

**(1) MEDINCELL**

**(2) MEDICINES PATENT POOL**

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**LICENCE AGREEMENT**

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THIS LICENCE AGREEMENT ("**Agreement**") is entered into as of the Effective Date and is made

**BETWEEN:**

(1) **MedinCell** a company incorporated in France at 3 rue des frères Lumière 34830 Jacou ("**MedinCell**")

and

(2) **Medicines Patent Pool Foundation** an independent, non-for profit foundation registered under the laws of Switzerland, and having its principle place of business at Rue de Varembe 7, 1202 Geneva Switzerland ("**MPP**").

Each of MedinCell and MPP is referred to in this Agreement as a "**Party**". MedinCell and MPP are collectively referred to in this Agreement as the "**Parties**".

**RECITALS**

- I. WHEREAS, MPP is a non- profit organisation with a mission to improve the health of people living in the developing world by increasing access to quality, safe, efficacious and affordable medicines by facilitating access to intellectual property on those medicines.
- II. WHEREAS, MedinCell owns or controls certain valuable rights, title and interest in and/or has the right to sublicense the Licensed Technology (as defined below) which would be incorporated in the Final Product.
- III. WHEREAS, MedinCell entered into a grant agreement n°2020-40-IMPACT with Unitaid on March 23, 2020 (the "**Unitaid Agreement**") with the key objective to Develop and Commercialise the Final Product as a complementary vector control method to reduce malaria transmission.
- IV. WHEREAS, under the Unitaid Agreement, MedinCell agreed to grant to MPP a licence under the Licensed Technology solely to allow MPP to enter into sublicense agreements for the Development and Commercialisation of the Final Product in the Field for the benefit of the Public Sector in the Territory in order to achieve the Access Objective required by Unitaid under the Unitaid Agreement.
- V. The rights granted under this Agreement will allow MPP to enter into sub-licensing agreements with Development Partners and/or Commercialisation Partners to Develop and/or Commercialise the Final Product for the purpose to achieve the Access Objective as mentioned above.
- VI. The intent of this Agreement is to provide access to Licensed Technology, and not to create any non-intellectual property-related barriers.

**Agreement**

**1. Interpretation**

1.1 In this Agreement, including the Recitals the following expressions have the meaning set opposite:

**Access Objective:** means the objective required by Unitaid under the Unitaid Agreement to ensure that the Final Product is made widely available, as quickly as possible, and on a continuing basis, at an

Affordable Price, to the Public Sector in the Territory and in sufficient quantities to meet the needs of those countries. In the event that the Final Product is made available in the Private Sector in the Territory, it shall be at affordable pricing (which, in the private sector, shall be considered to be no more than reasonable pricing, in line with industry standards). MPP shall ensure that each Development Partner and/or each Commercialisation Partner agrees in the Development Agreement or Commercialisation Agreement to comply with the Access Objective.

**Affiliate:** means, in relation to a Party, any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such Party, but only for so long as such control continues. For the purposes of this definition, “**control**” (including, with the correlative meanings “**controlled by**”, “**controlling**”, and “**under common control**”, shall mean: a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities or other ownership interests (whether directly or pursuant to any option, warrant, or other similar agreement) of such entity.

**Affordable Price:** means the means the maximum price at which a Final Product may be offered for sale to the Public Sector in the Territory reflective of the lowest, sustainable, competitive price level for the Final Product, and includes a reasonable margin to help ensure the economic sustainability of the product and distribution of the Final Product, such price is to be agreed upon between Unitaid and Medincell in accordance with the terms of the Unitaid Agreement and notified by Medincell to MPP as soon as reasonably possible.

**Commercialisation or Commercialise:** means any and all activities directed to the preparation for sale of, offering for sale of, or sale of the Final Product, including activities related to marketing, promoting, distributing, exporting and importing such Final Product. When used as verb “**to Commercialise**” and “**Commercialising**” means to engage in Commercialisation, and “**Commercialised**” has a corresponding meaning.

**Commercialisation Agreement:** means any sublicense agreement executed by MPP and a Commercialisation Partner pursuant to this Agreement and under the terms and conditions set forth in Schedule 4 to this Agreement.

**Commercialisation Partner:** means any firm, corporation, partnership, limited liability company, business trust, joint venture, or other form of business organization which has entered into a Commercialisation Agreement with MPP under the terms and conditions outlined in Schedule 4 to this Agreement.

<b>Confidential Information:</b>	means all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by any Party or any of its Affiliates, or has otherwise become known to a Party or any of its Affiliates, as well as any other information and materials that are deemed confidential or proprietary to or by a Party or any of its Affiliates (including all information and materials of a Party's (or its Affiliates') customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic or electronic form. Confidential Information of MedinCell will include the Licensed Know-How.
<b>Control or Controlled and Controlling:</b>	means in the context of Intellectual Property and Confidential Information, possession (whether by licence, other than pursuant to this Agreement, or ownership or corporate law) by a Party or its Affiliates of the right to grant the other Party the applicable access, licence, sub-licence or other right under this Agreement, without violating the terms of any agreement or other arrangement, existing before, on, or after the Effective Date, with any Third Party.
<b>Development or Develop:</b>	means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of applications to regulatory authorities, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a regulatory authority as a condition or in support of obtaining a regulatory approval. When used as a verb, " <b>Develop</b> " means to engage in Development.
<b>Development Agreement:</b>	means any sublicense agreement executed by MPP and a Development Partner pursuant to this Agreement and under the terms and conditions set forth in Schedule 3 to this Agreement.
<b>Development Partner:</b>	means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity or other form of business organization which has entered into a Development Agreement with MPP under the terms and conditions set forth in Schedule 3 to this Agreement.
<b>Effective Date:</b>	means the date of the last signature to this Agreement.
<b>Exploit or Exploitation:</b>	means to make, have made, import, use, sell, or offer for sale, including to research, Develop, Commercialise, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of.

<b>Field:</b>	means the administration to impact on malaria transmission.
<b>Final Product:</b>	means a long-acting formulation of ivermectin developed using MedinCell's proprietary BEPO® technology for use in the Field.
<b>High Income Countries or HICs:</b>	means all high-income countries in accordance with the World Bank country classification at the relevant time.
<b>Improvement:</b>	means any new or improved process, any new or improved manufacturing techniques or any further invention or know-how which relate to the manufacture or formulation of the Final Product, or incorporate or are based on the Licensed Technology, developed by or on behalf of an MPP Licensee.
<b>Intellectual Property:</b>	means patents, rights to inventions, copyright and related rights, trade marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, database rights, rights to use, and protect the confidentiality of, confidential information, know-how, and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
<b>Key Registration Countries:</b>	means those countries in the Territory for which in-country registration of the Final Product is a priority, as agreed by MedinCell and Unitaid.
<b>Licensed Know-how:</b>	means any and all technical information or know-how (including, without limitation, all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control and testing procedures) that is reasonably necessary for the making of the Final Product and: (i) was developed by MedinCell on or before the Effective Date; or (ii) is generated by MedinCell or acquired by MedinCell after the Effective Date. Licensed Know-How does not include any know-how related to the Polymer Manufacturing Technology.
<b>Licensed Patents:</b>	means any and all patents and patent applications filed by MedinCell either before on (as listed in Schedule 1), and/or after the Effective Date, as may be revised or amended from time to time describing: (i) the BEPO® drug delivery technology; (ii) the long-acting ivermectin formulation; or (iii) any other Intellectual Property, which is reasonably necessary for the making, using, selling, stock-piling, importing or marketing of the Final Product, but excluding the Polymer Manufacturing Technology. For information purposes only, a list of patents and patent applications relevant to the Final Product which have been granted or filed at the Effective Date is attached to this Agreement in Schedule 1.

<b>Licence Report:</b>	means the report set forth in clause 7 to be provided annually by MPP to MedinCell.
<b>Licensed Technology:</b>	means the Licensed Patents and the Licensed Know-how but excluding the Polymer Synthesis Technology including any improvements made by MedinCell or on its behalf thereto.
<b>Low- and Middle-Income Countries:</b>	means all low- and middle-income countries according to the World Bank country classification at the Effective Date; and reference to "LMICs" shall be construed accordingly.
<b>Minimum Supply Targets:</b>	means any targets agreed between Unitaid and MedinCell in relation to minimum production capacity, minimum annual production volumes, maximum order lead time for delivery and/or minimum order quantity for a Final Product, each for the benefit of the Public Sector in the Territory. For the avoidance of doubt, the Minimum Supply Targets may be expressed as a specific volume of the Final Product or a means of calculation of the volume, for example, "20% of the estimated target market for the Final Product in the Territory.
<b>Manufacture or Manufacturing:</b>	means all activities related to the production, manufacture, processing, filling, finishing, packaging, labelling, shipping, and holding of the Final Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control, but excluding all Manufacturing activities related to the Polymer Synthesis Technology.
<b>MPP Licensee:</b>	means any Commercialisation Partner and/or Development Partner that has entered a Commercialisation Agreement and/or Development Agreement with MPP.
<b>Non-Severable Improvement:</b>	means any Improvement which cannot be exploited without infringing the Licensed Technology.
<b>Polymer Synthesis Technology:</b>	means all Intellectual Property related to polymer manufacture, synthesis and purification, Controlled by MedinCell or any of its Affiliates before, on or after the Effective Date.
<b>Polymer Supplier:</b>	means CM Biomaterials B.V.
<b>Polymer Supply Agreement:</b>	means that certain supply agreement to be entered between the Polymer Supplier and a Commercialisation Partner.
<b>Public Sector:</b>	means (a) the following organizations to the extent that they are not for profit organizations or public benefit organization or entity: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison

services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to UNDP and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, etc.; and (vi) agencies based outside of an applicable country to the extent that they are supplying the Final Product in the Territory, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) above;

**Private Sector:** means any person or entity that is not included in the definition of Public Sector.

**Severable Improvement(s):** means an Improvement which if used or practiced without a license from MedinCell would not infringe any Intellectual Property Rights in the Licensed Technology.

**Stage Gates:** means the development stage gates of the Final Product during which Unitaid and MedinCell will review progress towards completion of the Final Products and Unitaid will determine, in its sole discretion and in relation to the Final Product being considered, whether to continue funding its development or terminate funding. The stages gates are decision making points focused on formulation optimization, manufacturing scale-up and non-clinical safety evaluation of the lead formulation, regulatory interactions and partnership strategy build up.

**Sub-Licence Agreement:** means the Development Agreement and/or the Commercialisation Agreement.

**Territory:** means all low and middle-income countries according to the World Bank country classification as of the Effective Date, set out in Schedule 2.

**Third Party:** means any person other than MPP, MPP Licensee or MedinCell and their respective Affiliates.

## **2. GRANT OF LICENCE AND RESERVATION OF RIGHTS**

2.1. Subject to the terms of this Agreement and with effect from the Effective Date, MedinCell hereby grants to MPP, and MPP hereby accepts:

2.1.1. a non-exclusive, royalty-free, non-transferable, worldwide licence, under the Licensed Technology to grant sub-licences, in accordance with the terms set forth in Schedule 3, to Development Partner(s) to Develop, or have Developed, the Final Product in the Field for the benefit of the Public Sector and the Private Sector in the Territory; and

2.1.2. a non-exclusive, non-transferable, worldwide licence under the Licensed Technology to grant sub-licences, in accordance with the terms set forth in Schedule 4, to Commercialisation Partner(s) to make, have made, use, offer for sale, sell, have sold,

export or import the Final Product in the Field exclusively for the benefit of the Public Sector and the Private Sector in the Territory. The sub-licences will be:

a)royalty-free for sales into the Public Sector for use in the Territory; and

b) royalty bearing, for sales into the Private Sector for use in the Territory, which royalty rate shall be reasonable, in line with industry practices and negotiated between MPP, the Commercialisation Partner and MedinCell before the signature of a Commercialisation Agreement . In the event that the Final Product is made available in the Private Sector in the Territory, it shall be at affordable pricing.

- 2.1.3. If determined necessary or appropriate by MedinCell or MPP in the interest of achieving the Access Objective, MedinCell shall grant to MPP so that MPP could grant to the Commercialisation Partner a separate licence of the Licensed Technology for the purpose of enabling such Commercialisation Partner to make, have made, use, offer for sale, sell, have sold, export, import or distribute the Final Product in High Income Countries, provided that such separate licence may be royalty-bearing and the amount of royalties remains reasonable in line with industry practices.
- 2.2. For the avoidance of doubt no rights are granted to MPP under this Agreement for MPP or MPP Licensees to:
- 2.2.1. use the Licensed Technology outside the Field; or
- 2.2.2. offer for sale, sell, have sold or otherwise commercialise the Final Product for use outside the Territory; or
- 2.2.3. have any right, title or interest to any Intellectual Property unless otherwise explicitly stated; or
- 2.2.4. in the case of MPP, to directly practice such licences or otherwise Exploit the Licensed Technology for any other purpose other than to grant sub-licences to MPP Licensees under clauses 3.1.1 and 3.1.2 of this Agreement.
- 2.3. Notwithstanding anything contained in this Agreement, it shall not be a breach of this Agreement for MPP, or MPP Licensees, to:
- 2.3.1. supply to a country where a compulsory licence has been issued by the government of such country or;
- 2.3.2. conduct any activities where such activities would not infringe a Licensed Patent granted and in force, and does not rely on or use the Licensed Know-How.
- 2.4. MedinCell reserves all rights not expressly granted to MPP under this Agreement, including (without limitation) the right to enter into separate licensing agreements with Commercialisation Partners for HICs with measures to protect volumes destined for purchase by the Public Sector in the Territory.
- 2.5. During the Term of this Agreement, the Parties will consider in good faith whether it may be possible to grant a separate licence to MPP allowing for the grant of sub-licences of the Licensed Technology to industry partners seeking to use it for the purposes of developing and/or commercializing additional products for the treatment of diseases or use of the Final Product outside the Field in the Territory.



- 2.6. MedinCell shall inform MPP about the status of the Development, including without limitation the Stage Gates, of the Final Product on a regular basis and at least biannually or upon MPP's request. MedinCell shall further provide, upon MPP request, the MPP Licensee with pre-clinical data and related documentation generated by MedinCell in relation to the Licensed Product to the extent that such documents are reasonably necessary for the Development or registration or commercialisation of the Final Product.
- 2.7. Once MedinCell and Unitaid have agreed on the Minimum Supply Targets and MedinCell has informed MPP thereof, the Parties will confer and come to mutual agreement on the question of whether a Development Partner is necessary for the further development of that Final Product, or alternatively whether the Development Partner can be bypassed in favor of proceeding directly from contract manufacturer to Commercialisation Partner(s).
- 2.8. MPP will use its best efforts to identify Commercialisation Partner(s) capable of commercially Exploiting the Licensed Technology and any Final Product in accordance with the terms of this Agreement.

### **3. RIGHT TO SUB-LICENSE TO MPP LICENSEES**

- 3.1. It is understood and agreed that MPP will not itself Develop and/or Commercialise the Final Product or Exploit the Licensed Technology, but it will do so through its MPP Licensees (without receiving compensation in exchange for such rights).
- 3.2. Identification of MPP Licensees. MPP may grant sublicenses to any Development Partner or Commercialisation Partner with demonstrated commitments (as defined below in clause 3.4.1) to achieve the Access Objective, ability and readiness to Develop and/or Commercialise the Final Product under the terms and conditions set forth in the form of Schedule 3 and/or Schedule 4.
- 3.3. MedinCell's consent. MedinCell shall have the right of approval over any proposed MPP Sublicensee within sixty (60) days following the written proposition of MPP, such approval not to be unreasonably withheld based on the criteria listed under clause 3.2. MedinCell's consent shall be understood as provided unless otherwise notified by MedinCell in writing stating the grounds for MedinCell's withholding of consent to MPP's initial written notice of the proposed MPP Sublicensee, such notice to include reasonably adequate information regarding the proposed MPP Sublicensee to permit MedinCell to assess the proposed MPP Sublicensee's compliance with the criteria defined in clause 3.2.
- 3.4. MPP may grant sub-licences and may disclose to MPP Licensees only such of the Confidential Information as is necessary for the exercise of the rights sub-licensed, subject in each case to the following conditions:
  - 3.4.1. MPP shall procure that any and all Development and/or Commercialisation Partner commits to achieve the Access Objective including the following specific commitments (the "**MPP Licensee Commitments**"):
    - i. legally commit to, in the Development and/or Commercialisation Agreement (as appropriate) and comply with the Specific Access Commitments (as defined below) for the Final Product;
    - ii. endeavour to ensure equitable access to the Final Product by the Public Sector in the Territory;
    - iii. undertake commercially reasonable efforts to Manufacture the Final Product at the lowest possible cost and pass on any significant reduction in the production and distribution

- costs of the Final Product to the benefit of the sale price offered to the Public Sector in the Territory;
- iv. agree that compliance with the Price Commitment will be subject to audit by an independent firm of accountants at any time. The result of the audit will be binding, and such Commercialisation Partner should agree to implement any adjustment to the Affordable Price which is deemed required as a result of the audit;
  - v. prioritise delivery of firm orders from the Public Sector over firm orders from the Private Sector;
  - vi. implement measures to protect volumes destined for purchase by the Public Sector in the Territory;
  - vii. possesses or will possess prior to any applicable activities related to the Final Product, sufficient known sources of supply and production capacity to ensure a continuity of supply of the Final Product to the Public Sector in the Territory in accordance with any Minimum Supply Targets, provided that MedinCell shares with MPP the Minimum Supply Targets in a timely manner;
  - viii. hold, or will hold prior to any applicable activities related to the Final Product, all necessary foreign, federal, state, local, and other governmental licenses, approvals and permits necessary to use, design, Develop, produce, Manufacture, offer for sale, sell, distribute, import and export the Final Product in the relevant country in the Territory; and
  - ix. make best efforts to ensure that the Final Product can be purchased by the Public Sector in the Territory through relevant governmental or international procurement mechanisms including, without limitation, Global Fund and the President's Malaria Initiative.

3.4.2. For the purposes of this Agreement and any Development and Commercialisation Agreement, the "**Specific Access Commitments**" are:

- a. "**Price Commitment**" – the Final Product will be made available to the Public Sector in the Territory at a price which is no more than the Affordable Price;
- b. "**Supply Commitment**" – the Final Product will be made available in a timely manner and in sufficient quantities to meet the needs of the Public Sector in the Territory, including in accordance with any Minimum Supply Targets;
- c. "**Registration Commitment**" – the Final Product will be registered in the Key Registration Countries when available and in accordance with the timeline agreed between Unitaid and MedinCell; MedinCell shall communicate the Key Registration Countries to MPP as soon as available and in any case in a timely manner.
- d. "**QA Commitment**" – the Final Product will be developed in accordance with appropriate quality standards and Commercialisation Partners will seek, when appropriate, approval or a positive recommendation for the Final Product from the WHO Prequalification Programme (PQ), Global Fund/Unitaid Expert Review Panel(ERP), US FDA and/or another WHO Listed Regulatory Authority as agreed between Unitaid, MedinCell and MPP.

3.4.3. MPP will not enter into Development Agreements or Commercialisation

Agreements for the Final Product prior to agreement between MedinCell and Unitaid on the Specific Access Commitments for such Final Product.

3.4.4. MPP will provide MedinCell with a copy of each Sub-Licence Agreement together with a summary of the same, within 10 days of execution of each Sublicense.

3.4.5. Any Sub-License Agreement will be entered into subject to the following:

(i) shall refer to this Agreement and will be subject to this Agreement; and

(ii) each MPP Licensee will accept obligations and conditions consistent with those in this Agreement including Schedule 3 and Schedule 4 (as applicable); and

(iii) each MPP Licensee will confirm in writing that it has received the terms and conditions of this Agreement and agree not to perform any acts or omissions that would place MPP in breach of this Agreement.

3.4.6. MPP will ensure that Sub-licence Agreements contain all the commitments stated in clause 3.4.2 herein, release language, indemnifying obligations against any loss, damages, costs, claims or expenses which are awarded against or suffered by MedinCell, its officers, employees, sub-contractors and agents as a result of any act or omission of the MPP Licensee, insurance requirements as included in Schedule 3 and Schedule 4; and MedinCell shall be considered a third-party beneficiary to the Sub-licence Agreement(s) and will have the right to enforce and rely on the terms of the Sub-licence Agreement(s), as if it were a party thereto.

3.5. MPP agrees to monitor compliance of each MPP Licensee. Such monitoring shall include:

3.5.1 reviewing with all reasonable skill and care any reports provided to MPP by the MPP Licensee under the relevant sections of the Sub-Licence Agreement;

3.5.2 fully exercising the audit right set out in the Sub-Licence Agreement(s) as soon as MPP has reasonable cause to believe (or as soon as MedinCell and MPP have agreed that they have reasonable cause to believe) an audit is necessary.

3.6. If MPP becomes aware of any act or omission of an MPP Licensee which constitutes a breach of the relevant Sub-Licence Agreement, then MPP shall notify MedinCell immediately and (i) if the breach is capable of correction and does not give rise to an immediate right of termination under the Sub-Licence Agreement, direct the relevant MPP Licensee in writing to cure the breach, with a simultaneous copy of that writing to MedinCell; and (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the Sub-Licence Agreement, and in each case if so requested by MedinCell, procure the termination of the relevant Sub-Licence Agreement in accordance with its terms.

#### **4. LICENSED KNOW-HOW**

4.1 For each Development Agreement and/or Commercialisation Agreement executed with an MPP Licensee, MedinCell will make reasonable efforts within reasonable amount of time to perform an initial transfer to MPP for use by an MPP Licensee, of the Licensed Know-how. All further transfer of Licensed Know-How to MPP may occur during the sublicense term if need by the MPP Licensee, except for transfer of Know-How which is not an advancement of the Licensed Technology for malaria and of no interest for MPP.

- 4.2 In the event a technical development that may improve the Licensed Technology used for malaria by MedinCell, is free from any Encumbrance, is not an advancement of the Licensed Technology and is of interest to MPP, then MedinCell and MPP shall discuss in good faith if both Parties agree to a new license agreement for said technical development.

## **5. POLYMER SUPPLY**

- 5.1. Concurrently with the execution and delivery of a Sub-License Agreement, MPP and MedinCell shall procure that the Development and/or the Commercialisation Partner and the Polymer Supplier have entered into the Polymer Supply Agreement under which the Development Partner and/or the Commercialisation Partner will exclusively purchase to Polymer Supplier all Polymers for the Development and Commercialisation of the Products.
- 5.2. MedinCell shall ensure that the Polymer Supplier will commit to the achievement of the Access Objective and will comply with the same commitments as the MPP Licensee Commitments.
- 5.3. MPP acknowledges that the exclusive purchase of all Polymers for the Development and/or Commercialisation of the Final Product, as per the terms and conditions of the Polymer Supply Agreement, is and will remain an essential condition of this Agreement and each Sub-License Agreement.
- 5.4. The exclusive supply of Polymers pursuant to clause 5.1 will terminate once this Agreement terminates and for each Development/Commercialisation Partner once such Development/Commercialisation Agreement terminates.

## **6. PUBLICITY AND PUBLICATION**

The Parties agree that neither Party will issue a press release or public announcement concerning the transactions contemplated hereby without the advance written consent of the other Party (such consent not to be unreasonably withheld or delayed). If either Party intends to issue a press release, it shall submit a draft of such proposed press release to the other Party at least five (5) business days prior to the date such Party intends to issue the release. After any initial press release or public announcement is made, however, each Party may disclose to third parties or make public statements, by press release or otherwise, regarding the existence of this Agreement, the identity of the Parties, the terms, conditions and subject matter of this Agreement, or otherwise in reference to this Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.

## **7. REPORTING**

- 7.1. During the period that MPP Sublicensees are Developing the Final Product, MPP will send to MedinCell within 30 days following the end of each quarter, a written report setting forth each MPP Licensee's (a) Final Product development pipeline, (b) status of Development of each Final Product in Development, (c) regulatory filing plan for each Final Product, and (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been obtained during the reporting period for any Final Product.
- 7.2. During the period that MPP Sublicensees are Commercializing the Final Product in the Territory, MPP will send MedinCell within 30 days following the end of each quarter the number of Final Products sold in the Territory.

## 8. INTELLECTUAL PROPERTY MANAGEMENT

8.1. The MPP shall have no rights in relation to the conduct of any matter relating to the Licensed Patents, including the filing, prosecution and maintenance thereof.

### 8.2. New Developments; Improvements

8.2.1. MedinCell (or its Affiliates) will own the entire right, title and interest in and to any and all inventions conceived solely by MedinCell (or its Affiliates), its respective employees and agents after the Effective Date relating to the Final Product, including any adaptation of any manufacturing process or proprietary drug delivery or formulation technology of MedinCell or its Affiliates for the production of the Final Product, and any patents covering such invention ("**MedinCell New Developments**"), subject to the license grant to MPP set out in clause 2.

8.2.2. MedinCell shall notify MPP in writing of any MedinCell New Developments made by MedinCell or on its behalf at the earliest convenience and in any case annually or at MPP's reasonable request.

8.2.3. The Improvements by the Development and Commercialisation Partner shall belong to such MPP Licensee. MPP will ensure that the Sub-Licence Agreement(s) will grant to MedinCell the rights as agreed in the relevant terms sheets attached hereto.

## 9. INTELLECTUAL PROPERTY MAINTENANCE, ABANDONMENT AND ENFORCEMENT

9.1. MedinCell, or any third party MedinCell elects, will be responsible (at its own expense and discretion) for, and be in control of, the prosecution, maintenance and enforcement of all Licensed Patents in the Territory.

9.2. In the event that MPP becomes aware of a suspected or actual breach of any Sub-License Agreement, MPP will notify MedinCell promptly, and following such notification, the Parties will confer.

9.3. MedinCell (and/or its Affiliates) will have the transferable right but not any obligation to bring an infringement action and any such action shall be at its own expense and entirely under its own direction and control, subject to the following:

- i. MPP and each MPP Sublicensee will reasonably assist MedinCell in any action or proceeding being prosecuted if so requested by MedinCell and such reasonable assistance is necessary for MedinCell to fully exercise its rights under such proceeding.
- ii. MPP will have the right to participate and be represented in any such suit by its own counsel at its own expense; and
- iii. No settlement of any such action or proceeding, which restricts the scope or adversely affects the enforceability of a Licensed Patent may be entered by MedinCell without the prior written consent of MPP.

9.4. Upon request, MedinCell shall provide promptly to MPP the freedom to operate analysis, performed in accordance with the Unitaid Agreement, to be shared with Development Partner or Commercialisation Partner.

9.5. MPP will promptly inform MedinCell if it becomes aware of any infringement or potential infringement of any of the Licensed Patents in the Field.

## 10. CONFIDENTIALITY

- 10.1. Each Party agrees that, for so long as this Agreement is in effect, a Party receiving Confidential Information of the other Party will:
  - (i) Maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own confidential information;
  - (ii) Not disclose such Confidential Information to any Third Party without the prior written consent of the other Party, except for disclosure expressly permitted under this Agreement; and
  - (iii) Not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (iii) will not create or imply any rights or licenses not expressly granted under clause 2 of this Agreement).
  
- 10.2. The obligations under clause 10.1 will not apply with respect to any portion of the Confidential Information that the receiving Party can show by written evidence:
  - (i) Is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party; or
  - (ii) Was known to the receiving Party without any obligations to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or
  - (iii) Is subsequently disclosed to the receiving Party by a third party lawfully in the possession thereof and without any obligation to keep it confidential or any restriction on its use; or
  - (iv) Is published by a Third Party or otherwise becomes publicly available, on a lawful basis, either before or after it is disclosed to the receiving Party; or
  - (v) Has been independently developed by employees or contractors of the receiving Party without the aid, application or use of Confidential Information of the disclosing Party.
  
- 10.3. The receiving Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:
  - (i) Regulatory filings;
  - (ii) Prosecuting or defending litigation;
  - (iii) Complying with applicable governmental laws and regulations;
  - (iv) Disclosure in connection with the performance of this Agreement and solely on a “need-to-know basis”, to Affiliates, UNITAID, actual or potential donors, potential collaborators, research collaborators, employees, consultants or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this clause 10; provided however that the receiving Party will remain responsible for any failure by any such person who receives Confidential Information pursuant to this clause 10 to treat such Confidential Information as required under this clause 10.
  
- 10.4. If any Confidential Information is disclosed in accordance with clause 10.3, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible, the receiving Party will notify the disclosing Party's

intent to make such disclosure pursuant to this clause 10.4 sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

- 10.5. The Parties agree that a copy of this Agreement as well as of each Sub-licence Agreement may be publicly disclosed on MPP's website. Such disclosure will not constitute a breach of either Party's obligations under this clause 10.

## **11. WARRANTIES AND LIABILITY**

11.1. MedinCell warrants that as of the Effective Date MedinCell has full ability to enter into this Agreement and the right to license the Licensed Technology and that, to the reasonable knowledge of MedinCell as of the Effective Date, there are no Encumbrances over the Licensed Technology that are inconsistent with this Agreement. Neither MedinCell nor MPP has granted or will grant to any Third Party any of its right, licence or interest in, to or under the Licensed Technology that would conflict the Parties' ability to comply with the terms of this Agreement.

11.2. Either Party warrants to the other Party that as of the Effective Date:

- i. it has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Agreement;
- ii. the execution of this Agreement and the performance by it of its obligations under this Agreement have duly been authorized by all necessary action on behalf of such Party;
- iii. this Agreement is legally binding and enforceable on either Party in accordance with its terms;

11.3. EXCEPT AS EXPRESSLY STATED IN CLAUSE 11.1, MEDINCELL DOES NOT MAKE ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO:

11.3.1. THE QUALITY OF THE LICENSED TECHNOLOGY;

11.3.2. THE SUITABILITY OF THE LICENSED TECHNOLOGY FOR ANY PARTICULAR USE;

11.3.3. THAT ANY OF THE LICENSED PATENTS IS OR WILL BE VALID OR SUBSISTING OR (IN THE CASE OF AN APPLICATION) WILL PROCEED TO GRANT.

11.4. EXCEPT FOR A BREACH OF CONFIDENTIALITY (CLAUSE 11) OR THE OBLIGATIONS OF INDEMNIFICATIONS (CLAUSE 13), NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR INCIDENTAL DAMAGES RELATED TO THIS AGREEMENT, INCLUDING WITHOUT LIMITING DAMAGES FOR LOST PROFITS OR LOST REVENUES WHETHER UNDER CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, AND REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES.

11.5. Nothing in this Agreement limits or excludes either Party's liability for for death, personal injury, any fraud or any liability that, by law, cannot be limited or excluded.

## **12. INDEMNITY AND INSURANCE**

12.1 Indemnification by MPP. MPP will indemnify, defend, and hold harmless MedinCell and its Affiliates, and their respective officers, directors, regents, employees, and agents (each, an "Indemnitee")

from all Third Party suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) or judgments, whether for money or equitable relief relating to or arising out of (each, a "**Claim**"):

- (i) any material breach by MPP of any of its obligations, representations or warranties under this Agreement;
- (ii) any gross negligence or willful misconduct by or on behalf of MPP;
- (iii) MPP's (or its Affiliates and MPP Sublicensees') use and practice otherwise of the Licensed Patents and Licensed Know-How, including claims and threatened claims based on:
  - (i) product liability, bodily injury, risk of bodily injury, death or property damage;
  - (ii) infringement or misappropriation of Third Party patents, copyrights, trademarks or other intellectual property rights; or
  - (iii) the failure to comply with applicable laws related to the matters referred to in the foregoing with respect to the Final Product except in any such case for Losses and Claims to the extent resulting from the gross negligence, recklessness or willful misconduct of MedinCell.

12.2 Indemnification by MedinCell. MedinCell will indemnify, defend, and hold harmless MPP and their respective officers, directors, regents, employees, and agents (each, an "**Indemnitee**") from all Third Party suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) or judgments, whether for money or equitable relief relating to or arising out of (each, a "**Claim**"):

- (i) any material breach by MedinCell of any of its obligations, representations, warranties under this Agreement;
- (ii) any gross negligence or willful misconduct by or on behalf of MedinCell.

12.3. Procedure. In connection with any Claim for which MedinCell seeks indemnification from MPP pursuant to this Agreement, MedinCell shall: (a) give MPP prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve MPP from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with MPP, at MPP's expense, in connection with the defense and settlement of the Claim; and (c) permit MPP to control the defense and settlement of the Claim; provided, however, that MPP may not settle the Claim without MedinCell r's prior written consent, which shall not be unreasonably withheld or delayed, in the event that such settlement materially adversely impacts MedinCell's rights or obligations. Further, MedinCell shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

12.3 Insurance. MPP will require the MPP Sublicensees to purchase and maintain appropriate commercial general liability and product liability insurance as per the terms of the Sub-License Agreement.

### 13. **DURATION AND TERMINATION**

13.1 This Agreement will take effect on the Effective Date and, unless terminated earlier as provided herein, shall continue in force until the date on which the last Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated.

13.2 A Party ("**non-breaching party**") shall have the right to terminate this Agreement in the event the



other Party ("**breaching party**") is in material breach of any of its material obligations under this Agreement. The non-breaching party shall provide written notice to the breaching party. The breaching party shall have a period of 30 days after such written notice to cure such breach, or to provide a timeline to cure such breach to the satisfaction of the non-breaching party. If such breach is not cured within such period, or other agreed timeline, this Agreement will be deemed terminated with effect from the end of the period or timeline.

13.3 Additional termination rights:

13.3.1 MedinCell will have the right to terminate this Agreement by giving a written notice to MPP if the development of all Licensed Technology has stopped in agreement with UNITAID.

13.3.2 Either Party will have the right to terminate this Agreement if the other Party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other Party's assets, or if the other Party makes any arrangement with its creditors or takes or suffers any similar or analogous action in any other jurisdiction.

**14. CONSEQUENCES OF TERMINATION**

14.1 In the event that this Agreement is terminated other than under clause 13.1:

- (i) all rights and licenses granted to MPP under clause 2 will terminate;
- (ii) all Sub-Licence Agreements will, upon written approval by MedinCell, such consent not to be unreasonably withheld, be converted into licences between MedinCell and the MPP Licensees on the same terms as agreed in the Sub-Licence Agreement, (x) provided that the MPP Licensee is not in breach of the Sub-Licence Agreement and such license does not provide MedinCell with obligations greater than under this Agreement, by way of the MPP, MedinCell and the relevant Licensee entering into a novation agreement transferring the rights and obligations of the MPP under the Sub-licence to MedinCell; and (y) provided that MedinCell reserves the right to terminate the licenses so converted on the same grounds as those having led to termination of this Agreement.

14.2 On termination or expiration of this Agreement, in the event that any MPP Licensees are not converted into licences between MedinCell and the MPP Licensee under Clause 14.1, MPP shall procure that MPP Licensees are terminated and immediately provide MedinCell with details of the stocks of Final Products held at the point of termination.

14.3 Clauses 10, 11.3, 11.4, 11.5, 13, and 14 will survive the expiry or termination of this Agreement. Clause 10 will survive the expiry or termination of this Agreement for a duration of 7 (seven) years from the Effective Date.

**15. GENERAL**

15.1 Force Majeure: If the performance by either Party of any of its obligations under this Agreement (except a payment obligation) is delayed or prevented by circumstances beyond its reasonable control, that Party will not be in breach of this Agreement because of that delay in performance. However, if the delay in performance is more than 3 months, the other Party may terminate this Agreement with immediate effect by giving written notice.

15.2 Notices: Any notice to be given under this Agreement must be in writing, may be delivered to the

other Party's representative as detailed below, and as updated from time to time:

**For MedinCell:**

Name Jaime Arango, Chief Financial Officer

Address: 3 rue des frères Lumière  
34830 Jacou, France

Email: Jaime.arango@medincell.com

**For MPP:**

Name: General Counsel

Address: Rue de Varembe 7  
1202 Geneva  
Switzerland

Email: cpark@medicinespatentpool.org

and by any of the methods set out below, and will be deemed to be received as set out below:

By hand or courier: the day of delivery and is sent concurrently by email

By pre-paid first class post: the second working day after posting and is sent concurrently by email

by email if receipt is confirmed.

15.3 Assignment/Change in Control: neither Party may assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the other Party. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. 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 Licenced Technology, or substantial assets owned or controlled by Medincell which are necessary to perform its obligations hereunder, or by a third party, including as a result of a Change in Control;

Medincell will ensure that such licensee, purchaser, transferee, acquirer or successor of the Licenced Technology or Medincell's assets agrees to be bound by the terms of this Agreement, in a written form agreement acceptable to MPP.

15.4 Waiver of rights: If a Party fails to enforce, or delays in enforcing, an obligation of the other Party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.

15.5 No agency: Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the Parties, or the relationship between them of principal and agent. Neither Party has any authority to make any representation or commitment, or to incur any liability, on behalf of the other.

15.6 Entire agreement: This Agreement constitutes the entire agreement between the Parties relating to its subject matter. Each Party acknowledges that it has not entered into this Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Agreement. For the avoidance of doubt, nothing in this Agreement shall prevent either Party from developing any research programs and entering into further collaborations with third parties, provided that they are not in breach of this Agreement and its Schedules.

15.7 Conflicts: In the event that there is a conflict between the terms of the main body of this Agreement and its Schedules, the former shall prevail.

15.8 Further assurance: Each Party will take any action and execute any document reasonably required by the other Party to give effect to any of its rights under this Agreement, or to enable their

registration in any relevant Territory provided the requesting Party pays the other Party's reasonable expenses.

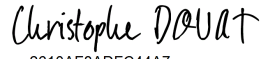
- 15.9 Amendments: No variation or amendment of this Agreement will be effective unless it is made in writing and signed by each Party's representative.
- 15.10 Third parties: No one except a Party to this Agreement has any right to prevent the amendment of this Agreement or its termination, and, save in relation to clause 13.1, no one except a Party to this Agreement may enforce any benefit conferred by this Agreement.
- 15.11 Severability: If any of the provisions of this Agreement is or becomes invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions will not in any way be affected or impaired. Where necessary the Parties will negotiate in good faith mutually satisfactory amendments achieving as nearly as possible the same effect to replace the provisions found to be void or unenforceable.
- 15.12 Resolution by senior executives: All disputes, controversies or claims between the Parties in connection with this Agreement, its construction, or the rights, duties or liabilities of either Party under this Agreement (a "**Dispute**") must be resolved pursuant to the following resolution process in this clause 15.12 and the jurisdiction clause 15.14. The Parties to any dispute may alter or amend these procedures by agreement in writing.
- 15.13 To commence the resolution process, any Party may serve notice to the other Party identifying: (i) the nature of the Dispute; and (ii) the amount in Dispute.
- 15.13.1 Once notice is received, the Parties must first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves.
- 15.13.2 In the event that such Dispute is not resolved on an informal basis within 30 days after such notice is received, either Party may, by written notice to the other Party, refer the Dispute to the Executive Director in the case of the MPP and to Chief Executive Officer in the case of MedinCell (together the "**Designated Officers**") for attempted resolution by good faith negotiation.
- 15.13.3 If any Dispute is not resolved by the Designated Officers within 30 days after the receipt of such notice referring such Dispute to the Designated Officers, then either Party may seek resolution in accordance to clause 15.15.
- 15.14 Governing law: This Agreement is governed by, and is to be construed in accordance with, laws of Switzerland.
- 15.15 Arbitration. Except as provided in clause 16.12 if any dispute is not resolved by the Designated Officers, then any Dispute which has arisen or may arise out of, or in connection with, this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the "**ICC**") by three arbitrators appointed in accordance with the said Rules.
- 15.16 The seat of arbitration shall be Geneva, Switzerland and the arbitration shall be conducted in English.
- 15.17 Each Party will have the right to seek injunctive or other equitable relief from a court of competent jurisdiction as may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration, including any breach or threatened breach of clauses 11.1 and 15. The parties agree that any such request for injunctive or equitable relief may be brought in a court sitting in Geneva, Switzerland and the Parties irrevocably and unconditionally consent to the exercise of personal jurisdiction by the courts in Geneva in such proceedings.

15.18 Counterparts. This Agreement may be executed with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed and will 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.

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

**SIGNED** on behalf of MedinCell:

Name: Christophe DOUAT  
Position: Chief Executive Officer

DocuSigned by:  
  
.....2610AEF8ADF0C44A7.....

Signature

Date: 2022-09-05 | 20:27:47 CEST

**SIGNED** on behalf of MPP:

Name: Charles Gore  
Position : Executive Director

DocuSigned by:  
  
.....4713D0F59C13482.....

Signature

Date : 05/09/2022

**Schedule 1****The Licensed Patent(s): Licensed Patents - granted or filed as at the Effective Date**

Country Name	Case Status	Application No	Filing Date	Publication Date	Publication No	Registration Date	Registration No
Austria	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
International Patent-PCT	Nat. Phase	PCT/IB2011/003323	2011-12-29	2012-07-05	WO2012090070		
Australia	Registered	2011350898	2011-12-29	2013-07-11		2016-12-22	2011350898
Belgium	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Bulgaria	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Brazil	Registered	BR 11 2013 016662 2	2011-12-29	2016-10-04	BR 11 2013 016662 2	2021-08-03	BR112013016662-2
Canada	Registered	2,822,854	2011-12-29			2020-01-07	2822854
Switzerland	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Chile	Registered	201301942	2011-12-29	2014-07-04	201301942	2019-11-14	58452
China	Registered	201180068770.4	2011-12-29	2014-01-01	103491946	2016-08-10	ZL 201180068770.4
Cyprus	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Czech Republic	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Germany	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Denmark	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Eurasian Patent-EAPO	Registered	201390783	2011-12-29			2017-06-30	027046
Estonia	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
European Patent	Nat. Phase	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
European Patent	Nat. Phase	17181676.2	2011-12-29	2017-12-20	3257498	2019-04-24	3257498
European Patent	Pending	19169971.9	2011-12-29	2020-01-01	3586825		
Spain	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Finland	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
France	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
United Kingdom	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Greece	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Hong Kong	Registered	14104135.2	2011-12-29	2014-07-18	1190925	2017-08-30	1190925
Hong Kong	Registered	18107873.7	2011-12-29	2018-10-12	1248146	2020-05-15	1248146
Croatia	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Indonesia	Registered	W00201302940	2011-12-29	2014-09-11	2014/03207	2018-01-24	IDP000049146
Ireland	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Israel	Registered	227235	2011-12-29	2013-08-29	227235	2016-09-01	227235

India	Registered	5731/DELNP/2013	2011-12-29	2016-06-10	5731/DELNP/2013	2020-08-24	344789
Iceland	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Italy	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Japan	Registered	2013-546780	2011-12-29	2014-02-03	2014-502613	2017-04-28	6134269
Japan	Registered	2016-203985	2011-12-29	2017-02-23	2017-39758	2018-03-09	6302983
Korea (South)	Registered	10-2013-7020159	2011-12-29			2017-05-23	10-1741055
Kazakhstan	Registered	201390783	2011-12-29			2017-06-30	027046
Lithuania	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Luxembourg	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Latvia	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Mexico	Registered	MX/a/2013/007682	2011-12-29			2017-04-11	MX 347090
Malaysia	Registered	PI 2013002458	2011-12-29			2018-04-18	MY-165655-A
Netherlands	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Norway	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
New Zealand	Registered	612326	2011-12-29	2014-10-31	612326	2015-02-03	612326
Poland	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Portugal	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Romania	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Russian Federation	Registered	201390783	2011-12-29			2017-06-30	027046
Sweden	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Singapore	Registered	2013050364	2011-12-29			2016-09-27	191414
Singapore	Registered	10201508568V	2011-12-29			2018-03-29	10201508568V
Slovenia	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Slovakia	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Thailand	Pending	1301003709	2011-12-29	2016-05-31	151376		
Turkey	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
Ukraine	Registered	a201309349	2011-12-29			2016-07-25	112069
Vietnam	Registered	1-2013-02029	2011-12-29	2013-12-25		2016-06-06	1-0015597-000
South Africa	Registered	2013/04687	2011-12-29			2014-03-26	2013/04687
United States of America	Registered	13/340,265	2011-12-29	2012-07-05	US-2012-0172454	2015-05-05	9023897
Hungary	Registered	11822867.5	2011-12-29	2013-11-06	2658525	2017-08-30	2658525
United States of America	Pending	16/983,189	2020-08-03	2021-05-27	US-2021-0154301		
United States of America	Pending	US17/070,493	2020-10-14	2021-02-11	US-2021-0038724-A1		

Country Name	Application No	Filing Date	Publication Date	Publication No	Registration Date	Registration No
Australia	2013282891	2013-06-27			2018-07-26	2013282891
International Patent-PCT	PCT/IB2013/001547	2013-06-27	2014-01-03	WO2014001904		
Brazil	BR 11 2014 031773 9	2013-06-27	2015-03-24	PI 11 2014 031773 9 A	2020-03-31	11 2014 031773 9
Canada	2,877,083	2013-06-27			2020-10-06	2,877,083
Chile	201403531	2013-06-27	2015-08-28	201403531		201403531
China	201380044335.7	2013-06-27	2015-04-29	104582733	2017-07-04	ZL 201380044335.7
Eurasian Patent-EAPO	201492172	2013-06-27	2015-09-30	201492172	2019-01-31	031522
European Patent	13758976.8	2013-06-27	2015-05-06	2866837		
Hong Kong	15109165.3	2013-06-27	2016-03-04	1208374		
Israel	236472	2013-06-27	2015-02-26	236472	2020-05-28	236472
India	11063/DELNP/2014	2013-06-27	2015-09-25	11063/DELNP/2014		
Japan	2015-519379	2013-06-27	2015-08-03	2015-522001	2017-04-28	6134788
Korea (South)	10-2015-7002309	2013-06-27			2020-12-04	KR 10-2189442
Mexico	2014015902	2013-06-27	2015-07-17	MX 2014015902 A	2018-01-05	353280
Malaysia	PI 2014003576	2013-06-27			2021-04-30	MY-185158-A
Singapore	11201408658P	2013-06-27	2015-02-27	SG11201408658PA	2017-09-27	11201408658P
Thailand	1401007814	2013-06-27	2016-07-06	154080		
Ukraine	a201413827	2013-06-27			2017-02-10	113549
Vietnam	1-2014-04433	2013-06-27	2015-03-25	41580	2020-12-11	27110
South Africa	2014/09291	2013-06-27			2017-05-31	2014/09291
United Arab Emirates	P1416/2014	2013-06-27				
Colombia	CO2014284191	2013-06-27				
Cuba	CU20140148	2013-06-27				
Egypt		2013-06-27				
Morocco	MA37809	2013-06-27				
Nigeria		2013-06-27				
Qatar		2013-06-27				
Tunisia	TN201400520	2013-06-27				

**Schedule 2**  
**The Territory**

All 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.

Afghanistan	Dominican Republic	Liberia	Solomon Islands
Albania	Ecuador	Libya	Somalia
Algeria	Egypt, Arab Rep.	Madagascar	South Africa
American Samoa	El Salvador	Malawi	South Sudan
Angola	Equatorial Guinea	Malaysia	Sri Lanka
Argentina	Eritrea	Maldives	St. Lucia
Armenia	Eswatini	Mali	St. Vincent and the Grenadines
Azerbaijan	Ethiopia	Marshall Islands	Sudan
Bangladesh	Fiji	Mauritania	Suriname
Belarus	Gabon	Mexico	Syrian Arab Republic
Belize	Gambia, The	Micronesia, Fed. Sts.	Tajikistan
Benin	Georgia	Moldova	Tanzania
Bhutan	Ghana	Mongolia	Thailand
Bolivia	Grenada	Montenegro	Timor-Leste
Bosnia and Herzegovina	Guatemala	Morocco	Togo
Botswana	Guinea	Mozambique	Tonga
Brazil	Guinea-Bissau	Myanmar	Tunisia
Bulgaria	Guyana	Namibia	Turkey
Burkina Faso	Haiti	Nepal	Turkmenistan
Burundi	Honduras	Nicaragua	Tuvalu
Cabo Verde	India	Niger	Uganda
Cambodia	Indonesia	Nigeria	Ukraine
Cameroon	Iran, Islamic Rep.	North Macedonia	Uzbekistan
Central African Republic	Iraq	Pakistan	Vanuatu
Chad	Jamaica	Papua New Guinea	Venezuela, RB
China	Jordan	Paraguay	Vietnam
Colombia	Kazakhstan	Peru	West Bank and Gaza
Comoros	Kenya	Philippines	Yemen, Rep.
Congo, Dem. Rep.	Kiribati	Russian Federation	Zambia
Congo, Rep.	Korea, Dem. People's Rep.	Rwanda	Zimbabwe
Costa Rica	Kosovo	Samoa	
Côte d'Ivoire	Kyrgyz Republic	São Tomé and Príncipe	
Cuba	Lao PDR	Senegal	
Djibouti	Lebanon	Serbia	
Dominica	Lesotho	Sierra Leone	



### Schedule 3 Development Agreement Term Sheet

1. Scope of the grant: MPP will grant a non-exclusive, royalty free, non-transferable worldwide licence under the Licensed Technology to allow Development Partners to develop, or have developed, Licensed Technology into Final Products in the Field. For the avoidance of doubt, Development Partner will be expressly prohibited from:
  - i) further sub-licensing, and
  - ii) except if the Development Partner is a Commercialisation Partner selling, or distributing in any manner, the Licensed Technology to any other Third Party.
  
2. Term: The Sub-licence Agreement will be in force from the date of its signature until the date on which the last Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated. MPP shall have the right to either terminate the Development Agreement, or to require the Development Partner to novate the Development Agreement to MedinCell (i.e. by entering into a Novation Agreement with MPP and MedinCell), in the event that the MPP-MedinCell Agreement is terminated.
  
3. Improvements:
  - 3.1 **Severable Improvements**: The Development Partner shall promptly disclose to MedinCell and MPP in such detail as MedinCell and/or MPP may reasonably require a written description of all Severable Improvements that it may develop, conceive or reduce to practice during the Term. The Parties shall discuss in good faith an arrangement suitable to both MedinCell and the Development Partner which should take into account a fair and reasonable compensation for the Development Partner as well as commercial strategy of MedinCell.
  
  - 3.2 **Non-Severable Improvements**:
    - a. The Development Partner shall grant to MedinCell a first option to discuss an assignment of Non-Severable Improvements against a fair and equitable compensation on an arm length basis; and in case such assignment is agreed upon, MedinCell grants to:
      - i. the Development Partner a non-exclusive, royalty-free, non-transferable, worldwide license to use the Non-Severable Improvements in the Field, in the Territory during the Term; and
      - ii. MPP a right to grant licences on the Non-Severable Improvements as follows: non-exclusive, royalty-free, non-transferable, worldwide license to use the Non-Severable Improvements in the Field, in the Territory during the Term.
  
    - b. If the Parties fail to reach an agreement in accordance with section 3.2 a) above within 6 months following the option grant to discuss an assignment, then the Development Partner grants to MedinCell a non-exclusive, worldwide, royalty-free, sub-licensable license over any Non-Severable Improvement for any use in the Field, irrespective of expiration or termination of this Agreement.
  
4. Representations and Warranties; Disclaimers:
  - a. Representations and Warranties. The Development Partner represents and warrants to MPP and MedinCell that:

- i. The Development Partner has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Development Agreement;
  - ii. the execution of this Development Agreement and the performance by the Development Partner of its obligations under this Agreement have duly been authorized by all necessary action on behalf of the Development Partner;
  - iii. this Agreement is legally binding and enforceable on the Development Partner in accordance with its terms;
  - iv. the performance of this Development Agreement by the Development Partner does not create a breach or default under any other agreement to which it is a party;
  - v. Development Partner will comply with the Access Objectives and the MPP Licensee Commitments (including the Specific Access Commitments) as described under the MPP- Medincell Agreement;
  - vi. Development Partner will not engage in any activities that use the Licensed Patents and/or Licensed Manufactured Know-How in a manner that is not compliant with this Development Agreement and that any modifications to the manufacturing process or Licensed Technology will be undertaken at the MPP Sublicensees' sole risk and in no event will Medincell indemnify, hold harmless or defend any Development Partner for any such modifications.
  - vii. The performance of this Development Agreement by the Development Partner does not infringe or misappropriate any Third Party patents, copyrights, trademarks or other intellectual property rights.
- b. As is License. The Development Partner will acknowledge and agree that the Licensed Technology is licensed to Licensee "as is". MedinCell and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Technology is suitable for any purpose for which it may be used by the Development Partner.

5. Development Partner's Release and Indemnification.

5.1. Release. The following language will be included in all Development Partner agreements:

"The Development Partner hereby releases MedinCell and its regents, employees, and agents forever from any suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of (a) the development, manufacture, use, of Licensed Technology; or (b) the assigning or sublicensing of Development Partner's rights under the Development Agreement provided however such liabilities are not resulting from the MedinCell's negligence or wilful misconduct.

5.2. Indemnification. Development Partner will indemnify, defend, and hold harmless MedinCell, its Affiliates and their respective officers, directors, employees, and agents (each, an "**Indemnitee**") from all Third Party claims, suits, actions, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and legal expenses and costs of litigation) arising out of, directly or indirectly (each, a "**Claim**"):

- i. Any breach by the Development Partner's of any provisions of this Development Agreement;
- ii. Infringement or misappropriation by the Development Partner of a Third Party patent, copyright, trademark or other intellectual property right;

- iii. Any negligence, wilful misconduct by or on behalf of the MPP Sublicensee;
  - iv. the exercise of any rights with respect to the Final Product, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to a Final Product, provided that the Development Partner will not have obligations to the extent resulting from the MedinCell's negligence or wilful misconduct.
6. General Insurance Requirement. Throughout the term of the Development Agreement, or during such period as the MedinCell agrees in writing, Development Partner will maintain in full force and effect commercial general liability (CGL) insurance and product liability insurance, with single claim limits consistent with industry standards.
7. Waiver of data exclusivity rights: Development Partner 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 Final Product.
8. Timelines: The Development Agreement will include timelines for the development of Licensed Technology into a Final Product.
9. Reporting: Within 30 days following the end of each calendar quarter, Development Partner will be required to provide MPP with a quarterly written report setting forth in relation to that quarter the following: (a) summary of project implementation and current schedule of anticipated events or milestones including status of readiness of labs, plants, machinery as required, (b) details of project related specific recruitments and a summary of resources (Euros value) spent in the reporting period if any, (c) the Final Product in its development pipeline, (e) status of development of each Final Product in development, (f) any Improvements; (g) any other information that MPP and MedinCell may require to monitor progress and implementation of the projects. MPP and the Development Partner will agree to meet on a quarterly basis regarding such reports. MPP agrees that information contained in quarterly and other such reports shall be treated as confidential; provided, however, that such information may be shared with MedinCell, MPP's funders, MedinCell's funder, and funders, if any, of the project under consideration; and that status update may be publicly disclosed by the MPP or MedinCell. Within thirty (30) days of the end of the Development Partner's programme they will deliver to MPP and MedinCell a complete dossier of information allow MPP to effect an efficient technology transfer to the Commercialisation Partner and MedinCell to effect an efficient technology transfer to its licensees including its licensees outside the Territory.
10. Audit: The Development Partner will permit MPP and MedinCell, individually or together, and when required, through an independent third party auditor or consultant nominated by MPP or MedinCell respectively to: (i) inspect and audit the performance of, and compliance with, the Development Agreement and the applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of the Development Agreement. Development Partner will cooperate with and provide all reasonable assistance to MPP or MedinCell, their respective officers, employees, agents, advisors, representatives or consultants exercising their rights under this provision. MPP or MedinCell will provide Development Partner with a commercially reasonable period of notice of the proposed audit. MPP and MedinCell, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Development Partner to perform in compliance with the Development Agreement or applicable laws.
11. Confidentiality: Confidentiality obligations similar to those established in Clause 10 of the Agreement will be included in the Development Agreement. The Confidential Information exchanged under the Development Agreement may be shared with MedinCell and Unitaid.
12. Trademarks and names: Development Partner will not use MedinCell's or MPP's name or logo nor the name of any of the inventors or other principal researchers in any kind of promotional material other

than for the purposes of complying with the Development Agreement, without the prior written agreement of both MPP and MedinCell.

13. Third Party Rights: MedinCell shall be considered a third-party beneficiary to the Development Agreement and will have the right to enforce and rely on the terms of the Development Agreement with the Development Partner, as if it were a party thereto.
14. Governing Law/ADR: The governing law for the Development Agreement will be the laws of Switzerland. All disputes will be resolved via an alternative dispute mechanism to be set forth in the agreement.
15. Eligibility: The Development Partner will be eligible to become a Commercialisation Partner by executing a separate Commercialisation Agreement in accordance with Schedule 4.
16. Compliance with Laws: The Development Partner shall ensure, solely at its own expense, that its performance, the Licensed Technology and the Final Product comply with all applicable laws, rules, regulations, orders, decrees, judgments and other governmental acts of any foreign governmental authorities having jurisdiction over the Development Partner (including any health and safety rules and regulations and any patent, copyright, trademark or other infringement laws), and that it will hold prior to any applicable activities related to the Final Product, all necessary foreign, federal, state, local, and other governmental licenses, approvals and permits necessary to develop or have developed the Final Product.
17. Additional Terms: The Development Agreement will contain other terms necessary or desirable to carry out the intent of the MPP-MedinCell Agreement, as well as other mutually agreeable language regarding other additional customary terms.

**Schedule 4**  
**Commercialisation Agreement Term Sheet**

1. Scope of the grant: MPP will grant a Commercialisation Partner a non-exclusive, non-transferable worldwide licence under the Licensed Technology to allow Commercialisation Partners to make, have made, use, offer for sale, sell, have sold, export and import the Final Product for the purposes of commercialising the Final Product in the Field for the benefit of the Public Sector and in the Territory. The Licence will be royalty-free for sales to Public Sector for use in the Territory and royalty-bearing for sales into the Private Sector for use in the Territory, which royalty rate shall be reasonable, in line with industry practice and shall be negotiated between MedinCell, MPP and the Commercialisation Partner before the execution of a Commercialisation Agreement. In the event that the Final Product is made available in the Private Sector in the Territory, it shall be at affordable pricing (which, in the private sector, shall be considered to be no more than reasonable pricing, in line with industry standards). For the avoidance of doubt, the Commercialisation Partner will be expressly prohibited from further sub-licensing the Licensed Technology to any other Third Parties.
  
2. Access Commitments: Commercialisation Partner will ensure that Final Products are made available in accordance with the following specific commitments (the “**MPP Licensee Commitments**”) and therefore shall:
  - i. legally commit to, in the Commercialisation Agreement and comply with the Specific Access Commitments (as defined below) for the Final Product;
  - ii. endeavour to ensure equitable access to the Final Product by the Public Sector in the Territory;
  - iii. undertake commercially reasonable efforts to Manufacture the Final Product at the lowest possible cost and pass on any significant reduction in the production and distribution costs of the Final Product to the benefit of the sale price offered to the Public Sector in the Territory;
  - iv. agree that compliance with the Price Commitment will be subject to audit by an independent firm of accountants at any time. The result of the audit will be binding, and the Commercialisation Partner should agree to implement any adjustment to the Affordable Price which is deemed required as a result of the audit;
  - v. prioritise delivery of firm orders from the Public Sector over firm orders from the Private Sector;
  - vi. implement measures to protect volumes destined for purchase by the Public Sector in the Territory;
  - vii. possesses or will possess prior to any applicable activities related to the Final Product, sufficient known sources of supply and production capacity to ensure a continuity of supply of the Final Product to the Public Sector in the Territory in accordance with any Minimum Supply Targets, provided that MedinCell shares with MPP the Minimum Supply Targets in a timely manner;
  - viii. hold, or will hold prior to any applicable activities related to the Final Product, all necessary foreign, federal, state, local, and other governmental licenses, approvals and permits necessary to use, design, Develop, produce,

Manufacture, offer for sale, sell, distribute, import and export the Final Product in the relevant country in the Territory; and

- ix. make best efforts to ensure that the Final Product can be purchased by the Public Sector in the Territory through relevant governmental or international procurement mechanisms including, without limitation, Global Fund and the President's Malaria Initiative.

For the purposes of the Commercialisation Agreement, the "**Specific Access Commitments**" are:

- a. "**Price Commitment**" – the Final Product will be made available to the Public Sector in the Territory at a price which is no more than the Affordable Price;
  - b. "**Supply Commitment**" – the Final Product will be made available in a timely manner and in sufficient quantities to meet the needs of the Public Sector in the Territory, including in accordance with any Minimum Supply Targets;
  - c. "**Registration Commitment**" – the Final Product will be registered in the Key Registration Countries when available and in accordance with the timeline agreed between Unitaid and MedinCell. MedinCell shall communicate the Key Registration Countries to MPP as soon as available and in any case in a timely manner
  - d. "**QA Commitment**" – the Final Product will be developed in accordance with appropriate quality standards and Commercialisation Partners will seek, when appropriate, approval or a positive recommendation for the Final Product from the WHO Prequalification Programme (PQ), Global Fund/Unitaid Expert Review Panel(ERP), US FDA and/or another WHO Listed Regulatory Authority as agreed between Unitaid and MedinCell.
2. Term: The Commercialisation Agreement will be in force from the date of its signature until the date on which the last Licensed Patent associated with the Licensed Technology has expired, lapsed or has been invalidated. MPP shall have the right to either terminate the Commercialisation Agreement, or to require the Commercialisation Partner to novate the Commercialisation Agreement to MedinCell (i.e. by entering into a Novation Agreement with MPP and MedinCell), in the event that the MPP-MedinCell Agreement is terminated. Upon termination, Commercialisation Partner will immediately provide MPP with details of the stocks of Final Products held at the point of termination.

5. Improvements:

5.1 **Severable Improvements**: The Commercialisation Partner shall promptly disclose to MedinCell and MPP in such detail as MedinCell and/or MPP may reasonably require a written description of all Severable Improvements that it may develop, conceive or reduce to practice during the Term. The Parties shall discuss in good faith an arrangement suitable to both MedinCell and the Commercialisation Partner which should take into account a fair and reasonable compensation for the Commercialisation Partner as well as commercial strategy of MedinCell.

5.2 **Non-Severable Improvements**:

- a. The Commercialisation Partner shall grant to MedinCell a first option to discuss an assignment of Non-Severable Improvements against a fair and equitable compensation on an arm length basis; and in case such assignment is agreed upon, MedinCell grants to:
    - i. the Commercialisation Partner a non-exclusive, royalty-free, non-transferable, worldwide license to use the Non-Severable Improvements in the Field, in the Territory during the Term; and
    - ii. MPP a right to grant licences on the Non-Severable Improvements as follows: non-exclusive, royalty-free, non-transferable, worldwide license to use the Non-Severable Improvements in the Field, in the Territory during the Term.
  - b. If the Parties fail to reach an agreement in accordance with 5.2 a) above within 6 months following the option grant to discuss an assignment, then the Commercialisation Partner grants to MedinCell a non-exclusive, worldwide, royalty-free, sub-licensable license over any Non-Severable Improvement for any use in the Field, irrespective of expiration or termination of this Agreement.
3. Waiver of data exclusivity rights: Commercialisation Partner 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 Final Product.
4. Representations and Warranties; Disclaimers:
- 5.1. Representations and Warranties. The Commercialisation Partner represents and warrants to MPP and MedinCell that:
- i. The Commercialisation Partner has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Commercialisation Agreement;
  - ii. the execution of this Commercialisation Agreement and the performance by the Commercialisation Partner of its obligations under this Agreement have duly been authorized by all necessary action on behalf of the Commercialisation Partner;
  - iii. this Agreement is legally binding and enforceable on the Commercialisation Partner in accordance with its terms;
  - iv. the performance of this Commercialisation Agreement by the Commercialisation Partner does not create a breach or default under any other agreement to which it is a party;
  - v. it will comply with the Access Objectives and the commitments as described under the MPP-MedinCell Agreement;
  - vi. it will not engage in any activities that use the Licensed Patents and/or Licensed Manufactured Know-How in a manner not compliant with this Commercialisation Agreement and that any modifications to the manufacturing process or Licensed Technology will be undertaken at the MPP Sublicensees' sole risk and in no event will MedinCell indemnify, hold harmless or defend any Commercialisation Partner for any such modifications.
  - vii. The performance of this Commercialisation Agreement by the Commercialisation Partner does not infringe or misappropriate any Third Party patents, copyrights,

trademarks or other intellectual property rights.

- viii. License “As is”. The Commercialisation Partner will acknowledge and agree that the Licensed Technology is licensed to Commercialisation Partner “as is”. MedinCell and MPP make no representation or warranty of non-infringement or any representation or warranty that the Licensed Technology is suitable for any purpose for which it may be used by the Licensee.
6. Indemnity: Commercialisation Partner will indemnify, defend, and hold harmless MedinCell and its regents, employees, and agents (each, an “**Indemnitee**”) from all third party suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys’ and investigative expenses) arising out of, directly or indirectly (each a “**Claim**”):
  - i. Any breach by the Commercialisation Partner’s of any provisions of this Commercialisation Agreement;
  - ii. Infringement or misappropriation by the Commercialisation Partner of a Third Party patent, copyright, trademark or other intellectual property right;
  - iii. Any negligence, wilful misconduct by or on behalf of the Commercialisation Partner;
  - iv. Commercialisation Partner’s exercise of any rights with respect to the Final Product, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to the Final Product, provided that the Commercialisation Partner will not have obligations to the extent resulting from the MedinCell’s negligence or willful misconduct.
7. General Insurance Requirement: Throughout the term of the Commercialisation Agreement, or during such period as MedinCell agrees in writing, Commercialisation Partner will maintain in full force and effect commercial general liability (CGL) insurance and product liability insurance, with single claim limits consistent with industry standards.
8. Timelines: The Commercialisation Agreement will include timelines for the development, regulatory approvals and placing of the Final Product in the market.
9. Reporting: Within 30 days following the end of each calendar quarter, Commercialisation Partner will be required to provide MPP with a quarterly written report setting forth in relation to that quarter (a) the Final Product in its development pipeline, (b) status of development of each Final Product in development, (c) regulatory filing plan for each Final Product, (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been filed or obtained for any Final Product and (e) the Final Product (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under the Commercialisation Agreement during such agreement quarter, on a country-by-country basis and the related royalties for the Private Sector; (f) any Improvements. MPP and Licensee will agree to meet on a quarterly basis regarding such reports and also review development and filing status of the Final Product. MPP will agree that information contained in quarterly and other such reports shall be treated as confidential; provided, however, that such information may be shared with MedinCell and Unitaid; and that aggregated data may be publicly disclosed by MPP.
10. Audit: Commercialisation Partner will permit MPP and MedinCell, individually or together, through an independent third party auditor or consultant nominated by MPP or MedinCell to: (i) inspect and audit the performance of, and compliance with, the Commercialisation Agreement and the applicable laws; and (ii) inspect and audit all documents and other records relating to the performance of the Commercialisation Agreement. Commercialisation Partner will cooperate with and provide all reasonable assistance to MPP or MedinCell. MPP or MedinCell will provide Commercialisation Partner with a commercially reasonable period of notice of the proposed audit.



MPP and MedinCell, each individually, agree that such audits will not be conducted more than once in any 12-month period, unless the prior audit has shown evidence of the failure of Licensee to perform in compliance with the Commercialisation Agreement or applicable laws. If any audit reveals a discrepancy of more than 5% to the detriment of MedinCell and/or MPP, Commercialisation Partner will reimburse MPP or MedinCell for the cost of that audit. The result of the audit will be binding, and in the event that the audit reveals a failure to comply with the Price Commitment, the Commercialisation Partner will implement any adjustment to the Affordable Price deemed required by MPP or MedinCell as a result of the audit.

11. Confidentiality: Confidentiality obligations similar to those established in Clause 10 of the Agreement will be included in the Commercialisation Agreement. The Confidential Information exchanged under the Commercialisation Agreement may be shared with MedinCell and Unitaid.
12. Trademarks and names: Commercialisation Partner will not use MedinCell's or MPP's name or logo nor the name of any of the inventors or other principal researchers in any kind of packaging and promotional material other than for the purposes of complying with the Commercialisation Agreement, without the prior written permission of both MPP's and MedinCell's authorised representative. The Final Product manufactured under the Commercialisation Agreement will be marked (to the extent not prohibited by law): (i) with a notice that such Final Product is sold under a license from MedinCell and MPP; and (ii) with all markings and notices as may be required by applicable law, including in relation to patent and other intellectual property.
13. Third Party Rights: MedinCell shall be considered a third-party beneficiary to the Commercialisation Agreement and will have the right to enforce and rely on the terms of the Commercialisation Agreement with the Commercialisation Partner as if it were a party thereto.
14. Governing Law/ADR: The governing law for the Commercialisation Agreement will be the laws of Switzerland. All disputes will be resolved via an alternative dispute mechanism to be set forth in the Commercialisation Agreement.
15. Compliance with Laws: Commercialisation Partner shall ensure, solely at its own expense, that its performance, the Licensed Technology and the Final Product comply with all applicable laws, rules, regulations, orders, decrees, judgments and other governmental acts of any foreign governmental authorities having jurisdiction over the Commercialisation Partner (including any health and safety rules and regulations and any patent, copyright, trademark or other infringement laws), and that it will hold prior to any applicable activities related to the Final Product, all necessary foreign, federal, state, local, and other governmental licenses, approvals and permits necessary to use, design, develop, produce, manufacture, offer for sale, sell, distribute, import and export the Final Product.
16. Insurance: Within 30 days prior to the first commercial launch by Commercialisation Partner of a Final Product, and each year thereafter for so long as the Commercialisation Agreement is in effect, Commercialisation Partner shall provide to MPP certificates of insurance by insurers acceptable to MPP evidencing comprehensive general liability coverage, including products liability, with a combined limit of no less than 10 million Euros (€10,000,000.00) for bodily injury, including personal injury, and property damage.
17. Additional Terms: The Commercialisation Agreement will contain other terms necessary or desirable to carry out the intent of the MPP-MedinCell Agreement, as well as other mutually agreeable language regarding other additional customary terms.