

## AGREEMENT

This amended and restated agreement (the "Agreement") dated July 1, 2018 retroactively ("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, having an office and place of business at Rue de Varembe 7, 1202 Geneva, Switzerland ("MPP").

WHEREAS, MPP and Roche have entered into an agreement on August 5, 2013 ("Original Agreement");

WHEREAS, MPP and Roche wish to amend and restate certain terms of the Original Agreement;

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, 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 ("Chugai") and its subsidiaries or Foundation Medicine, Inc., ("Foundation"), unless Roche opts for such inclusion of Chugai, Foundation and/or their subsidiaries as an Affiliate or Roche by giving written notice to MPP.

"Organisations" shall mean the not-for-profit HIV treatment organisations, National HIV treatment programmes, 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 the 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 functions at Roche and MPP shall be the contacted:

Nicole Steiner  
Order & Distribution Manager Direct Markets F. Hoffmann-La Roche Ltd,  
Building 228/3.30  
CH-4070 Basel, Switzerland  
Phone +41 61 688 8846

email: nicole.steiner@roche.com

Ms Sandra Nobre  
Business Development Director  
Medicines Patent Pool  
Rue de Varembé 7

1202 Geneva  
Phone: +41 79 957 81 71  
email: snobre@medicinespatentpool.org

### **3. Quantity**

- 3.1 The Organisations will place orders with Roche or a third party distributor designated by Roche, with a copy to the Business Development Director of the MPP (details in Section 2.5 above), pursuant to this Agreement. The maximum lead time for each order is three (3) months. Written orders shall be sent not later than two (2) business days prior to the last business day of each calendar month for the order lead time to start by such month's end, otherwise the lead time will be moved to the end of the following month. For clarity, nothing contained in this Agreement shall be construed as placing an obligation on Organisations to purchase *valganciclovir* exclusively from Roche.
- 3.2 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.

### **4. Delivery**

- 4.1 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.
- 4.2 Roche shall deliver Product to the Organisation FCA Basel airport Incoterms® 2010 (FCA pack price as per Exhibit A excluding VAT).
- 4.3 The Organisations shall be exclusively responsible for (i) obtaining the 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.

### **5. 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.

### **6. 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.

## **7. Warranty**

- 7.1 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.
- 7.2 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 the Organisation hereunder does not conform to the above referenced warranties, Roche shall, at the Organisations' discretion, either (a) replace such nonconforming product with Product that is conforming, at no additional cost to such Organisation; or (b) refund the Organisation the amount paid by the Organisation or invoiced to the Organisation for such nonconforming product.

## **8. Disclaimer of Further Warranties**

EXCEPT AS SET FORTH IN SECTION 7, 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.

## **9. Indemnification and Limitation of Liability**

- 9.1 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's negligence or willful act or omission or its material breach of this Agreement.
- 9.2 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's 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.

9.3 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.

9.4 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).

9.5 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.

## **10. Confidentiality and Publication**

10.1 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.

10.2 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.

## 11. Term

- 11.1 This Agreement shall enter into force on the Effective Date and will expire on December, 31, 2020 (the "Term"), renewable for further periods upon mutual consent of the Parties.
- 11.2 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.
- 11.3 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 11.3 shall not affect orders already placed.
- 11.4 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.

## 12. Pharmacovigilance

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

## 13. Governing Law, Dispute Resolution and Jurisdiction

- 13.1 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).
- 13.2 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 Operational Pricing   |
- 13.3 The courts of Basel-City shall have exclusive jurisdiction.

## **14. Miscellaneous**

- 14.1. 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.
- 14.2 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.
- 14.3 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.
- 14.4 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.
- 14.5 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.
- 14.6 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.
- 14.7 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.
- 14.8 All notices under this Agreement must be in writing and mailed or delivered to the following:

MPP:                    Medicines Patent Pool  
                              General Counsel  
                              Rue de Varembé 7  
                              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: Charles Gore

Name: Charles Gore

Title: Executive Director

Date: 7.12.2018



Medicines Patent Pool  
Rue de Varembe 7  
1202 Geneva  
Switzerland

**F. Hoffmann-La Roche Ltd**

By: René Imhof

Name: René Imhof

Title: Head Pricing

Date: 6.12.2018

By: U/R

Name: Dr. Melanie Wick  
Legal Counsel

Title:

## **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 50 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: 200 CHF / pack - FCA (Airport Basel) Incoterms® 2010; excluding VAT

**Exhibit B**  
**Territory**

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
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
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
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
- 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