not access information disclosed by the other Party under this Agreement.
- 12.2 If either Party intends to issue a public statement, press release or other publication ("Publication") concerning this Agreement, it shall submit a draft of such proposed Publication to the other Party at least fourteen (14) days prior to the date such party intends to issue the Publication. After any initial Publication is made, however, each Party may disclose to third parties or make Publications regarding the existence of this Agreement, the identity of the Parties, the terms, conditions and subject matter of this Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.



13. Term

- 13.1 This Agreement shall enter into force on the Effective Date and will expire on July, 1, 2018 (the "Term"), renewable for further periods upon mutual consent of the Parties.
- 13.2 Roche may terminate this Agreement on a country-by-country basis prior to the expiry of the Agreement with ninety (90) day prior written notice if a quality-assured generic source(s) of *valganciclovir* at a comparable or lower cost is available in such country.
- 13.3 In the event of a material breach by either Party of a fundamental obligation imposed by this Agreement and (i) failure to cure such breach within thirty (30) days after written notice of breach is given, or (ii) in the event the nature of the breach is such that it cannot be cured within such period, the breaching Party fails to commence to cure, the non-breaching Party may terminate this Agreement upon written notice to the breaching Party, effective immediately upon the expiration of that thirty (30) day period. Any termination exercised by MPP pursuant to this Section 13.3 shall not affect orders already placed.
- 13.4 Should either Party file a voluntary petition in bankruptcy, is declared bankrupt or make an assignment for the benefit of creditors, become insolvent or subject to receivership or have a receiver in bankruptcy appointed for such Party or its assets, the other Party may elect to terminate this Agreement, without penalty, upon written notice to the other Party, effective immediately. Notwithstanding the foregoing, the Parties shall use commercially reasonable efforts to ensure that supply of *valganciclovir* is not interrupted in the event of a termination under this provision.

14. Pharmacovigilance

The Organisations shall report ICSRs associated with the Product to Roche as the market authorization holder.

15. Governing Law, Dispute Resolution and Jurisdiction

- 15.1 This Agreement shall be governed by and construed in accordance with the laws of Switzerland, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).
- 15.2 In the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below or their designees, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For MPP: Business Development Director
For Roche: Head of Mature Products

- 15.3 The courts of Basel-City shall have exclusive jurisdiction.



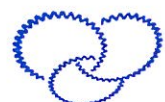
16. Miscellaneous

- 16.1. MPP shall not use the Roche house mark and/or any Roche trademark without the prior written approval of Roche, except as expressly stated in this Agreement.
- 16.2 Roche shall have the right to assign the present Agreement or any part thereof to its Affiliates and any third party without the prior written approval of MPP. MPP shall not have the right to assign the present Agreement or any part thereof to any third party other than Affiliates without the prior written approval of Roche.
- 16.3 No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the MPP legal relationship to Roche under this Agreement shall be that of independent contractor.
- 16.4 If any provision of this Agreement is held invalid or unenforceable by a court of competent jurisdiction, the validity and enforceability of the other provisions of this Agreement will not be affected unless severance of the invalid or unenforceable provision would unreasonably frustrate the purpose of this Agreement. The Parties agree to substitute for any invalid or unenforceable provision a mutually acceptable arrangement which achieve to the greatest extent possible the objectives of the invalid or unenforceable provision.
- 16.5 This Agreement may not be modified, altered, revised or otherwise amended except in writing, identified as such, and signed by an authorized officer of each of the Parties.
- 16.6 The paragraph headings are inserted only as a matter of convenience and for reference, and are in no way intended to define, limit or describe the scope or intent of the particular paragraph to which they refer.
- 16.7 This Agreement may be executed in two or more counterparts, each of which together shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 16.8 All notices under this Agreement must be in writing and mailed or delivered to the following:

MPP: Medicines Patent Pool
General Counsel
Chemin Louis Dunant 15, 2eme étage
1202 Geneva
Switzerland

Roche: F. Hoffmann-La Roche Ltd
Group Legal Department
Grenzacherstrasse 124
CH-4070 Basel
Switzerland

If either or both of the Parties employ purchase orders or acknowledgment of order forms or other commercial forms in administering this Agreement, none of the terms and conditions printed or otherwise appearing on such forms shall be applicable except to the



extent that they reflect the quantity, destination, mode of shipment, or timing of deliveries as set forth in this Agreement.

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IN WITNESS WHEREOF, MPP and Roche, each by duly authorized officers, have entered into this Agreement as of the Effective Date.

Medicines Patent Pool

By: 

Name: Greg Perry

Title: Executive Director

Date: 23 July 2013



F. Hoffmann-La Roche Ltd

By: 

Name: Daniel O'Day

Title: COO Pharma

Date: 24 July 2013

By: 

Name: Dr. Melanie Frey Wick

Title: Legal Counsel

Date: 24 July 2013

EXHIBITS

Exhibit A- Product Requirements and Pricing Schedules

Exhibit B- Territory



Exhibit A

Product Requirements and Agreed Price

Product Description/Pack Size:

Valganciclovir F.C. TABLETS 450 MG 60

Quantity required:

Organisation will place orders of not less than 40 packs per order per country and Organisation for the entire duration of the Term. For order quantities greater than 40 Organisation will accept additional lots, as required by lot size.

Agreed Price: 250 CHF / pack - FCA (Airport Basel) Incoterms® 2010; excluding VAT.



Exhibit B
Territory



<ol style="list-style-type: none"> 1. Afghanistan 2. Albania 3. Algeria 4. American Samoa 5. Angola 6. Antigua and Barbuda 7. Argentina 8. Armenia 9. Azerbaijan 10. Bangladesh 11. Belarus 12. Belize 13. Benin 14. Bhutan 15. Bolivia 16. Bosnia and Herzegovina 17. Botswana 18. Burkina Faso 19. Burundi 20. Cambodia 21. Cameroon 22. Cape Verde 23. Central African Republic 24. Chad 25. Chile 26. China 27. Comoros 28. Congo, Dem. Rep. 29. Congo, Rep. 30. Costa Rica 31. Cote d'Ivoire 	<ol style="list-style-type: none"> 32. Cuba 33. Djibouti 34. Dominica 35. Dominican Republic 36. Ecuador 37. Egypt, Arab Rep. 38. El Salvador 39. Equatorial Guinea 40. Eritrea 41. Ethiopia 42. Fiji 43. Gabon 44. Gambia, The 45. Georgia 46. Ghana 47. Grenada 48. Guatemala 49. Guinea 50. Guinea-Bissau 51. Guyana 52. Haiti 53. Honduras 54. India 55. Indonesia 56. Iran, Islamic Rep. 57. Iraq 58. Jamaica 59. Jordan 60. Kazakhstan 61. Kenya 62. Kiribati 	<ol style="list-style-type: none"> 63. Korea, Dem. Rep. 64. Kosovo 65. Kyrgyz Republic 66. Lao PDR 67. Latvia 68. Lebanon 69. Lesotho 70. Liberia 71. Libya 72. Lithuania 73. Macedonia, FYR 74. Madagascar 75. Malawi 76. Malaysia 77. Maldives 78. Mali 79. Marshall Islands 80. Mauritania 81. Mauritius 82. Micronesia, Fed. States 83. Moldova 84. Mongolia 85. Montenegro 86. Morocco 87. Mozambique 88. Myanmar 89. Namibia 90. Nepal 91. Nicaragua 92. Niger 93. Nigeria 	<ol style="list-style-type: none"> 94. Pakistan 95. Palau 96. Panama 97. Papua New Guinea 98. Paraguay 99. Peru 100. Philippines 101. Rwanda 102. Samoa 103. Sao Tome and Principe 104. Senegal 105. Serbia 106. Seychelles 107. Sierra Leone 108. Solomon Islands 109. Somalia 110. South Africa 111. South Sudan 112. Sri Lanka 113. St. Lucia 114. St. Vincent and the Grenadines 115. Sudan 116. Suriname 117. Swaziland 118. Syrian Arab Republic 119. Tajikistan 120. Tanzania 121. Thailand 122. Timor-Leste 123. Togo 	<ol style="list-style-type: none"> 124. Tonga 125. Tunisia 126. Turkmenistan 127. Tuvalu 128. Uganda 129. Ukraine 130. Uruguay 131. Uzbekistan 132. Vanuatu 133. Venezuela, RB 134. Vietnam 135. West Bank and Gaza 136. Yemen, Rep. 137. Zambia 138. Zimbabwe
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