

**THIS LICENCE AGREEMENT** (this "Agreement") is effective as of the date that it is executed by both Parties (the "Effective Date") and is made

**BETWEEN:**

- (1) **Novartis Pharma AG** ("**Novartis**"), a company incorporated under Swiss law, whose registered office is situated at Lichstrasse 35, Basel, Switzerland; and
- (2) **The Medicines Patent Pool** ("**MPP**"), a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, CH-1202 Geneva

each "Party" and collectively referred to as the "Parties".

**WHEREAS,**

- (A) Novartis holds rights to nilotinib and its pharmaceutically acceptable salts;
- (B) MPP is a non-profit organisation with a mission to improve the health of people by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property to allow for the rapid development and manufacturing of these medicines;
- (C) MPP desires to obtain a freedom- to-operate licence from Novartis under the Manufacturing Patent and the Patents solely to allow it to grant sublicences to the Manufacturing Patent and Patents to qualified third parties only for use and sale of the Product in the Field in the Territory;
- (D) Novartis is willing to grant such a licence provided that such sublicences are in the form of the Sublicence;

**THEREFORE**, the Parties agree as follows:

**1. Definitions**

For the purposes of this Agreement, including the preamble and annexes:

- 1.1. "Affiliate" in relation to a Party, means any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such Party. For the purposes of this definition, "control" means 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" means any period of three months ending on the last day of March or June or September or December;
- 1.3. "Business Day" has the meaning given to such term in the Sublicence;
- 1.4. "Calendar Month" means a period from a specified day in one month to the day numerically corresponding to that day in the following month, less one;
- 1.5. "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31;
- 1.6. "Change in Control" means:
  - i. the acquisition after the Effective Date, directly or indirectly, by any person or entity, of the beneficial ownership of more than fifty percent (50%) of

- the voting share capital of the company or the ability to direct the casting of more than fifty percent (50%) of the votes exercisable by the company;
- ii. a merger, consolidation or other similar transaction involving relevant the company; or
  - iii. the sale, transfer or other disposition (in one transaction or a series of transactions) of all or substantially all of the assets of relevant the company.
- 1.7. “Confidential Information” means 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, the confidential and proprietary information and materials, discoveries, processes, methods, protocols, formulas, reagents, assays, data, results, compositions of matter (including compounds), formulations, and any matter relating to, or arising in connection with, this Agreement or a Sublicence or the business or affairs of any of the Parties or their Affiliates. Neither this Agreement nor any Sublicence shall be considered as Confidential Information;
- 1.8. “Field” has the meaning given to such term in the Sublicence;
- 1.9. “Good Distribution Practice” or “GDP” means all applicable then-current good distribution practice standards that promote the safety and integrity of the pharmaceutical supply chain, including European Commission Directives 2001/83/EC (to combat counterfeit medicines) and 2003/94/EC (good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use), and 2011/62/EU (EU Falsified Medicines Directive) and any implementing acts, delegated acts and guidance thereunder, including the European Commission Guideline 2013/C 343/01 on Good Distribution Practice of medicinal products for human use and the European Commission Guideline 2015/C 95/01 on principles of Good Distribution Practice of active substances for medicinal products for human use, or in any similar set of laws, regulations, rules, or practices that are applicable in countries where development activities are or will be carried out under this Agreement or in parts of the Territory in which Product will be sold, including WHO Guidelines;
- 1.10. “Good Manufacturing Practice” or “GMP” means all applicable then-current principles and guidelines of good manufacturing practice for medicinal products for human use as set forth in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations, including U.S. 21 C.F.R. Sections 210 and 211; EU GMP Directive 2003/94/EC, the EU Guidelines to Good Manufacturing Practice in Volume 4 of the European Commission’s Rules governing medicinal products in the European Union and the current version of the ICH Q7 guideline “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” or in any similar set of laws, regulations, rules, or practices that are applicable in countries where the Product (including DS, DP or any Component of the Product) is or will be Manufactured under this Agreement or areas of the Territory in which the Products are or will be sold, including WHO Guidelines;
- 1.11. “Licensee Selection Process” means the process set out in Clause 3.
- 1.12. “Manufacturing Patent” has the meaning given to such term in the Sublicence;
- 1.13. “Manufacturing Territory” has the meaning given to such term in the Sublicence;

- 1.14. "Non-Territory Patents" has the meaning given to such term in the Sublicence;
- 1.15. "Novartis Trademarks" shall mean trademarks, service marks, design marks, trade dress, trade names, corporate names, logos, domain names, now existing or hereafter adopted or acquired, whether registered or unregistered, including without limitation any applications or registrations therefor, and all goodwill connected with the use thereof and symbolized thereby, that are owned, controlled or used by Novartis or its Affiliates.
- 1.16. "Novartis Trade Dress" shall mean any aspect of the Product labelling, artwork or packaging, and associated marketing and advertising, including, but not limited to fonts, colours and such other distinguishing features and elements comprising the look and feel or overall appearance of the Novartis Products;
- 1.17. "Patents" has the meaning given to such term in the Sublicence;
- 1.18. "Patent Territory" has the meaning given to such term in the Sublicence;
- 1.19. "Products" has the meaning given to such term in the Sublicence;
- 1.20. "Raw Materials" has the meaning given to such term in the Sublicence;
- 1.21. "Relevant Regulatory Authority" has the meaning given to such term in the Sublicence;
- 1.22. "Sublicence" means a licence agreement in the form set out in Schedule 1 hereto;
- 1.23. "Sublicensee" means a Third Party which:
- (A) is selected pursuant to the Licensee Selection Process;
  - (B) in the opinion of MPP and Novartis (both acting reasonably) has demonstrated willingness and capability to (a) manufacture Products in a manner consistent with World Health Organization ("WHO") pre-qualification standards or the standards of any regulatory authority which was a member or observer of the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"), or associated with an ICH member through a legally-binding, mutual recognition agreement, in each case as before 23 October 2015 and GMP; and (b) make Products available according to GDP and on terms for access to Products in the Territory; and
  - (C) has entered into a Sublicence;
- 1.24. "Territory" has the meaning given to such term in the Sublicence;
- 1.25. "Third Party(ies)" means any party other than a Party to this Agreement;
- 1.26. "WIPO Arbitration Rules" means the arbitration rules adopted by the World Intellectual Property Organization from time to time.

## **2. Grant of Licence**

- 2.1 Subject to the terms and conditions of this Agreement, Novartis hereby grants to MPP (a) a non-exclusive, royalty-free, non-transferable, non-sublicensable (except to Sublicensees) licence under the Manufacturing Patent and Patents to enter into Sublicences with Sublicensees to make, have made, export or import the Raw Materials and the Products in the Manufacturing Territory exclusively for Sublicensee's use, offer for sale, sale, or import

of the Product in the Field in the Territory, and (b) a non-exclusive, royalty-bearing, non-sublicensable (except to Sublicensees), non-transferable licence under the Patents to enter into Sublicences with Sublicensees exclusively for Sublicensee's use, offer for sale, sale, export, or import of the Product in the Field in the Patent Territory, as set out in the Sublicence as attached as Schedule 1 of this Agreement. MPP shall request from each Sublicensee the royalties (as defined in the Sublicence Agreement) to be paid in accordance with the requirements of applicable Sublicence Agreement. Royalties shall be paid for the Patent Territory only, and such royalties shall be re-invested into the ATOM coalition, as described in further details in the ATOM coalition frame agreement.

- 2.2 No rights are hereby granted for any other purpose and MPP agrees that it will not use or exploit the Manufacturing Patent or the Patents itself or grant sublicences or other rights thereto: (i) to entities other than Sublicensees; and/or (ii) other than in the form of the Sublicence.
- 2.3 MPP will coordinate the Licensee Selection Process as described below and the subsequent execution of Sublicences between MPP and Sublicensees.
- 2.4 No rights in any Novartis Trademarks or Novartis Trade Dress are granted to MPP or Sublicensees under this Agreement.
  - (A) MPP shall require that Sublicensees do not, appropriate or otherwise use, apply to register or register any Novartis Trademarks or Novartis Trade Dress on or in connection with the Products anywhere in the world, including without limitation in connection with any sale, distribution, promotion, or marketing of the Product.
  - (B) MPP will require that a complete description of any trademark to be used by Sublicensees in connection with the sale of the Products in the Territory shall be submitted to MPP to be transmitted to Novartis for Novartis's written approval prior to use or filing an application to register such trademark or trade dress. Such written approval shall be given within thirty (30) days following receipt by Novartis from MPP of all relevant documentation necessary to consider the Sublicensee's request. Such approval may be withheld if the subject trademark is determined by Novartis, in its sole discretion, to be identical or confusingly similar to any Novartis Trademark or Novartis Trade Dress; provided, however, that any such approval shall not waive any rights of Novartis or its Affiliates with respect to the Novartis Trademarks.
  - (C) In addition to the foregoing, for the avoidance of doubt, MPP shall require that Sublicensees do not: (a) register or, in connection with the sale of any Products, use any trademark, trade name or trade dress which is identical to or confusingly similar (as Novartis shall determine in its sole discretion) to any Novartis Trademark or Novartis Trade Dress; (b) use trade dress, packaging (both internal and external) or labelling which is the same as or similar (as Novartis shall determine in its sole discretion) to that of Novartis or any Affiliate of Novartis in connection with the sale of any Products; or (c) give the impression to the public, to physicians or to the trade that the Products are manufactured by, or in any way connected with, Novartis or any of its Affiliates.
  - (D) Notwithstanding the foregoing, in reviewing and/or granting approval to any Sublicensee for use of any trademark and trade dress in connection with the sale of any Products, MPP agrees that Novartis shall have no obligation to (i) assess the availability or validity of, any proposed trademark or trade dress; (ii) determine the ability of the Sublicensee to use or register any proposed trademark or trade dress; or (iii) determine whether the proposed trademark or trade dress is the same or similar to any other trademark or trade dress of any party, including but not limited to the Sublicensee or any other MPP Licensee in connection with any products,

including the licensed Products. Novartis shall have no liability to MPP, Sublicensee or any other party, for the use or registration of any trademark or trade dress that is the same or similar to that used by Sublicensee or another MPP Licensee.

### **3. Licensee Selection Process**

3.1 Promptly after the Effective Date (and in any event within sixty (60) days of the Effective Date), MPP will identify proposed sublicensees who have:

- (A) demonstrated possession of adequate infrastructure and capabilities to enable the Sublicensee to distribute and supply Product to every country in the Territory under GDP;
- (B) production facilities operating under current Good Manufacturing Practice;
- (C) adequate, ESG, health and safety measures in place;
- (D) undergone and passed an anti-bribery and corruption assessment in accordance with agreed criteria for assessing anti-bribery and corruption to ensure compliance with applicable anti-corruption laws; and
- (E) undergone and passed export controls and trade compliance assessment in accordance with agreed criteria for assessing export controls and trade compliance.

3.2 During the Licensee Selection Process, MPP shall keep Novartis informed of the proposed Sublicensees and shall upon completion of the Licensee Selection Process promptly notify Novartis in writing of the entities MPP proposes to become the Sublicensees. Novartis shall within thirty (30) Calendar Days of such notification (acting reasonably) either approve or reject one or more of the proposed Sublicensees. For the avoidance of doubt if the proposed Sublicensee intends to use subcontractors including for supply of active ingredients, such subcontractor shall be approved by both MPP and Novartis as part of the Licensee Selection Process.

3.3 MPP shall not authorize or agree to any amendments to the terms of the Sublicense as set out in Schedule 1, whether before or after the execution of such Sublicense, without Novartis's express prior consent in writing, signed by or on behalf of Novartis.

3.4 Novartis shall provide to any Sublicensee such consents which it has the legal capacity to give as are reasonably necessary to enable such Sublicensee to perform its obligations under the Sublicense.

### **4. Reporting**

Within 90 days after the end of each Agreement Quarter, MPP shall deliver a written report to Novartis consolidating the contents of all reports provided to MPP by each Sublicensee and setting out on a country-by-country, Sublicensee-by-Sublicensee and Product-by-Product basis in the Manufacturing Territory and Territory:

- i. the total amount of Products sold and/or supplied by each Sublicensee on a country-by-country and pack type-by-pack type basis under the Sublicenses for the immediately preceding Agreement Quarter incl. the royalty paid by the

Sublicensee to be reinvested into the ATOM coalition.

- ii. information on any regulatory activities including pharmacovigilance information as reported to MPP in accordance with each Sublicence;
- iii. anti-bribery, environmental social governance and export control compliance.

**5. Regulatory Waiver**

Novartis will as reasonably requested provide the Sublicensee with applicable regulatory exclusivity waivers, to the extent required by the Relevant Regulatory Authorities for national registration in the Territory of the Products.

**6. Sublicence Compliance Monitoring - Audits**

MPP shall, using all reasonable care, diligence and skill, actively monitor each Sublicensee's compliance with the terms of its Sublicence, including:

- (A) procuring that all Sublicensees provide the sales and royalty reports referred to in the Sublicence in a timely manner and in accordance with the terms of the Sublicence. If, notwithstanding MPP's efforts, a Sublicensee does not provide a sales report referred to in the Sublicence within five (5) Business Days after the required ten (10) Business Day period under the terms of the Sublicence, MPP shall notify Novartis of the same and provide details of its efforts to procure such sales report to date;
- (B) procuring that all Sublicensees provide the regulatory reports referred to in the Sublicence in a timely manner and in accordance with the terms of the Sublicence. If, notwithstanding MPP's efforts, a Sublicensee does not provide such a regulatory report, MPP shall notify Novartis of the same and provide details of its efforts to procure such regulatory report to date; and
- (C) fully exercising the audit right set out in the Sublicence at MPP's or Novartis own cost as soon as MPP or Novartis has reasonable cause to believe an audit is necessary.

**7. Liability and Indemnity**

7.1 MPP undertakes in respect of any and all losses, claims, liabilities, costs, awards, fines, penalties, damages and expenses including, legal costs and other professional expenses of any nature whatsoever and whether or not reasonably foreseeable or avoidable ("Losses") incurred by Novartis and/or its Affiliates arising out of, or in connection with any claim by a Third Party relating to:

- (A) any breach by the Sublicensees that causes or results into a breach by MPP of any provisions of this Agreement;
- (B) any breach by the Sublicensees of any provisions of the Sublicence;
- (C) any possession, manufacture, sale, use or other disposition of any Product by the Sublicensee;
- (D) any negligence or wilful misconduct by or on behalf of Sublicensee;

to: (i) provide Novartis with prompt written notice of such Third Party claims or potentials for Third Party claims; and (ii) grant Novartis the right to control the defence or negotiation

of settlement of such Third Party claims and/or Sublicensee breaches; and (iii) to grant Novartis the exclusive right to claim Losses from the Sublicensee relating to breach of the Sublicence Agreement, and (iv) make available all reasonable assistance which is reasonably requested by Novartis in defending any claims.

- 7.2. MPP undertakes to indemnify, defend and hold harmless Novartis and its Affiliates in respect of any and all losses, claims, liabilities, costs, awards, fines, penalties, damages and expenses including, legal costs and other professional expenses of any nature whatsoever and whether or not reasonably foreseeable or avoidable ("Losses") incurred by Novartis and/or its Affiliates arising out of, or in connection with any claim by a Third Party relating to:
- (A) any breach by MPP of any provisions of this Agreement;
  - (B) any negligence or wilful misconduct by or on behalf of MPP; and/or
- except to the extent arising or resulting from Novartis's negligence or wilful misconduct.
- 7.3. If Novartis exercises its rights under Clause 7.2, Novartis shall: (i) provide MPP with prompt written notice of such Third Party claims; and (ii) grant MPP the right to control the defence or negotiation of settlement of such Third Party claims (except to the extent such claims relate to the validity or enforcement of the Manufacturing Patent, the Patents or Non-Territory Patents); and (iii) make available all reasonable assistance which is reasonably requested by MPP in defending any claims.
- 7.4. Novartis will not be liable to MPP or any Sublicensee for any Losses incurred by MPP or a Sublicensee as a result of: (i) MPP's exercise of the rights granted to it under this Agreement; or (ii) a Sublicensee's exercise of the rights granted to it under a Sublicence, in both cases including any Losses in relation to any infringement of the intellectual property rights of any Third Party.
- 7.5. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES REGARDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF INTELLECTUAL PROPERTY OR OTHER THIRD PARTY RIGHTS, VALIDITY OR ENFORCEABILITY OF INTELLECTUAL PROPERTY RIGHTS, THE GRANT OF ANY PENDING PATENT APPLICATIONS, OR RELEVANCE OF THE MANUFACTURING PATENT OR THE PATENTS TO THE PRODUCTS, ARE MADE OR GIVEN BY OR ON BEHALF OF NOVARTIS AND, EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.
- 7.6. Novartis did not conduct any studies to determine whether any salt, hydrate or polymorph of nilotinib other than crystal Form B of the monohydrochloride monohydrate salt of nilotinib (active ingredient of Tasigna®) has the same food effect and/or QT prolongation as Tasigna or whether any product containing a form other than the crystal Form B of the monohydrochloride monohydrate salt of nilotinib (active ingredient of Tasigna) can be safely administered to patients by dispersing the content in apple sauce. Novartis reserves the right to share this information with relevant Regulatory Authorities.
- 7.7. Notwithstanding the foregoing, nothing in this Agreement shall limit or exclude the liability of either Party for death or personal injury resulting from negligence or fraud or fraudulent misrepresentation or other matters, the exclusion of liability for which is not allowable under applicable laws.

## **8. Intellectual Property**

- 8.1 Novartis does not transfer to MPP or any Sublicensee any right, title or interest to any inventions, patent applications, patents, trademark applications, trademarks, copyright applications, copyrights or data or any other proprietary rights except as expressly set forth in this Agreement.
- 8.2 Novartis shall have the exclusive right, but shall be under no obligation, to maintain, prosecute, renew, defend or enforce the Manufacturing Patent or any of the Patents. MPP shall have no rights to maintain, prosecute, renew, defend or enforce the Manufacturing Patent or any of the Patents and nor shall it purport to grant any such rights to any Sublicensee or Third Party.

## **9. Compliance**

- 9.1. Each Party agrees that it shall comply fully at all times with all applicable laws and regulations, including but not limited to drugs' safety, pharmacovigilance, anti-corruption laws, and that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or the other Party in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents and any other Third Parties, subject to its control or determining influence, from doing so.
- 9.2. Each Party represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity); and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates. Each Party shall be respectful of its employees' right to freedom of association and shall encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.

## **10. Confidentiality**

- 10.1. Each Party shall hold the Confidential Information disclosed to it under or in connection with this Agreement in strict confidence and shall not use such Confidential Information for any other purpose than the performance of this Agreement.
- 10.2. The Party that releases, exchanges, or discloses Confidential Information (the "Disclosing Party") shall use reasonable efforts to mark such Confidential Information as "Confidential". In the event that Confidential Information is disclosed and not so marked, the receiving Party agrees to treat such information as confidential to the extent that a reasonable person would consider such information to be confidential given the content and circumstances of the disclosure.



- 10.3. A receiving Party shall not disclose any Confidential Information received from the Disclosing Party and/or any of their Affiliates under or in connection with this Agreement, or otherwise developed by any party in the performance of activities in furtherance of this Agreement, except to such of its officers, employees, agents, representatives, Affiliates, advisors, consultants, governing bodies, and potential or actual Sublicensees to whom disclosure is necessary to exercise the Party's rights or perform the Party's obligations under this Agreement, *provided that* (1) any such officers, employees, agents, representatives, Affiliates, advisors, consultants, governing bodies, and potential or actual Sublicensees is bound by written obligations of confidentiality and non-use (i) at least as restrictive as those set forth in this Clause 10, and (ii) enforceable by the Disclosing Party and (2) the receiving Party remains liable for the compliance of such officers, employees, agents, representatives, Affiliates, advisors, consultants, governing bodies, and potential or actual Sublicensees with such obligations .
- 10.4. The obligations in Clauses 10.1, 10.2 and 10.3 shall not apply to the following as established by reasonable, contemporaneous written records or other proof:
- (a) information which at the time of disclosure is in the public domain; or
  - (b) information which, after its disclosure, becomes part of the public domain by publication or otherwise part of the public domain after its disclosure, except by breach of this Agreement; or
  - (c) information that a Party can demonstrate was lawfully possessed by it prior to disclosure under or in connection with this Agreement; or
  - (d) information that a Party receives from a Third Party who had no obligation, both legal and contractual, to the Disclosing Party (or Novartis or its Affiliates where the Confidential Information relates to or belongs to Novartis or its Affiliates) not to disclose such information to others; or
  - (e) information a Party is required by law to disclose, provided that the other Party is promptly notified of any such requirement; or
  - (f) information which is independently developed by the receiving Party or its Affiliates who had no knowledge of the Disclosing Party's Confidential Information.
- 10.5. If a receiving Party becomes obligated by law to disclose Confidential Information received under or in connection with this Agreement, or any portion thereof, to any Third Party, governmental authority or court, that Party shall immediately notify the Disclosing Party thereof of each such requirement prior to its disclosure and identify the Confidential Information to be disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and, to the extent necessary, waive the receiving Party's compliance with the confidentiality obligations of this Agreement.
- 10.6. The Parties acknowledge that disclosure of any Confidential Information in breach of this Agreement could give rise to irreparable injury to the non-breaching Party or its Affiliates and that such injury will not be adequately compensated by damages. Accordingly, the non-breaching Party and its Affiliates shall be entitled to the remedies of specific performance and injunctive relief or other equitable relief for any threatened or actual breach of this Clause 10. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.
- 10.7. 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, 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.

10.8. Novartis shall treat any unpublished information disclosed to it under the Sublicence as Confidential Information provided that Novartis shall be entitled to disclose information about the quantities of Products sold or supplied by Sublicensees on an aggregate basis provided such disclosure does not reveal any Confidential Information of any Sublicensee.

## **11. Publicity and external communications**

11.1. Either Party shall be entitled, subject to the other Party's prior written approval, to make an initial press release or public announcement concerning the grant, scope or terms of this Agreement ("Initial Announcement"), or any other publication regarding this Agreement ("Other Announcement") (collectively, "Initial Announcement" and "Other Announcement" is referred to as "Agreement Announcements"). Each Party shall have the right to use the other Party's name and logo in any Agreement Announcement published pursuant to this Clause 11.1. Following the Initial Announcement, neither Party shall be required to seek the other Party's consent to respond to reactive statements to the Initial Announcement, provided such statements are accurate and not misleading and subject to Clause 10.

11.2. Subject to Clauses 10 and 11.1, neither Party shall be required to obtain the other Party's prior consent for any external communication relating to this Agreement. Each Party shall ensure that any external communication relating to this Agreement is accurate and not misleading. Novartis understands and agrees that MPP will publish this Agreement and any Sublicences on MPP's website.

11.3. With exception of any Agreement Announcement or external communication relating to this Agreement permitted in Clauses 11.1 and 11.2 herein, neither Party shall have any right, express or implied, to use in any manner the name (alone or as part of another name) or other designation of the other Party or any other trade name, trademark, logo, marks or other words, names, symbols or devices of the other Party for any purpose in connection with the performance of this Agreement. These restrictions shall not apply to any information required by applicable law to be disclosed to any governmental entity.

11.4. Each Party acknowledges that it is solely responsible and liable for its communications relating to this Agreement, including compliance with any applicable codes, laws and/or regulations.

## **12. Term and termination**

12.1. The term of this Agreement shall commence on the Effective Date and, unless terminated earlier in accordance with its terms, this Agreement shall continue in force, on a country-by-country basis, until the expiration, lapse or invalidation of the last remaining (i) Manufacturing Patent (expiry 4 July 2023) for use, offer for sale, sale, export or import of the Product in the Territory or (ii) or any Patent. Clause 2.1(a) of this Agreement which grants MPP a non-exclusive license under the Manufacturing Patent shall expire upon expiry, lapse, or invalidation of the Manufacturing Patent (expiry 4 July 2023), and clause 2.1(a) of this Agreement which grants MPP a non-exclusive license under the Patents and clause 2.1(b) of this Agreement shall continue in force on a country-by-country basis pursuant to Clause 12.1 after such expiry, lapse or invalidation of the Manufacturing Patent as applicable.

- 12.2. If Novartis believes that MPP is in breach of its obligations hereunder, then Novartis may deliver notice of such breach to MPP, and MPP shall have thirty (30) days from such notice to cure such breach. If MPP fails to cure that breach within such time period, then Novartis may terminate this Agreement effective on written notice of termination to MPP.
- 12.3. Either Party may terminate this Agreement in accordance with Clause 14 "Force Majeure".
- 12.4. Either Party may immediately terminate this Agreement at any time upon written notice to the other Party if:
- (A) such other Party is unable to pay its debts when due or (being a company) is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986; or
  - (B) a petition is filed, a resolution is passed, or an order is made, for or in connection with the winding-up of such other Party other than for the sole purpose of a scheme for a solvent amalgamation of such other Party with one or more other companies or the solvent reconstruction of that other Party, if not dismissed, bonded or stayed within forty-five (45) days, to the extent applicable; or
  - (C) an application is made to court, or an order is made, for the appointment of an administrator, or if an administrator is appointed over such other Party, if not dismissed, bonded or stayed within forty-five (45) days, to the extent applicable; or
  - (D) any event occurs, or proceeding is taken, with respect to the other Party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in this Clause 12.4.

**13. Consequences of expiry and termination**

- 13.1 Upon the expiry of this Agreement, or in the event that this Agreement is terminated earlier in accordance with its terms:
- (A) all rights and licences granted hereunder (including those in Clause 2.1) shall immediately terminate;
  - (B) In the event that this Agreement is terminated by Novartis prior to the expiry of this Agreement, Novartis agrees, that each Sublicence granted and in full force and effect at the time of termination of this Agreement shall be:
    - (1) at the discretion of Novartis, immediately terminated in accordance with its terms if that Sublicensee is in breach of the terms of the Sublicence; or
    - (2) converted into a licence between Novartis and the relevant Sublicensee under the same terms and conditions of the Sublicence, provided that Sublicensee is not in breach of the Sublicence and Sublicensee continues to meet the conditions of clause 3.1 of the Head Licence.
  - (C) each Party shall promptly return or (at the other Party's election) destroy and irretrievably erase all embodiments of the other Party's Confidential Information which are in its power, possession, custody or control; provided, that and each Party may retain one copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes or as

(and to the extent) required by applicable laws and shall continue to comply with the terms of Clause 13 in respect of the same.

- 13.2. Expiration or termination of this Agreement shall not affect any rights or remedies, obligations or liabilities of either Party that have accrued up to the date of termination or which later accrues from an act or omission which occurred prior to the expiration or termination date. Without limiting the foregoing, the provisions of Clauses 7, 8, 10, 11.3, 13, 21 and 24 of this Agreement and the relevant provisions of the Sublicence which are expressly or by implication intended to survive the termination or expiration of the Sublicence shall survive the expiration or termination of this Agreement.

**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 ninety (90) days, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party. Without limitation as to the possible types of Event of Force Majeure, an epidemic, pandemic, government collapse, government-imposed isolation or government-imposed quarantine shall be capable of constituting an Event of Force Majeure, provided that the elements of the definition of that term specified in this Clause 14 are satisfied.

**15. Severability**

- 15.1. 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.
- 15.2. 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.
- 15.3. In the event that the terms and conditions of this Agreement are materially altered as a result of Clauses 15.1 and 15.2, the Parties 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 resolve their dispute in accordance with Clause 24 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.

**16. Entire Agreement**

- 16.1. 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.

16.2. 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.

**17. Notices**

17.1. Any notice given by a Party under this Agreement shall:

- (A) be in writing and in English;
- (B) be signed by, or on behalf of, the Party giving it; and
- (C) and be sent to the relevant Party at the address set out in Clause 17.3.

17.2. Notices may be given, and are deemed received:

- 17.2.1. by hand: on receipt of a signature at the time of delivery;
- 17.2.2. by pre-paid recorded delivery or registered post: on the third (3<sup>rd</sup>) Business Day after posting;

17.3. Notices shall be sent to:

- a. **the Medicines Patent Pool Foundation** for the attention of the General Counsel at: Rue de Varembe 7, CH-1202 Geneva, Switzerland
- b. **Novartis** for the attention of President Global Health with copy to Head Legal Global Health at: Novartis, Lichtstrasse 35, CH-4056 Basel

17.4. The provisions of this Clause 17 shall not apply to notices given in legal proceedings or arbitration.

17.5. Although a notice given under this Agreement is not valid if sent by e-mail, Clause 17 is not intended to prohibit the use of e-mail for day-to-day operational communications between the Parties, including where this Agreement requires written approval by a Party.

**18. Assignment and Sub-Contracting**

18.1. Neither this Agreement nor any interest arising out of or under this Agreement shall be assignable by either Party, without first obtaining the written consent of the other Party, except that Novartis shall be entitled without consent to assign this Agreement to an Affiliate and shall inform MPP without undue delay

18.2. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and permitted assigns.

18.3. Furthermore, in the event of either:

- a) a Change in Control; or

- b) the license, transfer, sale, spin-off, split-off or acquisition of the licensed Manufacturing Patent or the Patents, divestment of the Products, or substantial assets owned or controlled by Novartis which are necessary to perform its obligations hereunder, or by a Third Party, including as a result of a Change in Control;

18.4. Novartis will ensure that such licensee, purchaser, transferee, acquirer or successor of the Manufacturing Patent or the Patents and Novartis's assets agrees to be bound by the terms of this Agreement, in a written from agreement acceptable to MPP.

18.5. Neither Party shall be entitled to subcontract any of its rights or obligations under this Agreement provided however that each Party shall have the right to engage professional agents, advisors and/or consultants in relation to performance of this Agreement.

**19. Costs**

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

**20. 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 each of the Parties.

**21. 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.

**22. No Agency**

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties, nor constitute either Party as the agent of the other Party.

**23. 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. For the convenience of the Parties, an executed copy of this Agreement may be transmitted by email in portable document format (PDF), and such .pdf file shall be deemed equivalent to an original.

**24. Governing Law and Jurisdiction**

- 24.1. This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Switzerland.
- 24.2. Any dispute between the Parties relating to this Agreement will first be submitted in writing by one Party to the other Party's senior executive who shall (unless otherwise notified in writing) be the President Global Health for Novartis and the Executive Director

for MPP, who will promptly meet and confer in an effort to resolve such dispute.

- 24.3. In the event the executives are unable to resolve any dispute within fourteen (14) days after submission to them in accordance with Clause 24.2, then, subject to Clause 24.4, all disputes arising out of or in connection with this Agreement shall be exclusively referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Geneva, Switzerland. The language to be used in the arbitral proceedings shall be English.
- 24.4. Without prejudice to the foregoing in relation to MPP, nothing in this Clause 24 shall prevent or restrict Novartis from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country, to which election the Parties hereby agree.

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

Signed for and on behalf of: **Novartis**

Signature  C1125F28894E4AA...

Name: Thomas Lang

Position: Global Head, Medical Affairs, Access & Partnerships

Date: 18/10/2022

Signed for and on behalf of: **Novartis**

Signature  8F2A48E25CE64AB...

Name: Martin Eschbach

Position: Head, Global Health Legal

Date: 18/10/2022

Signed for and on behalf of:  
**THE MEDICINES PATENT POOL FOUNDATION**

Signature  4713D0F59C13482...

Name: Charles Gore

Position: Executive Director

Date: 18/10/2022

## SCHEDULE 1 : FORM OF SUBLICENCE

### LICENCE AGREEMENT

**THIS LICENCE AGREEMENT** (this “**Agreement**”) is made as of [DATE] (the “**Sublicence Effective Date**”).

#### **BETWEEN:**

**THE MEDICINES PATENT POOL FOUNDATION**, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, CH-1202 Geneva (the “**Licensor**”); and

**[NAME OF LICENSEE]**, a company incorporated under the laws of [*Licensee country of incorporation*] and having its registered office at [*Licensee address*] including its Affiliates (the “**Licensee**”),

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

#### **WHEREAS**

- A. The Licensor has been granted by Novartis the right to sublicense certain patents and patent applications, which relate to nilotinib and its pharmaceutically acceptable salts;
- B. The Licensee desires to obtain a licence from the Licensor to use the aforesaid patents and patent applications 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;
- C. The intent of this Agreement is to provide access to Novartis’ Patents and therefore facilitate access to medicines for people, and not to create any non-patent-related barriers in the Territory;

**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 – and which for Licensee are duly notified in writing to Licensor to be covered by this Agreement.
- 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 “**Approval Date**” shall mean, in relation to each Product, the date on which that Product first receives Regulatory Approval from a Relevant Regulatory Authority.
- 1.4 “**ATOM**” means Access to Oncology Medicines (ATOM) coalition.
- 1.5 “**Business Day**” shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in London.
- 1.6 “**Calendar Month**” shall mean a period from a specified day in one month to the day numerically corresponding to that day in the following month, less one.



- 1.7 **“Calendar Year”** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.8 **“Confidential Information”** means 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, the confidential and proprietary information and materials, discoveries, processes, methods, protocols, formulas, reagents, assays, data, results, compositions of matter (including compounds), formulations, and any matter relating to, or arising in connection with, this Agreement or a Sublicence or the business or affairs of any of the Parties, Novartis, and/or any of their Affiliates. Neither this Agreement nor any Sublicence shall be considered as Confidential Information;
- 1.9 **“Sublicence Effective Date”** shall mean the date of this Agreement.
- 1.10 **“Event of Force Majeure”** shall have the meaning given in Clause 16.
- 1.11 **“Field”** shall mean with respect to a particular Product any use that is consistent with the label approved by Relevant Regulatory Authority in the country of sale for the use of such Product.
- 1.12 **“First Commercial Sale”** shall mean, with respect to the Product, the first sale of such Product by Licensee or its Affiliate to a Third Party or governmental authority in a country following Regulatory Approval for sale of such Product in such country.
- 1.13 **“Good Distribution Practice”** or **“GDP”** means all applicable then-current good distribution practice standards that promote the safety and integrity of the pharmaceutical supply chain, including European Commission Directives 2001/83/EC (to combat counterfeit medicines) and 2003/94/EC (good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use), and 2011/62/EU (EU Falsified Medicines Directive) and any implementing acts, delegated acts and guidance thereunder, including the European Commission Guideline 2013/C 343/01 on Good Distribution Practice of medicinal products for human use and the European Commission Guideline 2015/C 95/01 on principles of Good Distribution Practice of active substances for medicinal products for human use, or in any similar set of laws, regulations, rules, or practices that are applicable in countries where development activities are or will be carried out under this Agreement or in parts of the Territory in which Product will be sold, including WHO Guidelines;
- 1.14 **“Good Manufacturing Practice”** or **“GMP”** means all applicable then-current principles and guidelines of good manufacturing practice for medicinal products for human use as set forth in the current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations, including U.S. 21 C.F.R. Sections 210 and 211; EU GMP Directive 2003/94/EC, the EU Guidelines to Good Manufacturing Practice in Volume 4 of the European Commission’s Rules governing medicinal products in the European Union and the current version of the ICH Q7 guideline “Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients” or in any similar set of laws, regulations, rules, or practices that are applicable in countries where the Product (including DS, DP or any Component of the Product) is or will be Manufactured under this Agreement or areas of the Territory in which the Products are or will be sold, including WHO Guidelines;
- 1.15 **“Head Licence”** shall mean the licence agreement entered into between Novartis and the Licensor dated [to be completed] under which the Licensor’s right to license the Manufacturing Patents and Patents exclusively for use, offer for sale, sale, export or import of the Product in the Field in the Territory under this Agreement is derived.

- 1.16 **“Import Waiver”** shall mean, in respect of a country of the Territory in which, at the time of the intended sale or supply, the Product(s) do(es) not have Regulatory Approval, all export and import licences, authorisations, permits, consents or approvals necessary to supply, sell and/or offer for sale that Product (or those Products) in that country.
- 1.17 **“Improvement”** shall mean any new or improved composition, use, process, Know-How, or manufacturing techniques or any further invention which relate to the composition, use, manufacture or formulation of the Products or Raw Materials or which incorporate or are based on the Manufacturing Patent, the Patents or Confidential Information of Novartis.
- 1.18 **“Know-How”** shall mean any and all confidential and proprietary information and materials, discoveries, processes, methods, protocols, formulas, molecular constructs, reagents, assays, data, results, inventions, improvements, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise, and including any copyrights therein.
- 1.19 **“Manufacturing Patent”** shall mean shall mean the patents as set out in Appendix A1.
- 1.20 **“Manufacturing Territory”** shall mean the country of India and the Patent Territory.
- 1.21 **“Net Sales”** shall mean the net sales recorded by Licensee or any of its Affiliates (excluding, for clarity, any distributors or wholesalers) for any Product sold to Third Parties as determined in accordance with Licensee’s Accounting Standards as consistently applied. The deductions booked on an accrual basis by Licensee and its Affiliates under its Accounting Standards to calculate the recorded net sales from gross sales include the following:
- i. normal trade and cash discounts;
  - ii. amounts repaid or credited by reasons of defects, rejections, recalls or returns;
  - iii. delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions;
  - iv. fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information); and
  - v. other reductions or specifically identifiable amounts deducted for reasons similar to those listed above in accordance with Licensee’s Accounting Standards.

With respect to the calculation of Net Sales:

(a) Net Sales only include the value charged or invoiced on the first arm’s length sale to a Third Party. Sales between or among Licensee and its Affiliates shall be disregarded for purposes of calculating Net Sales;

(b) If a Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Licensee’s Accounting Standards are met;

- 1.22 **“Non-Territory Patents”** shall mean, in relation to those countries falling outside of the Manufacturing Territory and Territory, any patents and patent applications in such countries equivalent to the Patents.
- 1.23 **“Novartis”** shall mean Novartis Pharma AG, a company incorporated under Swiss law, whose registered office is situated at Lichtstrasse 35, 4056 Basel and/or its Affiliates, as the context admits.
- 1.24 **“Novartis Trademarks”** shall mean trademarks, service marks, design marks, trade dress, trade names, corporate names, logos, domain names, now existing or hereafter adopted or acquired, whether registered or unregistered, including without limitation any applications or registrations therefor, and all goodwill connected with the use thereof and symbolized thereby, that are owned, controlled or used by Novartis or its Affiliates.
- 1.25 **“Novartis Trade Dress”** shall mean any aspect of the Product labelling, artwork or packaging, and associated marketing and advertising, including, but not limited to fonts, colours, and such other distinguishing features and elements comprising the look and feel or overall appearance of the Novartis Products;
- 1.26 **“Patents”** shall mean the patents and patent applications as set out in Appendix A2.
- 1.27 **“Patent Territory”** shall mean all those countries as are set out in Appendix A2 hereto.
- 1.28 **“Product(s)”** shall mean any pharmaceutical product containing nilotinib or a pharmaceutically acceptable salt thereof as the sole active pharmaceutical ingredient.
- 1.29 **“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 Clause 2.1.
- 1.30 **“Regulatory Approval”** shall mean, in relation to each country of the Territory and each Product, the receipt of a marketing authorisation associated with that Product for that country.
- 1.31 **“Relevant Regulatory Authority”** shall mean (i) in relation to a particular country in the Territory, any applicable federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Products in that country, or (ii) WHO pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).
- 1.32 **“Royalty Term”** shall have the meaning given in Clause 9.2.
- 1.33 **“Stringent Regulatory Authority”** shall a regulatory authority which is: (a) a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or (b) an ICH observer, being the European Free Trade

Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

- 1.34 “**Territory**” shall mean all those countries as are set out in Appendix C hereto.  
 1.35 “**Third Party(ies)**” shall mean any party other than a Party to this Agreement.  
 1.36 “**WHO**” shall mean the World Health Organization.  
 1.37 “**WIPO Arbitration Rules**” shall mean the arbitration rules adopted by the World Intellectual Property Organization from time to time.

## 2 GRANT OF SUBLICENCE

- 2.1 Subject to the terms and conditions of this Agreement (including without limitation Clauses 2.3, 2.4, and 2.5) and to the extent to which the Licensor has the right to grant a licence in respect of the Manufacturing Patent and the Patents, the Licensor hereby grants to the Licensee (a) a non-exclusive, royalty-free, non-sublicensable, non-transferable licence under the Manufacturing Patent and Patents to make, have made, export or import the Raw Materials and the Products in the Manufacturing Territory exclusively for Licensee’s use, offer for sale, sale, or import of the Product in the Field in the Territory, and (b) a non-exclusive, royalty-bearing, non-sublicensable, non-transferable licence under the Patents exclusively for Licensee’s use, offer for sale, sale, export, or import of the Product in the Field in the Patent Territory.
- 2.2 Notwithstanding anything contained in this Agreement, nothing in this Agreement shall be construed to prevent the Licensee from engaging in any activities inside or outside of the Manufacturing Territory and Territory that would not infringe a Manufacturing Patent, Patent or Non-Territory Patent granted and in force in such country.
- 2.3 **[NAME OF LICENSEE]** undertakes to pay the royalties for the Patent Territory to Licensor as further set out in Appendix D.
- 2.4 If **[NAME OF LICENSEE]** wishes to involve any of its Affiliates in the performance of the Agreement, prior to doing so, **[NAME OF LICENSEE]** shall notify in writing the Licensor of the entity’s name and provide appropriate supporting documents evidencing that the entity is an Affiliate of **[NAME OF LICENSEE]** . **[NAME OF LICENSEE]** shall ensure that such Affiliate agrees in writing to be bound by the terms of this Agreement prior to its performance. The Licensor shall notify in writing Novartis of **[NAME OF LICENSEE]**’s Affiliates, if any, as soon as possible but no later than ten (10) Business Days for every Affiliate.
- 2.5 The Licensee’s licence to have manufactured by Third-Parties, listed in Appendix B, Raw Materials and Products in accordance with Clause 2.1 shall be limited solely to manufacture on behalf of the Licensee of (i) Raw Materials for supply solely to the Licensee for Licensee’s use and sale of the Product in the Field in the Territory and (ii) Products for supply solely to the Licensee for its use and sale in the Field in the Territory. Clause 2.1 shall not be construed as conferring any right for a Third Party to manufacture Raw Materials and/or Products for its own development, use, or sale of the Raw Materials and/or Products inside or outside of the Territory, for supply of the Raw Materials and/or Products to the Licensee and/or an Affiliate for any use or sale outside of the Field or outside of the Territory, or for supply of the Raw Materials and/or Products to any entity other than the Licensee.

- 2.6 No supplies prior to regulatory approvals. Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or otherwise supply a Product in a country of the Territory prior to:

A. Regulatory Approval in that country, unless the sale or supply is made pursuant to an Import Waiver; and

B. WHO prequalification or Stringent Regulatory Authority approval, or through any provisional authorizations available through WHO or a Stringent Regulatory Authority.

### **3 QUARTERLY REPORTS**

- 3.1 Within 10 Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a written quarterly report, in a format to be indicated by MPP, on:

A. all Products (in terms of smallest units and patient packs for each formulation) on a country-by-country basis sold or supplied by the Licensee under this Agreement during such Agreement Quarter including royalties due as per Appendix D; and

B. all regulatory activities regarding the Products in the Territory in relation to that Agreement Quarter i.e. (a) the regulatory filing status and plan for every Product in the Territory, and (b) a list of the countries in the Territory in which applications for Regulatory Approval have been filed and/or Regulatory Approvals have been obtained for any Product; and

C. Products' development timelines and the status of development including the Improvements, if any; and

D. environmental social governance, anti-bribery and trade compliance

- 3.2. The Parties agree to confer on a quarterly basis regarding such reports.

- 3.3. The Licensor agrees that information contained in quarterly and other such reports shall be treated as Confidential Information.

### **4 DEVELOPMENT AND REGISTRATION**

- 4.1 As of the Sublicense Effective Date and subject always to Novartis's retained rights to the Manufacturing Patent and the Patents (and those of its licensees), the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation of the Products to be sold or supplied by the Licensee in the Field in the Territory under this Agreement.

- 4.2 The Licensee agrees that it will manufacture and distribute Raw Materials and Product pursuant to this Agreement in full compliance with (i) WHO pre-qualification standards; (ii) GMP and GDP and (ii) the standards of any Stringent Regulatory Authority. Where such standards are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and

if applicable.

- 4.3 The Licensee shall obtain from the relevant authorities in each country of the Territory and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorisations relating to the importation, manufacture and sale of the Products (including but not limited to Import Waivers where applicable) which are necessary to enable the Products to be sold or supplied in each country of the Territory in accordance with this Agreement.
- 4.4 Licensee shall file for WHO Pre-qualification or any Stringent Regulatory Authority approval as soon as possible and in any event not later than within 36 months from the Sublicense Effective Date in each case using the fastest approval route possible and will diligently pursue such applications following submission.
- 4.5 The Licensee shall file for Regulatory Approval for the Product before the Relevant Regulatory Authority in each country of the Territory as soon as possible and in any event not later than 36 months from the Sublicense Effective Date and will diligently pursue such applications following submission.
- 4.6 If the Licensee sells, supplies or otherwise disposes of any Product in the Territory but has not obtained the necessary approvals as per this Agreement, the Licensor shall be entitled to immediately terminate this Agreement by providing written notice to the Licensee.

## **5 SUPPLY AND DISTRIBUTION**

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

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

- 6.1 Each Party shall hold the Confidential Information disclosed to it under or in connection with this Agreement in strict confidence, and shall not use such Confidential Information for any other purpose than the performance of this Agreement.
- 6.2 The Party that releases, exchanges, or discloses Confidential Information (the "Disclosing Party") shall use reasonable efforts to mark such Confidential Information as "Confidential." In the event that Confidential Information is disclosed and not so marked, the receiving Party agrees to treat such information as confidential to the extent that a reasonable person would consider such information to be confidential given the content and circumstances of the disclosure.
- 6.3 Neither Party shall disclose any Confidential Information received from the other Party (or Novartis and/or any of their Affiliates where applicable) under or in connection with this Agreement, or otherwise developed by any party in the

performance of activities in furtherance of this Agreement, except to such of its officers, employees, agents, representatives, Affiliates, advisors and consultants, governing bodies (and in the case of the Licensor to Novartis and/or any of its Affiliates) to whom disclosure is necessary to exercise the Party's rights or perform the Party's obligations under this Agreement (and in the case of the Licensor, under the terms of the Head Licence); *provided that* (1) any such officers, employees, agents, representatives, Affiliates, advisors and consultants, governing bodies (and in the case of the Licensor to Novartis and/or any of its Affiliates) is bound by written obligations of confidentiality and non-use (i) at least as restrictive as those set forth in this Clause 6 and (ii) enforceable by the Disclosing Party (and where the Confidential Information belongs or relates to Novartis or its Affiliates, enforceable by Novartis) and (2) the receiving Party remains liable for the compliance of such officers, employees, agents, representatives, Affiliates, advisors and consultants, governing bodies (and in the case of the Licensor to Novartis and/or any of its Affiliates) with such obligations.

- 6.4 The obligations in Clauses 6.1, 6.2 and 6.3 shall not apply to the following as established by reasonable, contemporaneous written records or other proof:
- (a) information which at the time of disclosure is in the public domain; or
  - (b) information which, after its disclosure, becomes part of the public domain by publication or otherwise part of the public domain after its disclosure, except by breach of this Agreement; or
  - (c) information that a Party can demonstrate was lawfully possessed by it prior to disclosure under or in connection with this Agreement; or
  - (d) information that a Party receives from a Third Party who had no legal or contractual obligation to the Disclosing Party (or Novartis or its Affiliates where the Confidential Information relates to or belongs to Novartis or its Affiliates) not to disclose such information to others; or
  - (e) information a Party is required by law to disclose, provided that the other Party is promptly notified of any such requirement; or
  - (f) information which is independently developed by the receiving Party or its Affiliates who had no knowledge of the Disclosing Party's Confidential Information.
- 6.5 If a receiving Party becomes obligated by law to disclose Confidential Information received under or in connection with this Agreement, or any portion thereof, to any Third Party, governmental authority or court, that Party shall immediately notify the Disclosing Party of each such requirement prior to its disclosure and identify the Confidential Information to be disclosed so that such Disclosing Party (or Novartis or its Affiliates where the Confidential Information relates to or belongs to Novartis or its Affiliates) may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and, to the extent necessary, waive the receiving Party's compliance with the confidentiality obligations of this Agreement.
- 6.6 The Parties acknowledge that disclosure of any Confidential Information in breach of this Agreement could give rise to irreparable injury to the non-breaching Party or Novartis or its Affiliates and that such injury will not be adequately compensated by damages. Accordingly, the non-breaching Party, and Novartis and its Affiliates where the non-breaching Party is the Licensor and the Confidential Information belongs to Novartis or its Affiliates, shall be entitled to the remedies of specific performance and injunctive relief or other equitable relief for any threatened or actual breach of this Clause 6. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.

- 6.7 All Confidential Information shall remain the property of the Disclosing Party, except for Confidential Information disclosed under or in connection with this Agreement relating to the business or affairs of Novartis and/or any of its Affiliates and Confidential Information disclosed by Novartis and/or its Affiliates under or in connection with this Agreement relating to the Raw Materials or Product, in each case such Confidential Information belongs to and shall remain the property of Novartis and/or its Affiliates. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement, based on the insolvency or bankruptcy of such Party (or based on any other analogous or similar status of that Party under foreign laws), the bankrupt or insolvent Party shall promptly notify the court or other tribunal:
- (a) that Confidential Information remains the property of the Disclosing Party (or Novartis and/or its Affiliates as applicable); and
  - (b) of the confidentiality obligations under this Agreement.
- 6.8 Nothing in this Agreement shall be construed as preventing or in any way inhibiting the Licensor, Licensee or Novartis from complying with statutory and regulatory requirements relating to, or arising out of, its rights under this Agreement.

## **7 PHARMACOVIGILANCE**

- 7.1 Licensee undertakes that it will comply with all applicable laws and regulations regarding the Products in the Territory including without limitation those laws and regulations relating to risk management, drug safety and pharmacovigilance. Licensee undertakes that it will maintain until the termination of this Agreement (or, as applicable, until the rights and obligations intended to survive termination of this Agreement have been fulfilled) pharmacovigilance and risk management systems, procedures and documentation needed to perform and comply with its regulatory obligations and its related obligations under this Agreement.
- 7.2 Licensee will be responsible for fulfilling all pharmacovigilance activities as per the local regulations and requirements for the Products in the Territory and provide Licensor, at Licensor's request, with a report containing information regarding all such activities upon reasonable request by the Licensor.
- 7.3 If Licensee becomes aware of any adverse reaction relating to the Products in connection with this Agreement, Licensee shall inform MPP and Novartis within 5 Business Day of it becoming aware and cooperate with Novartis in fulfilling Novartis's reporting responsibilities under applicable laws and regulations.

## **8 NON-DIVERSION**

- 8.1 Except as provided under this Agreement and to the extent that such restrictions comply with applicable law, the Licensee shall not, directly or indirectly, donate, distribute, sell or supply:
- (a) Products or Raw Materials outside the Territory where there is a Manufacturing Patent or Non-Territory Patent, for the duration of the relevant Manufacturing Patent or Non-Territory Patent; or
  - (b) Products or Raw Material to any Third Party in the Territory that the



Licensee knows, believes or ought reasonably to suspect will sell or supply Products or Raw Material outside the Territory where there is a Manufacturing Patent or Non-Territory Patent, for the duration of the relevant Manufacturing Patent or Non- Territory Patent.

- 8.2 The Licensee shall maintain a quick and efficient batch trace procedure following the GS1 Global Traceability or comparable standards so as to enable the identification and location of Product from individual batches with minimal delay.
- 8.3 If at any time the Licensee becomes aware that it, or a Third Party to which it has sold or supplied Product(s), has sold or supplied Product(s) for use in breach of the terms of this Agreement, the Licensee shall:
- i. immediately notify the Licensor and Novartis in writing, providing details of such breach; and
  - ii. provide to the Licensor and Novartis, within thirty (30) days of such notification, details of a mitigation plan to ensure that such sale or supply in breach of this Agreement is not repeated.

## 9 FINANCIAL PROVISIONS

- 9.1 In consideration of the licenses and rights granted to Licensee hereunder, during the applicable Royalty Term, Licensee will make royalty payments to ATOM recipient of five percent (5%) of aggregate Net Sales of Products in each Calendar Year in the Patent Territory by Licensee or its Affiliates.
- 9.2 Royalties will be payable on a Product-by-Product and country-by-country basis within the Patent Territory from First Commercial Sale of such Product in such country until the earlier of termination of this Agreement according to clause 13.2 or the expiration of the last to expire Patent which covers such Product in such country ("**Royalty Term**"). For the avoidance of doubt, royalties shall be payable only once with respect to the same unit of Product.
- 9.3 Royalties shall be reported pursuant to the terms of Clause 3.1A of this Agreement.
- 9.4 Payment Terms. The royalties shall be paid by the Licensee to a designated nominee of the ATOM coalition in accordance with this Agreement within 30 calendar days from receiving an invoice from MPP in respect of the royalties due for each Agreement Quarter, based on the report produced by Licensee pursuant to Clause 3.1A.

## 10 INTELLECTUAL PROPERTY

- 10.1 If at any time during the term of this Agreement the Licensee (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement, it shall communicate such Improvement to the Licensor and Novartis in full together with all available information concerning the mode of working and using the same. The Licensor and Novartis shall treat this information as Confidential Information.
- 10.2 The Licensee hereby grants to the Licensor and Novartis a perpetual, irrevocable, worldwide, royalty-free, fully paid-up, non-exclusive licence to use any Improvement, Improvement Patent and related Know-How (and shall promptly execute such document as Novartis may reasonably request accordingly). Novartis shall be

entitled to grant sublicences (without further right to sublicense) under such licence only to its:

- Affiliates; and/or
- contract manufacturers, distributors, research collaborators, and service providers solely for development, manufacture, sale, import, export and/or commercialising Novartis products and/or
- purchasers of Novartis' rights in the Product and/or Raw Materials.

10.3 The Licensee shall have no rights in relation to the conduct of any matter relating to the Manufacturing Patent, the Patents or any other patents or patent applications owned or controlled by Novartis, including the filing, prosecution and maintenance thereof.

10.4 If any suit or claim by a Third Party is instituted against the Licensor or the Licensee for patent infringement involving the Products and/or the Raw Materials, the party sued shall promptly notify the Licensor and Novartis in writing. Novartis shall have the sole 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 Novartis and co-operate in any such litigation at Novartis's request and expense.

10.5 Novartis (and in no circumstances the Licensee) shall have the exclusive right, but not obligation, to bring infringement action at its own expense. To the extent Novartis decides not to bring any such infringement action, Novartis shall not be liable to the Licensee in any respect for such decision. The Licensee shall assist Novartis and co-operate in any such litigation at Novartis's request without expense to the Licensee.

## 11 TRADEMARKS

11.1 No rights in any Novartis Trademarks or Novartis Trade Dress are granted to Licensee under this Agreement.

- (A) Licensee shall not appropriate or otherwise use, register to use or register any Novartis Trademarks or Novartis Trade Dress in connection with the Products anywhere in the world, including without limitation in connection with the sale, distribution, promotion, or marketing of the Products.
- (B) A complete description of any trademark or trade dress proposed to be used or registered by Licensee in connection with the sale of the Product in the Territory shall be submitted to MPP for Novartis's written approval prior to use or filing an application to register such trademark. MPP shall promptly review such request and refer it to Novartis.
- (C) Licensee shall provide any additional information required by MPP in relation to such request. The response to Licensee for any request for approval shall be given within thirty (30) days of receipt by Novartis from MPP of all relevant documentation necessary to consider Licensee's request. Such approval may be withheld if the subject trademark is determined by Novartis, in its sole discretion, to be identical to or confusingly similar to any Novartis Trademarks or Novartis Trade Dress; provided, however, that any such approval shall not waive any rights of Novartis or its Affiliates with respect to the Novartis Trademarks or Novartis Trade Dress.
- (D) Notwithstanding the foregoing, in reviewing and/or granting approval to

Licensee for use of any trademark or trade dress in connection with the sale of any Product, Licensee acknowledges and agrees that Novartis shall have no obligation to assess the availability or validity of, or the ability of the Licensee to use, the proposed trademark or trade dress or determine whether the proposed trademark or trade dress is the same or is similar to any trademark proposed to be used by and/or approved by Novartis for use by Licensee or any other MPP Licensee in connection with the Products. Novartis shall have no liability to any party, including the Licensee or any other MPP Licensee, for the use or registration of any trademark, or trade dress that is the same or similar to that of Licensee or any other party.

- (E) In addition to the foregoing, for the avoidance of doubt, Licensee agrees that it shall not or cause any other party to: (i) register apply to register or, in connection with the sale of any Product, use any trademark, logo or trade name which is identical to or confusingly similar (as Novartis shall determine in its sole discretion) to any Novartis Trademark; (ii) use trade dress, packaging (both internal and external) or labelling, advertising or marketing material which is the same as or similar (as Novartis shall determine in its sole discretion) to that of Novartis or any Affiliate in connection with the sale of any Product; or (iii) give the impression to the public, to physicians or to the trade that the Product is manufactured by, or in any way connected with, Novartis or its Affiliates.
- 11.2 Licensee, at its expense, shall be responsible for the selection, registration, maintenance, defence and enforcement of all trademarks 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 trademarks. Nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensee to use the name (alone or as part of another name) or other designation or any other trade name, trademark, logo, or other words, names, symbols or devices owned or licensed by the MPP, Novartis, and/or any of their Affiliates anywhere in the world for any purpose.
- 11.3 If the Licensor and/or Novartis become aware that the Licensee or any party affiliated with the Licensee is in breach of this Clause 11.3, the Licensee shall immediately stop or compel any affiliated party to immediately stop any such use and withdraw any such trademark application and/or registration upon request by the Licensor and/or Novartis.
- 11.4 The Licensee shall ensure that packaging (whether external, intermediate or internal), data sheets and promotional materials for the Products to be sold or otherwise supplied by the Licensee under this Agreement shall carry, to the extent permitted by the applicable law, clear statements in bold type that:
- (a) the Products have been produced under a licence from the Medicines Patent Pool;
  - (b) any other use is not authorised.

## 12 AUDIT

- 12.1 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 in accordance with its Accounting Standards in relation to this Agreement for a period of five (5) years of all quantities of Raw Materials and

Products manufactured, sold and/or supplied including Net Sales and royalties under the licences granted by this Agreement and such information of the type and in sufficient detail at MPP's discretion.

- 12.2 The Licensor and Novartis shall each have the right (and the Licensee shall procure such right), through a certified public accountant or like person appointed by it, to examine such records in order to verify the compliance with this Agreement during regular business hours during the term of this Agreement and for six months after its termination or expiry; provided, however, that such examination:
- (i) shall be at the expense of the person exercising such right (save where such examination reveals a breach of this Agreement by the Licensee, or an underpayment by Licensee of more than five percent (5%) of the total payments due for the applicable audit period is discovered, in which cases the Licensee shall pay for all costs incurred by Novartis and/or the Licensor in carrying out the examination),
  - (j) not take place more often than twice in any Calendar Year and shall not cover such records for more than the preceding five Calendar Years.

### 13 TERM AND TERMINATION

- 13.1 This Agreement shall be deemed to come into effect on the Sublicence Effective Date and shall continue thereafter subject to the further provisions of this Clause 13.
- 13.2 Unless otherwise terminated, this Agreement shall expire, on a country-by-country basis, upon the expiration, lapse or invalidation of the last remaining (i) Manufacturing Patent (expiry 4 July 2023) for use, offer for sale, sale, or import of the Product in the Territory or (ii) any Patent. Clause 2.1(a) of this Agreement which grants the Licensee a nonexclusive license under the Manufacturing Patent shall expire upon expiry, lapse, or invalidation of the Manufacturing Patent (expiry 4 July 2023), clause 2.1(a) of this Agreement which grants MPP a non-exclusive license under the Patents and and clause 2.1(b) of this Agreement shall continue in force on a country-by-country basis pursuant to Clause 13.2 after such expiry, lapse or invalidation of the Manufacturing Patent as applicable.
- 13.3 Save as otherwise provided in this Agreement, if the Licensee breaches any provision of this Agreement and if such breach is material and (i) is incapable of correction; or (ii) is capable of correction but is not corrected within thirty (30) days after the Licensee receives written notice with respect to such default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the party in default. A breach by the Licensee of Clauses 3 and 4 shall be a material breach of this Agreement.
- 13.4 If:
- (a) the Licensee breaches any of the provisions of Clause 8 ;
  - (b) the legal or beneficial ownership or control of the Licensee and/or any of its Affiliates changes in such a manner as Licensor shall in its sole discretion consider significant; or
  - (c) the Licensee repeatedly fails to comply with or to timely provide the Licensor with any report or statement under this Agreement;
  - (d) any time after the second (2<sup>nd</sup>) anniversary of the Sublicence Effective Date and in its reasonable opinion, the Licensor considers that the price(s) at which the Licensee offers the Product(s) for sale in the Territory do(es) not enable sufficient access to Product(s) in the Territory, as determined by the Licensor in its reasonable opinion;

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

- 13.5 The provisions of Clauses 13.4(a), 13.4(b) and 13.4(d) are without prejudice to the Licensor's or Novartis's rights to claim all damage and loss suffered by the Licensor, Novartis and/or any of their Affiliates arising out of, or in relation to, the event giving rise to termination. In respect of such damage or loss under Clauses 13.4 (a), 13.4(b) and 13.4(d) the Licensee hereby agrees to indemnify the Licensor and Novartis subject to the Licensor and Novartis (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.
- 13.6 Either Party may terminate this Agreement with immediate effect by providing a written termination notice to the other Party if, at any time, the other Party shall compound or make arrangements with its creditors or be adjudicated bankrupt or have a receiver appointed over all or any part of its assets or go into liquidation (whether voluntary or otherwise) otherwise than as part of a bona fide amalgamation or reconstruction without insolvency or suffer any insolvency event or analogous process under foreign laws.
- 13.7 Any change in the legal or beneficial ownership or control of the Licensee shall be immediately notified in writing to the Licensor by the Licensee. For the purposes of this Clause 12.7, "control" shall mean the ability of a person, entity or corporation to ensure, whether through ownership of shares or otherwise, that the affairs of a party are conducted in accordance with the wishes of such person, entity or corporation.
- 13.8 If the Licensee fails to file for Regulatory Approval in accordance with Clause 4, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.
- 13.9 Unless notice to the contrary is given by Novartis, this Agreement shall terminate immediately in the event that the Head Licence is terminated or expires. This Agreement shall be converted into a licence between Novartis and the Licensee on the same terms and provisions agreed in this Agreement, provided that the Licensee is not in breach of this Agreement and that Novartis has notified both the Licensor and Licensee of such conversion.
- 13.10 The Licensee may terminate this Agreement at any time by providing thirty (30) days' written notice to the Licensor.

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

- 14.1 Upon termination or expiry of this Agreement, the Licensee shall immediately notify the Licensor and Novartis of the amount of Product the Licensee then has available to it and, provided that such amount is, in the opinion of Novartis, reasonable in all the circumstances, the Licensee shall be permitted to sell that amount of Product in the Territory. This provision shall only apply to the extent that such termination would deprive the Licensee of legal rights with respect to Product and Raw Materials.
- 14.2 Termination or expiry of this Agreement shall not affect those provisions of this Agreement which are expressly or by implication intended to survive the termination or expiration of this Agreement. In addition, any other provisions required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent that such survival is required for

the full observation and performance of this Agreement by the Parties.

- 14.3 Termination of this Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available in law or equity and shall be without prejudice to any rights that any person may have pursuant to this Agreement for antecedent breaches.

## 15 WARRANTIES, INDEMNITIES, COMPLIANCE WITH LAW

- 15.1 Each of the Parties warrants that, to the best of its knowledge and belief:
- (a) it has power to execute and deliver this Agreement and to perform its obligations under it and has taken all action necessary to authorise such execution and delivery and the performance of such obligations; and
  - (b) this Agreement constitutes legal, valid and binding obligations of that Party in accordance with its terms.
- 15.2 The Licensee warrants that the Licensee has independently evaluated any information supplied by the Licensor and Novartis (including, but not limited to, such information related to the Products), as well as the viability of this Agreement, before making its decision to enter into this Agreement and to undertake the commitments and obligations set forth herein.
- 15.3 The Licensee hereby agrees to indemnify the Licensor, Novartis, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgments, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("**Losses**"), that arise in connection with (i) the Licensee's breach of this Agreement; or (ii) the Licensee's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Products manufactured by or on behalf of the Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Clause shall not apply to the extent such Losses arise out of negligence or wilful misconduct by Novartis, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. Novartis shall, or shall procure that the Indemnified Person shall, provide the Licensee with prompt written notice of such claims. Subject to Clause 10, the Indemnified Person and the Licensee will agree on the appropriate party to assume control of the defence or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.
- 15.4 Immediately upon the first administration of a Product to a human in accordance with this Agreement, and for a period of ten (10) 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 Novartis 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.

- 15.5 The Licensee represents and warrants that it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity) and aims to achieve greater equity along those lines in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates.
- 15.6 The Licensee shall be respectful of its employees' right to freedom of association and shall encourage compliance with the standards referred to in Clause 15.5 by any supplier of goods or services that it uses in performing its obligations under this Agreement.
- 15.7 The Licensee shall comply fully at all times with all applicable laws and regulations, including but not limited to drugs' safety, pharmacovigilance, anti-corruption laws, and that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents and any other Third Parties, subject to its control or determining influence, from doing so.
- 15.8 The Licensee shall 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, including without limitation GMP and GDP.
- 15.9 Further, the Licensor warrants that Novartis has warranted in the Head Licence that Novartis did not conduct any studies to determine whether any salt, hydrate or polymorph of nilotinib other than crystal Form B of the monohydrochloride monohydrate salt of nilotinib (active ingredient of Tassigna®) has the same food effect and/or QT prolongation as Tassigna or whether any product containing a form other than the crystal Form B of the monohydrochloride monohydrate salt of nilotinib (active ingredient of Tassigna) can be safely administered to patients by dispersing the content in apple sauce. Novartis reserves the right to share this information with relevant Regulatory Authorities.

## 16 FORCE MAJEURE

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

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

## **17 THIRD PARTY BENEFICIARY**

- 17.1 Novartis and/or any of its Affiliates shall be considered a third-party beneficiary to this Agreement and shall have the right to enforce and rely on the terms of this Agreement. The Licensee expressly agrees that Novartis and/or any of their Affiliates shall be entitled to enforce any of the provisions of this Agreement as if they were named as a party to this Agreement in place of the Licensor.
- 17.2 The rights of the Licensor under this Agreement shall be applicable to Novartis to the same extent as for the Licensor and the Licensor shall exercise such rights on behalf of Novartis if so requested by Novartis.

## **18 SEVERABILITY**

- 18.1 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.
- 18.2 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to the minimum extent necessary to procure conformity with such statute or rule of law.

## **19 ENTIRE AGREEMENT**

- 19.1 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.
- 19.2 Each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of any other party before the date of this Agreement. Each Party waives all rights and remedies which, but for this Clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

## **20 NOTICES**

- 20.1 Any notice given by a Party under this Agreement shall:
- (a) be in writing and in English;
  - (b) be signed by, or on behalf of, the Party giving it; and
  - (c) and be sent to the relevant Party at the address set out in Clause 20.2 .



- 20.2 Notices may be given and are deemed received:
- (a) by hand: on receipt of a signature at the time of delivery;
  - (b) by pre-paid recorded delivery or registered post: on the third (3rd) Business Day after posting;

Notices shall be sent to:

- (a) the Licensor at:

Rue de Varembé 7  
CH-1202 Geneva  
Switzerland,

marked for the attention of General Counsel,

- (b) the Licensee at:

[*Licensee address*],

marked for the attention of [*Licensee contact*],

to Novartis at:

- (c)

Lichtstrasse 35, 4056 Basel

marked for the attention of President Global Health with a copy to Head Legal Global Health

20.3 All references to time are to the local time at the place of deemed receipt.

20.4 The provisions of this Clause 20 shall not apply to notices given in legal proceedings or arbitration. For the avoidance of doubt, and although a notice given under this Agreement is not valid if sent by e-mail, this Clause 20 is not intended to prohibit the use of e-mail for day-to-day operational communications between the Parties, including where this Agreement requires written approval by a Party.

## **21 ASSIGNMENT AND SUB-CONTRACTING**

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

21.2 Save as expressly set out in Clause 2, neither the Licensor nor the Licensee shall be entitled to subcontract any of its rights or obligations under this Agreement.

## **22 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.

## **23 COSTS**

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

## **24 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) Novartis.

Notwithstanding the aforesaid, the Licensor (pursuant to approval from Novartis) shall have the right to amend Appendix A1 and A2 of this Agreement at any time without the Licensee's consent in order to include additional patents in Appendix A1 and A2.

**25 WAIVER**

The rights of each Party and Novartis 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.

**26 NO PARTNERSHIP OR AGENCY**

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties (or between either Party and Novartis), nor constitute either Party as the agent of the other Party (or either Party as the agent of Novartis or Novartis as the agent of either Party).

**27 EXECUTION**

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. For the convenience of the Parties, an executed copy of this Agreement may be transmitted by email in portable document format (PDF), and such .pdf file shall be deemed equivalent to an original.

**28 GOVERNING LAW AND JURISDICTION**

- 28.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Switzerland.
- 28.2 All disputes arising out of or in connection with this Agreement shall be exclusively referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Geneva, Switzerland. The language to be used in the arbitral proceedings shall be English. The foregoing however shall not prevent any Party from seeking and obtaining injunctive relief at any time in any country.
- 28.3 Without prejudice to the foregoing in relation to the Licensee, nothing in this Clause 28 shall prevent or restrict Novartis from electing to bring proceedings in relation to patent infringement or from applying for injunctive relief in any country, to which election the Licensor and the Licensee hereby agree.

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

Signed for and on behalf of:  
**THE MEDICINES PATENT POOL  
FOUNDATION**  
Signature  
Name  
Position  
Date

Signed for and on behalf of:  
**[LICENSEE]**  
Signature  
Name  
Position  
Date

**APPENDIX A1 - MANUFACTURING PATENT**

India Patent No. 237430

**APPENDIX A2 – THE PATENTS AND PATENT TERRITORY**

<i>Country</i>	<i>Patent App No.</i>	<i>Patent No.</i>
<i>Egypt</i>	634/2003	Pending
	PCT/79/2008	Pending
	PCT58/2008	Pending
	PCT/387/2009	Pending
<i>Guatemala</i>	PI-20060315	5486
	PI-20060316	5352
	PI-200900067	5835
<i>Indonesia</i>	W00200500026	ID0019883
	W00200800161	IDP0050718
	W00200900740	ID0034381
	W00201303641	IDP0049864
	W00201201854	IDP0041869
<i>Morocco</i>	PV31809	30807
<i>Pakistan</i>	808/06	142172
	809/06	Pending
	1121/07	143645
	967/2010	143724
<i>Philippines</i>	1-2005-500004	1-2005-500004
	1-2007-502829	1-2007-502829
	1-2007-502744	1-2007-502744
	1-2009-500406	1-2009-500406
	1-2012-500965	1-2012-500965
<i>Tunisia</i>	SN08028	SN08028
	TN/2009.0093	20841

**APPENDIX B – Approved Subcontractors**

**APPENDIX C: “LIST OF COUNTRIES FORMING THE TERRITORY FOR MANUFACTURING PATENT”**

The Territory shall include the foregoing list of low- and middle-income countries (LMICs) as at the Effective Date. In the event that the World Bank changes its own classification of LMICs following the Effective Date, the Parties may, by agreement in writing, amend the Territory accordingly.

India is defined in Appendix A1 as Manufacturing Territory only.

1. BANGLADESH
2. BELIZE
3. BENIN
4. BHUTAN
5. BOLIVIA
6. BURUNDI
7. CAMBODIA
8. CAMEROON
9. CONGO\_BRAZZAVILLE (CONGO, REP.)
10. ETHIOPIA
11. GHANA
12. GUINEA
13. HAITI
14. HONDURAS
15. KENYA
16. KOSOVO
17. LAO PDR
18. MADAGASCAR
19. MALAWI
20. MONGOLIA
21. MOZAMBIQUE
22. NEPAL
23. NICARAGUA
24. PAPUA NEW GUINEA
25. RWANDA
26. SENEGAL
27. TANZANIA
28. TOGO
29. UGANDA
30. ZAMBIA
31. ANGOLA
32. CÔTE D’IVOIRE
33. EGYPT
34. EL SALVADOR
35. GEORGIA
36. GUATEMALA
37. INDONESIA
38. MOROCCO
39. PAKISTAN
40. PHILIPPINES
41. SRI LANKA
42. TAJIKISTAN
43. TUNISIA
44. UZBEKISTAN

**APPENDIX D – FORM OF SALES AND ROYALTY REPORTING**Reporting Template for Royalties to be completed for each Agreement Quarter

Country	Local Currency (LC)	Customer Sector	Net Sales of Product (LC)	Exchange Rate (USD per LC)	Net Sales of Product (USD)	Royalty Rate (%)	Royalties due (USD)
						5%	

Reporting Template for Product to be completed for each Agreement Quarter

Country of Sale	Product Sold	Strength	Formulation	Pack Size	Packs Sold	Country of Manufacture

**AMENDMENT NO. 1**

**("Amendment No. 1")**

**to the Licence Agreement dated as of 18 October 2022**

**between**

- (1) **Novartis Pharma AG** ("Novartis"), a company incorporated under Swiss law, whose registered office is situated at Lichstrasse 35, Basel, Switzerland; and
- (2) **The Medicines Patent Pool** ("**MPP**"), a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, CH-1202 Geneva

Each "Party" and collectively referred to as the "Parties".

THIS AMENDMENT NO. 1, made and entered into this day of 5 July 2024 ("Amendment No. 1 Effective Date") amends the Licence Agreement (hereinafter "Agreement") between Novartis and MPP, which has an effective date of 18 October 2022.

NOW THEREFORE, the Parties hereto agree as follows:

1. This definition of "Third Party(ies)" is amended in its entirety:

1.25. "Third Party(ies)" means any party other than a Party to this Agreement (excluding Approved Local Distributors solely in Clause 7.1, 7.2, and 7.3 of this Agreement )

2. The following definitions are added to the Agreement:

1.27. "Approved Local Distributor" has the meaning given in Clause 18.6.

1.28. "Local Distributor" has the meaning given to such term in the Sublicence.

3. The following is added to Section 2 of the Agreement

2. Grant of License

2.4. (E) **Capsule color.** MPP will require that Sublicensees do not use the colors beige, light brown, yellow, light red, or similar colors for capsules. Furthermore, capsules should not be embossed with the letters, "NVS", "NVR", "TKI", "BCR", "ABL" or any other abbreviation that is similar or identical to any Novartis trademark. Notwithstanding the foregoing, Sublicensees may submit requests to MPP for transmittal to Novartis seeking written approval from Novartis to waive such restrictions on capsule colors only in cases where such request may expedite Products to market and SRA approval has been obtained. Such requests must be submitted prior to use by Sublicensee. Approval by Novartis shall not waive any rights of Novartis or its Affiliates with respect to any Novartis Trademarks or Novartis Trade Dress.

4. The title of Section 18 of the Agreement is replaced in its entirety as follows:

18. **Assignment, Sub-Contracting, and Local Distributors**



5. The following is added to Section 18 of the Agreement.

**18.6 Local Distributors.** Where Product can only be lawfully sold or otherwise supplied in a country of the Territory by a Local Distributor, and the Sublicensee or its approved Affiliate cannot act as such Local Distributor pursuant to Clause 2.6 of the Sublicense Agreement, MPP may submit a written request to Novartis for Novartis's approval for its Sublicensee to use a Third Party that is not an Affiliate as a Local Distributor in such country of the Territory. MPP's request shall be supported by appropriate documentation on (a) the Sublicensee's need to use a Local Distributor and (b) due diligence on the Third Party. Novartis, acting reasonably, shall consider the request and respond within thirty (30) days of receipt of all appropriate supporting documents from the MPP, with an approval or a written statement of why the request is not approved. Any Third Party approved in writing by Novartis pursuant to this Clause 18.6 shall be referred to in this Agreement as an "Approved Local Distributor". The Sublicensee shall have the right, pursuant to the licence granted to it under Clause 2.1(b) of the Sublicense Agreement, to grant a sublicense (without the right to further sublicense) to such Approved Local Distributor, solely to the extent necessary for such Approved Local Distributor to obtain Regulatory Approval and/or sell or otherwise supply the Product in the relevant country of the Territory on behalf of the Sublicensee and subject to the Approved Local Distributor's written agreement to be bound by the terms of the Sublicense Agreement. MPP shall be responsible for obtaining the Approved Local Distributor's written agreement to be bound by the terms of the Sublicense Agreement. Clause 18.6 of this Agreement and Clause 2.6 of the Sublicense Agreement shall not be construed as conferring any right for the Approved Local Distributor or any Third Party to manufacture, distribute or supply Products for its own development, use, or sale of the Products inside or outside the relevant country of the Territory, to manufacture, distribute or supply of the Products to the Sublicensee and/or an Affiliate for any use or sale outside of the Field or outside of the relevant country of the Territory, or to manufacture, distribute or supply of the Products on behalf of any entity other than the Sublicensee. In the event an Approved Local Distributor fails to comply with any terms of this Agreement, Novartis shall have the right to withdraw its approval of such Approved Local Distributor with immediate effect by providing written notice to MPP.

6. This definition of "Third Party(ies)" is amended in its entirety in Schedule 1: Form of Sublicense to the Agreement is replaced in its entirety as follows:

1.35. "**Third Party(ies)**" means any party other than a Party to this Agreement (excluding Approved Local Distributors solely in Clause 1.12 and 1.21 of this Agreement).

7. The definition of "Net Sales" in Schedule 1: Form of Sublicense to the Agreement is replaced in its entirety as follows:

1.21 "**Net Sales**" shall mean the net sales recorded by Licensee or any of its Affiliates (excluding, for clarity, any distributors or wholesalers, other than Approved Local Distributors) for any Product sold to Third Parties as determined in accordance with Licensee's Accounting Standards as consistently applied. The deductions booked on an accrual basis by Licensee and its Affiliates under its Accounting Standards to calculate the recorded net sales from gross sales include the following:

- i. normal trade and cash discounts;
- ii. amounts repaid or credited by reasons of defects, rejections, recalls or returns;
- iii. delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions;
- iv. fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information); and
- v. other reductions or specifically identifiable amounts deducted for reasons similar to those listed above in accordance with Licensee's Accounting Standards.

With respect to the calculation of Net Sales:

- (a) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party. Sales between or among Licensee and its Affiliates shall be disregarded for purposes of calculating Net Sales;
- (b) If a Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Licensee's Accounting Standards are met;
- (c) In case of Clause 2.6, sales or other supply of the Product by the Approved Local Distributors in the relevant country of the Territory shall be on behalf of the Licensee.

8. The following definitions are added to Schedule 1: Form of Sublicense to the Agreement:

- 1.38 "**Approved Local Distributor**" shall have the meaning given in Clause 2.6.
- 1.39 "**Local Distributor**" shall have the meaning given in Clause 2.6.

9. The first paragraph of Clause 2.1 of the Schedule 1: Form of Sublicense to the Agreement is replaced in its entirety as follows:

2.1 Subject to the terms and conditions of this Agreement (including without limitation Clauses 2.3, 2.4, 2.5 and 2.6) and to the extent to which the Licensor has the right to grant a licence in respect of the Manufacturing Patent and the Patents, the Licensor hereby grants to the Licensee (a) a non-exclusive, royalty-free, non-sublicensable, non-transferable licence under the Manufacturing Patent and Patents to make, have made, export or import the Raw Materials and the Products in the Manufacturing Territory exclusively for Licensee's use, offer for sale, sale, or import of the Product in the Field in the Territory, and (b) a non-exclusive, royalty-bearing, non-sublicensable, non-transferable licence under the Patents exclusively for Licensee's use, offer for sale, sale, export, or import of the Product in the Field in the Patent Territory.

10. The following is added to Section 2 of the Schedule 1: Form of Sublicense to the Agreement:

**2.6 Local Distributors.**

The Licensor acknowledges that in some countries of the Territory, for the Product to be lawfully sold or otherwise supplied, Regulatory Approval must be held in the name of a local entity registered in such country ("**Local Distributor**"). Where Product can only be lawfully sold or otherwise supplied in a country of the Territory by a Local Distributor, and an approved Affiliate of the Licensee cannot act as such Local Distributor pursuant to Clause 2.6, the Licensee may submit a written request to the Licensor to use a Third Party that is not an Affiliate as a Local Distributor in such country. Such request shall be supported by appropriate documentation on (a) the need to use a Local Distributor and (b) due diligence on the Third Party. The Licensor, acting reasonably, shall consider the request and respond within forty-five (45) days of receipt of all appropriate supporting documents from the Licensee, with an approval or a written statement of why the request is not approved. Any Third Party approved in writing by the Licensor pursuant to this Clause 2.6 shall be referred to in this Agreement as an "**Approved Local Distributor**". The Licensee shall have the right, pursuant to the licence granted to it under Clause 2.1(b), to grant a sublicense (without the right to further sublicense) to such Approved Local Distributor, solely to the extent necessary for such Approved Local Distributor to obtain Regulatory Approval and/or sell or otherwise supply the Product in the

relevant country of the Territory on behalf of the Licensee and subject to the Approved Local Distributor's written agreement to be bound by the terms of this Agreement. Clause 2.6 shall not be construed as conferring any right for the Approved Local Distributor or any Third Party to manufacture, distribute or supply Products for its own development, use, or sale of the Products inside or outside the relevant country of the Territory, for manufacture, distribute or supply of the Products to the Licensee and/or an Affiliate for any use or sale outside of the Field or outside of the relevant country of the Territory, or for manufacture, distribute or supply of the Products on behalf of any entity other than the Licensee. Licensee shall ensure that Approved Local Distributor complies with all the terms of this Agreement as if it was the Licensee under this Agreement, and Licensee shall be liable for the acts and omissions of such Approved Local Distributor as if such acts and/or omissions were the act and/or omissions of the Licensee. In the event an Approved Local Distributor fails to comply with any terms of this Agreement, the Licensor shall have the right to withdraw its approval of such Approved Local Distributor with immediate effect by providing written notice to the Licensee, who will ensure that the Approved Local Distributor withdraws or otherwise doesn't make use of the Market Authorization obtained in the name of the Approved Local Distributor.

11. The original paragraph of Clause 2.6 of the Schedule 1: Form of Sublicense to the Agreement is renumbered as Clause 2.7 and is replaced in its entirety as follows:

2.7 No supplies prior to regulatory approvals. Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or otherwise supply a Product in a country of the Territory prior to:

- A. Regulatory Approval in that country, unless the sale or supply is made pursuant to an Import Waiver; and
- B. WHO prequalification or Stringent Regulatory Authority approval, or through any provisional authorizations available through WHO or a Stringent Regulatory Authority.

12. The first paragraph of Clause 5.1 of the Schedule 1: Form of Sublicense to the Agreement is replaced in its entirety as follows:

5.1 Subject to Clause 2.6, 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.

13. The first paragraph of Clause 10.4 and first paragraph of Clause 10.5 of the Schedule 1: Form of Sublicense to the Agreement are each replaced in its entirety as follows:

10.4 If any suit or claim by a Third Party is instituted against the Licensor or the Licensee (or other persons acting under Licensee's authority) for patent infringement involving the Products and/or the Raw Materials, the Licensor or the Licensee sued shall promptly notify the Licensor and Novartis in writing. Novartis shall have the sole 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 Novartis and co-operate in any such litigation at Novartis's request and expense.

10.5 Novartis (and in no circumstances the Licensee or other persons acting under Licensee's authority) shall have the exclusive right, but not obligation, to bring infringement action at its own expense. To the extent Novartis decides not to bring any such infringement action, Novartis shall not

be liable to the Licensee in any respect for such decision. The Licensee shall assist Novartis and co-operate in any such litigation at Novartis's request without expense to the Licensee.

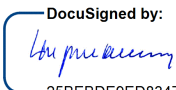
14. The first paragraph of Clause 15.3 of the Schedule 1: Form of Sublicense to the Agreement are each replaced in its entirety as follows:

15.3 The Licensee hereby agrees to indemnify the Licensor, Novartis, their Affiliates and their respective officers, directors, shareholders, representative s, agents, employees, successors and assigns (each an "Indemnified Person") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgments, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("Losses"), that arise in connection with (i) the Licensee's and Approved Local Distributor's breach of this Agreement; or (ii) the Licensee's and Approved Local Distributor's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Products manufactured, sold or supplied by or on behalf of the Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Clause shall not apply to the extent such Losses arise out of negligence or wilful misconduct by Novartis, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. Novartis shall, or shall procure that the Indemnified Person shall, provide the Licensee with prompt written notice of such claims. Subject to Clause 10, the Indemnified Person and the Licensee will agree on the appropriate party to assume control of the defence or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.

15. All other terms and conditions of the Agreement remain unchanged and in effect.

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Amendment No. 1 effective as 5 of July 2024.

Signed for and on behalf of: **Novartis**

**Signature**   
**Name** Dr Lutz Hegemann

**Position** President, Global Health and

Sustainability

06-Jul-2024 | 8:09:44 AM GMT

**Date** \_\_\_\_\_

Signed for and on behalf of: **Novartis**

**Signature**   
**Name** Martin Eschbach

**Position** Head Legal, Global Health and

Sustainability

08-Jul-2024 | 3:35:32 AM EDT

**Date** \_\_\_\_\_

Signed for and on behalf of:  
**THE MEDICINES PATENT POOL FOUNDATION**

**Signature**  DocuSigned by:  
*Chan Park*  
7B78084E923C4D0...

**Name** Chan Park

**Position** General Counsel

07-Jul-2024 | 4:11:28 AM PDT

**Date** \_\_\_\_\_