

**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 Sublicence 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 Sublicence Agreement, to grant a sublicence (without the right to further sublicence) 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 Sublicence Agreement. MPP shall be responsible for obtaining the Approved Local Distributor's written agreement to be bound by the terms of the Sublicence Agreement. Clause 18.6 of this Agreement and Clause 2.6 of the Sublicence 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 Sublicence 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 Sublicence 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 Licensors 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 Licensors or the Licensee (or other persons acting under Licensee's authority) for patent infringement involving the Products and/or the Raw Materials, the Licensors or the Licensee sued shall promptly notify the Licensors 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.

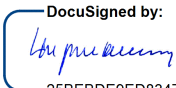
14. The first paragraph of Clause 15.3 of the Schedule 1: Form of Sublicense to the Agreement are each replaced in its entirety as follows:

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

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** 7B78084E923C4D0...

**Name** Chan Park

**Position** General Counsel

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

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