LICENCE AGREEMENT

THIS LICENCE AGREEMENT (this "**Agreement**") is made on 8 May 2026 (the "**Effective Date**")

BETWEEN:

F. HOFFMANN-LA ROCHE LTD, a company incorporated under the laws of Switzerland and having its registered office at Grenzacherstrasse 124, CH-4070 Basel, Switzerland ("**Roche**");

and

MEDICINES PATENT POOL FOUNDATION, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva ("**MPP**"),

with Roche and MPP collectively referred to as the "**Parties**".

WITNESSETH THAT:

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 these medicines;

WHEREAS Roche or its Affiliates own certain rights, title and interest in and/or have the right to sublicense the Licensed Technology (as defined below);

WHEREAS MPP desires to obtain a licence from Roche under the Licensed Technology solely to allow it to grant sublicences of the Licensed Technology to various third parties in order to promote access to antiviral drugs in the Territory (as defined below);

WHEREAS Roche is willing to grant such a licence provided that such sublicences are in the form of the Sublicence (as defined below);

WHEREAS the intent of this Agreement is to increase access to the Licensed Technology, and not to create any non-patent-related barriers where Patents or Non-Territory Patents (as defined below) do not exist or would not be infringed;

WHEREAS the Parties acknowledge the potential relevance of the Licensed Technology in relation to future pandemic threats and recognise the need to consider relevant international instruments—including but not limited to the Pandemic Influenza Preparedness Framework, the International Health Regulations (2005), and the WHO Pandemic Agreement adopted in May 2025, where applicable—and the principles of pandemic preparedness, equitable access to pandemic-related health products, and sustainable and geographically diversified local production of pandemic-related health products;

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the Parties agree as follows:

1. DEFINITIONS

For the purposes of this Agreement:

1.1 "**Affiliate**", in relation to a party, shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such party. For the purposes of this definition, "control" shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of a party hereto are conducted in accordance with the wishes of such corporation, firm, partnership or other entity. With respect to Roche, the term Affiliate shall not include Chugai Pharmaceutical Co. Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan and its respective subsidiaries, unless Roche opts for such inclusion of Chugai and its respective subsidiaries by giving written notice to MPP;

1.2 "**Agreement Quarter**" has the meaning given to such term in the Sublicence;

1.3 "**Business Day**" has the meaning given to such term in the Sublicence;

1.4 "**Compound**" has the meaning given to such term in the Sublicence;

1.5 "**Confidential Information**" has the meaning given to such term in the Sublicence;

1.6 "**Event of Force Majeure**" has the meaning given in Clause 7.3;

1.7 "**FDA**" means the United States Food and Drug Administration;

1.8 "**Licensed Know-How**" has the meaning given to such term in the Sublicence;

1.9 "**Licensed Technology**" has the meaning given to such term in the Sublicence;

1.10 "**Non-Territory Patents**" has the meaning given to such term in the Sublicence. Roche shall update the list of Non-Territory Patents (set out in Appendix D to the Sublicence) upon reasonable written request by MPP;

1.11 "**Patents**" has the meaning given to such term in the Sublicence;

1.12 "**Product(s)**" has the meaning given to such term in the Sublicence;

1.13 "**Regulatory Approval**" has the meaning given to such term in the Sublicence;

1.14 "**Roche Supplier**" has the meaning given to such term in the Sublicence;

1.15 **"Stringent Regulatory Authority"** has the meaning given to such term in the Sublicence;

1.16 "**Sublicence**" means a licence agreement in the form set out in Schedule 1 hereto;

1.17 "**Sublicensee**" means a third party which:

(a) in the opinion of MPP (acting reasonably) has demonstrated willingness and capacity (or, in the case of local and regional manufacturers, potential capacity) to (i) manufacture Compound and/or Products in a manner consistent with WHO pre-qualification standards or the standards of any Stringent Regulatory Authority or WHO-Listed Authority; and (ii) make Products widely available on terms that will facilitate access to Products in the Territory. MPP may take into account the importance of sustainable and geographically-diversified local production of pandemic-related health products and, to promote this objective, may vary regulatory filing deadlines in accordance with Clauses 5.3 and 16.10 of the Sublicence; and

(b) in the opinion of MPP (acting reasonably) is not an entity or person identified as a target under applicable sanctions, export control, or anti-boycott laws, regulations, orders, directives, designations, or decisions of any country (including, without limitation, those referred to in Clause 14.2 of the Sublicence or enforced by the US Office of Foreign Assets Control); and

(c) is a party whom Roche has approved in writing, such approval not to be unreasonably withheld or delayed, based on its review of the criteria in (a) and (b) above, any other relevant due diligence information provided by MPP and, if required, the receipt of any necessary approval(s) from competent authorities including the Swiss State Secretariat for Economic Affairs and the US Bureau of Industry and Security (which Roche shall be solely responsible for obtaining); and

(d) has entered into a Sublicence;

1.18 "**Territory**" has the meaning given to such term in the Sublicence;

1.19 "**Third Party(ies)**" shall mean any party other than a party to this Agreement.

1.20 "**WHO**" means the World Health Organization;

1.21 "**WIPO Mediation Rules**" means the mediation rules adopted by the World Intellectual Property Organization from time to time.

2. GRANT OF LICENCE

2.1 Subject to the terms and conditions of this Agreement, Roche hereby grants to MPP a non-exclusive, non-transferable licence under the Licensed Technology to enter into Sublicences with Sublicensees. No rights are hereby granted for any other purpose and MPP agrees that it will not use the Licensed Technology itself or grant sublicences: (i) to entities other than Sublicensees; and/or (ii) other than in the form of the Sublicence, unless it has obtained Roche's prior written approval.

2.2 MPP shall, within thirty (30) days of the execution of a Sublicence, provide to Roche a fully executed copy of the Sublicence.

2.3 Roche hereby covenants with MPP that it shall not bring legal action against a Sublicensee for infringement of any Non-Territory Patents where such Sublicensee is carrying on activities outside of the Territory solely for purposes which are expressly permitted by the relevant Sublicence.

2.4 Notwithstanding anything to the contrary in this Agreement, it shall not be a breach of the Sublicence for Sublicensees to engage in any lawful activity, inside or outside of the Territory, that would not infringe any Patents or Non-Territory Patents granted and in force, including, without limitation, where a compulsory licence has been issued, provided such activity is within the scope of the compulsory licence.

2.5 MPP and Roche together commit to meet and review on an annual basis the operational elements of this Agreement and will work in good faith to ensure effective use of the resources of both Parties.

2.6 In the event that the WHO declares a Public Health Emergency of International Concern (including a pandemic emergency) in relation to an influenza virus, a regional intergovernmental agency declares an equivalent health emergency in relation to an influenza virus (for example, a declaration of a Public Health Emergency of Continental Security by the Africa Centres for Disease Control and Prevention), and/or at any other time where Roche and MPP form the reasonable opinion that there is a pandemic risk in relation to an influenza virus:

(a) MPP and Roche shall promptly meet to assess (i) the actual or potential need for pandemic-related health products containing the Compound in countries within and outside of the Territory, in consultation with WHO as appropriate, and (ii) the current manufacturing capacities of Roche and of Sublicensees with respect to the Compound and/or Products;

(b) MPP and Roche shall collaborate with an intent to remove access barriers including but not limited to supply constraints, territory restrictions, and royalties, as appropriate. The Parties commit to enter into good faith negotiations to address any such issues to respond to the health emergency and to promote access to pandemic-related health products;

(c) MPP may execute Sublicences with additional Sublicensee(s) and, in doing so, take into account criteria other than those set out at Clause 1.17(a), such criteria to be agreed with Roche, so as to effectively respond to the health emergency.

In the event that the Parties agree to any changes to this agreement pursuant to Clause 2.6(b) such that the Territory includes high-income economies (as defined by the World Bank), MPP shall monitor Sublicensees' compliance with Clause 2.8 of the Sublicence and shall exercise its rights thereunder as necessary to ensure that Sublicensees prioritise low, lower-middle and upper-middle income countries (as defined by the World Bank).

3. OBLIGATIONS OF MPP

3.1 MPP shall within ninety (90) days of the expiry of the ten (10) Business Day period referred to in Clauses 13.2 and 13.3 of the Sublicence, send to Roche consolidated reports provided to MPP under Clauses 13.2 and 13.3 of the Sublicence. For reports provided to MPP under Clause 13.2 of the Sublicence, MPP shall additionally send a copy of the consolidated reports to:

global.pvagreementmanagement@roche.com

or such other person as shall be nominated by Roche in writing from time to time.

3.2 MPP shall promptly notify Roche of any notices received from Sublicensees pursuant to Clauses 2.2 (Affiliates) and 5.6 (Local Distributors) of the Sublicence.

3.3 MPP agrees to monitor compliance with each Sublicence by each Sublicensee, including but not limited to by:

(a) using reasonable endeavours to procure that Sublicensees provide the reports to MPP in accordance with Clauses 13.2 and 13.3 of the Sublicence, reviewing with all reasonable skill and care any such reports;

(b) within thirty (30) days following expiry of the ten (10) Business Day period referred to in Clauses 13.2 and 13.3 of the Sublicence, reporting to Roche which Sublicensees (if

any) have not complied with their obligations under Clauses 13.2 and 13.3 of the Sublicence and what action the MPP has taken to facilitate compliance of such Sublicensees;

(c) fully exercising the audit right set out in Clause 13.1 of the Sublicence at MPP's own cost as soon as MPP has reasonable cause to believe an audit is necessary (including without limitation where MPP has reasonable grounds for suspecting non-compliance with the Sublicence); and

(d) assessing with reasonable skill and care whether any requests for prior written approval for trade or service marks, trade dress (where applicable), symbols or devices provided to the MPP by Sublicensees under Clause 12.4 of the Sublicence comply with the requirements of Clause 12.2 of the Sublicence, and submitting to Roche for written approval those requests which the MPP considers meet said requirements. Roche shall respond to any request for approval within thirty (30) days of receipt by Roche of all the relevant documentation necessary to consider the Sublicensees' request.

Roche agrees to treat any information of Sublicensees provided to it under this Clause 3.3 as Confidential Information and the confidentiality obligations of Clauses 8.1 to 8.5 of the Sublicence shall apply, *mutatis mutandis*, to Roche with respect to such information.

3.4 Where the Sublicence requires the Sublicensees to obtain approval from Roche, MPP shall facilitate the provision of such approval in accordance with Clause 2.10 of the Sublicence.

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

3.6 The MPP agrees to exercise the rights of Roche as granted under Clause 21.3 of any Sublicence only as requested in writing by Roche. For the avoidance of doubt, this shall not affect Roche exercising its rights directly under any Sublicence.

3.7 MPP's obligations under this Clause 3 constitute direct, primary and unconditional obligations of MPP and shall not require Roche to first take any steps against any Sublicensee or any other person.

3.8 MPP shall provide to Roche a consolidated summary of the royalty calculations as contemplated by Clause 4.4 of the Sublicence within ninety (90) days of the end of each Agreement Quarter. MPP shall take all reasonable steps to ensure (i) the timely delivery to Sublicensees of invoices issued by Roche in respect of royalties owed pursuant to (and in accordance with) Clause 4 of the Sublicence, and (ii) that the royalties contemplated by Clause 4 of each Sublicence (together with any interest due) are paid to Roche in accordance therewith. For the avoidance of doubt and without prejudice to the audit rights set out in Clause 13.1 of the Sublicence, MPP is not required to verify that the amounts of royalties paid under Clause 4 of the Sublicence are correct for every payment made by the Sublicensees under that clause. In the event that an error in royalty calculations is identified, MPP shall inform Roche as soon as reasonably practical, and in any event within five (5) Business Days of discovering such error,

and shall take all the necessary steps to ensure that the error is rectified and that the correct amount of royalty is paid to Roche by the Licensee.

4. ASSISTANCE WITH PRODUCT DEVELOPMENT & REGULATORY APPROVAL

4.1 **Data package**. In the event MPP receives (pursuant to Clause 6 of a Sublicence) a written request for Roche to provide a data package to expedite development and filing for Regulatory Approval in the Territory, MPP shall promptly forward such request to Roche. As soon as practicable after receipt of the request, and unless there are reasonable grounds to refuse the request in relation to individual Sublicensee(s), Roche shall assemble and make available to each Sublicensee a single discrete data package subject to each Sublicensee, with a copy provided to MPP. Without limitation, the data package must include at least the following information to fully enable Sublicensees to manufacture Compound and Product at commercial-scale quantities and in compliance with the required quality standards:

(a) formula and composition;

(b) manufacturing process descriptions, specifications and methods;

(c) stability data;

(d) analytical method validation; and

(e) discussion of impurities.

4.2 **Reference Products**.

(a) Roche commits to provide to each Sublicensee, free of charge and subject to reasonable terms, up to 100 tablets of baloxavir marboxil (40mg oral tablet) and up to 550 tablets of baloxavir marboxil (80mg oral tablet), solely for use in (i) *in vitro* research related to the Sublicensee's Product and (ii) bioequivalence studies required to obtain Regulatory Approval.

(b) In the event MPP receives (pursuant to Clause 6 of a Sublicence) a written request for Roche to provide Roche Product to a Sublicensee, MPP shall promptly forward such request to Roche and, provided the request is for amounts and purposes consistent with Clause 4.2(a), Roche shall fulfil the request as soon as practicable.

(c) In the event Roche or its Affiliates have or receive Regulatory Approval from the FDA and/or the EMA for additional dosage formulation(s) of the Compound and Roche has launched such formulations, Roche commits to provide to each Sublicensee, free of charge and subject to reasonable terms, said dosage formulation(s) in an amount comparable to that specified in Clause 4.2(a) and pursuant to with the terms and conditions set out in Clause 4.2(b) (*mutatis mutandis*).

4.3 **Exclusivity waivers; other consents**.

(a) Roche shall waive data exclusivity, market exclusivity and any other regulatory exclusivities, inside or outside of the Territory, to the extent required by the applicable regulatory authorities in order for each Sublicensee to manufacture or sell Product in the Territory in accordance with the terms of the Sublicence.

(b) Upon MPP's written request, Roche shall provide such documentation and assistance and shall take such steps as are necessary to give effect to Clause 4.3(a).

(c) In addition, and without prejudice to the foregoing, Roche shall provide to any Sublicensee such consents which it has the legal capacity to give as are necessary to enable such Sublicensee to perform its obligations under Clauses 5.2 and 5.3 of the Sublicence.

5. COMPLIANCE

5.1 MPP shall comply fully at all times with all applicable laws and regulations, including but not limited to applicable anti-corruption laws and applicable sanctions laws, of the territories in which MPP conducts business with Roche and/or grants Sublicences. MPP represents and warrants that it is not in any way involved with the manufacture or sale of arms or ammunition.

5.2 MPP declares that it is not a terrorist organisation, nor does it finance, make items or funds available or otherwise assist in the commission of terrorist acts by any individual or entity designated under applicable counter-terrorism sanctions or other measures, including that of the UN Security Council, pursuant to Security Council Resolution 1267 (1999) and 1989 (2011) or any other terrorism-related resolutions, included those managed by the US Office of Foreign Assets Control.

5.3 The Parties shall comply with all pharmacovigilance obligations applicable under Clause 9 of the Sublicence, including the obligations set forth in Appendix E thereto, including the provision of all required safety and regulatory documents within the timelines specified therein.

MPP shall be responsible for overseeing and monitoring the Sublicensee's fulfilment of its pharmacovigilance obligations under Clause 9 of the Sublicence, including the obligations set forth in Appendix E thereto. MPP shall take all reasonable measures to ensure and procure the Sublicensee's compliance with such obligations.

Roche shall have the right, upon sixty (60) days' prior written notice to MPP, to audit (a) MPP's compliance with this Clause 5.3 and (b) the Sublicensee's compliance with applicable pharmacovigilance obligations under the Sublicence, including access to the Sublicensee's relevant facilities, personnel, and records. MPP shall take all reasonable measures to ensure and procure that the Sublicensee grants such access and cooperates fully with the audit.

5.4 Roche shall provide to MPP the reports specified at Section B.4 of Appendix E to the Sublicence according to the timelines set out therein.

6. PUBLIC AND EXTERNAL COMMUNICATIONS

6.1 Each Party shall seek each other Party's written approval of any initial press release or public announcement concerning the grant, scope or terms of this Agreement prior to such press release or public announcement being made. 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.

6.2 Except as provided for under Clause 6.1 above, neither Party shall use the other Party's name, logo, or trade marks for any purpose including without limitation publicity or advertising, except with the prior written consent of the other Party.

6.3 Each Party shall ensure that any external communication relating to this Agreement is accurate and not misleading.

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

7. GENERAL

7.1 **Term**. The term of this Agreement shall commence on the Effective Date and expire upon the later of the expiration, lapse or invalidation of the last remaining Patent in the Territory (unless terminated earlier in accordance with its terms).

7.2 **Termination rights**. In addition to any other rights to terminate at law or as expressly provided in this Agreement:

(a) either Party may terminate this Agreement immediately (or on such date that it sets out in the notice of termination) upon written notice to the other Party if the other Party commits a material breach of any provision of this Agreement that is (i) not capable of being remedied or (ii) is capable of being remedied but the other Party fails to remedy such material breach within thirty (30) days following receipt of a written notice specifying the nature of the breach; and

(b) Roche may terminate this Agreement immediately on written notice to MPP if, acting reasonably and based on objectively verifiable grounds, Roche determines that MPP has contravened applicable anti-corruption laws.

7.3 **Force majeure**. If the performance of any part of this Agreement by any Party, or of any obligation under this Agreement (other than those provisions which in any respect concern the payment under any indemnity or otherwise under this Agreement) is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform (an "**Event of Force Majeure**"), unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable endeavours to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If the Event of Force Majeure continues for a period of more than six (6) months, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party.

7.4 **Conversion to direct licences**. In the event that this Agreement is terminated in accordance with its terms prior to expiry pursuant to Clause 7.1, MPP shall procure that any Sublicences already granted and in effect shall be converted (by way of MPP, Roche and the relevant Sublicensee entering into a novation agreement transferring the rights and obligations of MPP under the Sublicence to Roche) into a direct licence between Roche and the relevant Sublicensee(s) under the same terms and conditions of the Sublicence. Such a novation agreement shall be subject to the following conditions: (i) the Sublicensee not being in breach of its Sublicence; and (ii) Roche confirming, following a renewed assessment, that the

Sublicensee continues to satisfy the approval criteria set forth in Clauses 1.17(a) and 1.17(b), specifically taking into account any changes to the applicable sanctions, export controls, or anti-boycott laws that may have occurred since Roche's initial approval of the Sublicensee. This Clause 7.4 shall survive any termination of this Agreement.

7.5 **No other intellectual property rights**. Other than as set out under Clause 2.1, this Agreement confers: (a) no intellectual property rights whatsoever on MPP; and (b) no rights on MPP to sublicense its rights hereunder, which is expressly prohibited.

7.6 **Patent management**. MPP shall have no rights in relation to the conduct of any matter relating to the Patents, including the filing, prosecution, and maintenance thereof.

7.7 **Assistance**. MPP agrees that it shall provide such assistance as Roche reasonably requires to enable Roche to exercise its rights under this Agreement and any Sublicence.

7.8 **Roche Suppliers**. On or before the Effective Date or within thirty (30) days thereafter, Roche shall provide MPP with a written list of Roche Suppliers. MPP shall provide said list to Sublicensees in accordance with Clause 3.1 of the Sublicence.

7.9 **Improvements; Confidentiality**. Roche agrees only to exercise the rights granted to it under Clause 11.2 of the Sublicence in accordance with the licence granted therein. Roche shall treat any information disclosed under Clause 13 of the Sublicence as Confidential Information and the confidentiality obligations of Clauses 8.1 to 8.5 of the Sublicence shall apply, *mutatis mutandis*, to Roche with respect to such information provided, for the avoidance of doubt, that Roche shall be entitled to disclose information about the quantities of Products manufactured by Sublicensees on an aggregate basis.

7.10 **Amendment**. This Agreement may only be amended in writing signed by duly authorised representatives of each Party. For the avoidance of doubt, and notwithstanding the rights of MPP pursuant to Clause 28 of the Sublicence, MPP shall not amend Appendix C or Appendix D of the Sublicence without Roche's express consent in writing.

7.11 **Waiver**. The rights of each Party under this Agreement: (a) may be exercised as often as necessary; (b) except as otherwise expressly provided in this Agreement, are cumulative and not exclusive of rights and remedies provided by law; and (c) may be waived only in writing and specifically. Delay in exercising or non-exercise of any such right is not a waiver of that right.

7.12 **Counterparts**. This Agreement may be executed in counterparts, which taken together shall constitute one and the same agreement, and any Party (including any duly authorised representative of a Party) may enter into this agreement by executing a counterpart.

7.13 **Entire agreement**. This Agreement sets forth the entire agreement between the Parties and supersedes all prior agreements, arrangements and understandings, oral or written, between the Parties with respect to the subject matter hereof.

7.14 **Third party rights**. A person who is not a Party may not enforce any of the terms of this Agreement.

7.15 **Disclaimer of warranty**. Nothing in this Agreement shall be construed as a warranty that (a) the information set out in Appendix C or Appendix D of the Sublicence accurately reflects the status of Roche's patents and patent applications relating to the Compound and/or Products, (b)

any of the Patents or Non-Territory Patents are valid or enforceable or (c) that their exercise does not infringe any patent rights of any Third Parties.

8. GOVERNING LAW AND JURISDICTION

8.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Switzerland.

8.2 The Parties wish to facilitate the resolution of any dispute arising out of or relating to this Agreement including but not limited to the breach, termination, interpretation or validity thereof (a "**Dispute**") in an expedient manner by mutual cooperation and agree to follow the procedures set forth in this Clause 8.

8.3 **Escalation**. If a Dispute cannot be resolved between the Parties within thirty (30) days of written notice by one Party to another, such Dispute shall be referred in writing to the Parties' respective executive officers or their designees for attempted resolution by good faith negotiations which shall take place within thirty (30) days after such referral (or within such other time period as may be agreed by the Parties in writing).

8.4 **Mediation**. Any Dispute remaining unresolved thirty (30) days (or such other time period as may be agreed by the Parties in writing) after referral to the Parties' executive officers pursuant to Clause 8.3 shall be submitted to mediation in accordance with the WIPO Mediation Rules.

8.5 **Arbitration**. Any Party may refer any Dispute not resolved by mediation within forty-five (45) days (or within such other time period as may be agreed by the Parties in writing) after the appointment of the mediator, for resolution by final and binding arbitration conducted in accordance with the Rules of Arbitration of the International Chamber of Commercial (the "**ICC Rules**") provided that, to the extent that any of the following provisions of this Clause conflict with the said ICC Rules, the following provisions shall prevail:

(a) the arbitration shall be conducted by three (3) arbitrators;

(b) the seat of the arbitration shall be Geneva, Switzerland;

(c) the language of the arbitration shall be English;

(d) the decision of the arbitrator shall be final and binding on the Parties;

(e) judgment upon the arbitration award may be entered by any court having jurisdiction thereover or having jurisdiction over the relevant Party and its assets; and

(f) all documents and proceedings in any arbitration pursuant to this Clause 8.5 shall be confidential and all hearings shall be held in private, save to the extent necessary to enforce any award or to comply with any requirement of any lawful authorities. No public statement shall be made with regard to any arbitral proceedings save to the extent agreed between the Parties in writing.

8.6 **Injunctive relief**. Nothing in this Agreement shall prevent or restrict either Party from seeking or obtaining injunctive 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 arbitration proceedings referred to at Clause 8.5 above.

9. NOTICES

9.1 Any notice given by a Party under this Agreement shall be:

(a) be in writing and in English;

(b) be signed by, or on behalf of, the Party giving it; and

(c) be sent to the relevant Party at the address set out in Clause 9.3.

9.2 Notices may be given, and are deemed received:

(a) by hand—at the time of delivery;

(b) by commercial courier—on the date and at the time of signature of the courier's delivery receipt;

(c) by registered or certified mail (postage paid)—on the third Business Day after posting; or

(d) by email—on the date of delivery (receipt confirmed).

9.3 Notices shall be sent to:

(a) **MPP** for the attention of the General Counsel at:

Medicines Patent Pool
Rue de Varembé 7, Fifth Floor
CH-1202 Geneva
Switzerland

Email: Legal@medicinespatentpool.org

(b) **Roche** for the attention of Legal and Compliance at:

124 Grenzacherstrasse
4070 Basel
Switzerland

9.4 Either party may change its address for communications by a notice in writing to the other party in accordance with Clause 9.3.

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

9.6 The provisions of this Clause 9 shall not apply to notices given in legal proceedings or arbitration.

9.7 This Clause 9 is not intended to prohibit the use of email for day-to-day operational communications between the Parties, including where this Agreement requires written approval by a Party.

[*Signature page follows*]

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

Signed for and on behalf of:
F. HOFFMANN-LA ROCHE LTD

Signature	Signed by: Tamara Schudel 71D4F61F820C46E...	**Signature**	DocuSigned by: AE29FE9C36BF45C...
Name	Tamara Schudel	**Name**	Markus Hasselblatt
Position	Head of Global Policy & Advocacy	**Position**	Global Portfolio Leader
Date	08 May 2026	**Date**	08 May 2026

Signed for and on behalf of:
MEDICINES PATENT POOL FOUNDATION

Signature	DocuSigned by: Charles Gore 4713D0F59C13482...
Name	Charles Gore
Position	Executive Director
Date	08 May 2026

SCHEDULE 1

FORM OF SUBLICENCE

LICENCE AGREEMENT

THIS LICENCE AGREEMENT (this "**Agreement**") is made on [*insert date*] (the "**Effective Date**")

BETWEEN:

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

and

[*LICENSEE*], a company incorporated under the laws of [*country*] and having its registered office at [*address*] (the "**Licensee**"),

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

WITNESSETH THAT:

WHEREAS the Licensor has been granted by Roche (as defined below) the right to sublicense certain patents, patent applications and know-how which relate to the compound known as baloxavir marboxil;

WHEREAS the Licensee desires to obtain a licence from the Licensor to use the Licensed Technology (as defined herein) and the Licensor is willing to grant to the Licensee such a licence in accordance with the terms and subject to the conditions of this Agreement;

WHEREAS the intent of this Agreement is to provide access to the Licensed Technology (and therefore facilitate access to medicines for patients in resource-limited jurisdictions), and not to create any non-patent-related barriers where Patents or Non-Territory Patents (as defined below) do not exist or would not be infringed;

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the parties agree as follows:

1. DEFINITIONS

For the purposes of this Agreement:

1.1 "**Affiliate**", in relation to an entity, shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such entity. For the purposes of this definition, "control" shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of an entity are conducted in accordance with the wishes of such corporation, firm, partnership or other entity. With respect to Roche, the term Affiliate shall not include Chugai Pharmaceutical Co. Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan and its respective subsidiaries, unless Roche opts for such inclusion of Chugai and its respective subsidiaries by giving written notice to Licensor.

1.2 "**Agreement Quarter(s)**" shall mean any period of three months ending on the last day of March or June or September or December.

1.3 "**Approval Date**" shall mean, in relation to each Product, the date on which that Product first receives Regulatory Approval from a Relevant Regulatory Authority.

1.4 "**Approved Affiliate**" shall mean an Affiliate of Licensee (i) which the Licensee has demonstrated by means of appropriate supporting documents is an Affiliate of Licensee, and (ii) approved in writing by the Licensor and Roche, such approval not to be unreasonably withheld. Licensor and Roche shall respond to any requests for approval within thirty (30) days of receipt by Roche of the appropriate supporting documents from Licensor.

1.5 "**Business Day**" shall mean a day (other than a Saturday or Sunday) on which the banks are open for normal business in Switzerland.

1.6 "**Compound**" shall mean the chemical compound known generically as baloxavir marboxil, the specific chemical name and structure of which is set out in Appendix A, or any other compound or substance that would infringe the Patents and/or Non-Territory Patents but for this Agreement.

1.7 "**Confidential Information**" shall mean all information that would reasonably be regarded as, or is designated as, of a confidential or commercially sensitive nature by the party to which the information relates including, without limitation, any matter relating to, or arising in connection with, this Agreement or the business or affairs of any of the parties, Roche, and/or any of their Affiliates.

1.8 "**EMA**" means the European Medicines Agency.

1.9 "**Event of Force Majeure**" has the meaning given in Clause 19.

1.10 "**FDA**" means the United States Food and Drug Administration.

1.11 "**Field**" shall mean any use that is consistent with an indication approved by the FDA and/or the EMA in relation to the Compound.

1.12 "**Head Licence**" means the Licensor's agreement with Roche dated 8 May 2026 (as amended from time to time) under which its right to license the Licensed Technology is derived.

1.13 "**Import Waiver**" means, in respect of a country in the Territory where, at the time of the intended sale or supply, the Products do not have regulatory approval, all export and import licences, authorisations, permits, consents or approvals necessary to supply, sell and/or offer for sale that Products in that country.

1.14 "**Improvement**" shall mean any new or improved process any new or improved manufacturing techniques or any further invention which relate to the manufacture or formulation of the Products and/or Compound or incorporate or are based on the Licensed Technology.

1.15 "**Improvement Patents**" shall mean any patents or patent applications which generically or specifically claim any Improvements which are developed by the Licensee, or to which the Licensee party otherwise has the right to grant licences, now or in the future.

1.16 "**Licensed Know-How**" means all confidential and proprietary information that is actually transferred or otherwise made available to Licensee pursuant to Clause 4.1 of the Head Licence.

1.17 "**Licensed Technology**" shall mean the Patents, the Non-Territory Patents, and the Licensed Know-How.

1.18 "**Net Sales Value**" means gross sale price of the Licensee or its Affiliates (or any person acting on their behalf) to their customers multiplied by the number of units sold, less the value of the sales taxes, products rejected due to quality failure or damage, clearing and forwarding, freight, and insurance charges.

1.19 "**Non-Territory Patents**" means those patents and pending patent applications listed in Appendix D and any foreign equivalents thereof in countries outside the Territory, as well as any divisionals, continuations, continuations-in-part, reissues, renewals, re-examinations, extensions, supplementary protection certificates, paediatric exclusivities, and the like of any such patents or applications. For the avoidance of doubt, to the extent international (e.g. WIPO) or regional (e.g. EPO) patents or patent applications are included in the Patents, such international and regional patent applications are Non-Territory Patents with respect to countries that are not included in the Territory. Appendix D shall be updated by Roche upon reasonable written request by Licensor.

1.20 "**Patents**" means those patents and patent applications as set out in Appendix C, and includes any divisionals, continuations, continuations-in-part, reissues, renewals, re-examinations, extensions, supplementary protection certificates, paediatric exclusivities, and the like of any such patents or patent applications, as well as any international (e.g. WIPO), regional (e.g. EPO), and foreign national equivalents thereof, in each case to the extent owned and/or controlled by Roche or any of its Affiliates.

1.21 "**Product(s)**" shall mean any pharmaceutical product(s) containing the Compound as an active pharmaceutical ingredient for use in the Field.

1.22 "**Regulatory Approval**" shall mean, in relation to each country of the Territory and each Product, the receipt of a marketing authorisation associated with that Product for that country. For the avoidance of doubt, this shall include a marketing authorisation obtained under an accelerated, abbreviated, emergency use, or similar regulatory pathway available under the laws of that country.

1.23 "**Relevant Regulatory Authority**" means (i) in relation to a particular jurisdiction in the Territory, the local regulatory authority having jurisdiction over the manufacture and/or commercialisation of the Products in that jurisdiction, or (ii) WHO pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).

1.24 "**Reporting Guidance**" means the guidance on reporting (as required in Clauses 13.2 and 13.3 of this Agreement on, inter alia, development timelines, regulatory activities, manufacturing and sales of Compound and Products) that will be issued by Licensor to Licensee, and as may be amended from time to time.

1.25 "**Roche**" means F. Hoffmann-La Roche Ltd and/or its Affiliates, as the context admits.

1.26 "**Roche Supplier**" shall mean any entity, as at the Effective Date, that (i) supplies Roche with materials for the manufacture of Compound, and (ii) is identified in a written list provided by Roche to Licensor and Licensee.

1.27 "**Royalty Countries**" means all countries in the Territory except for those classified by the World Bank as "Low-Income Economies".

1.28 "**Shionogi**" means Shionogi & Co., Ltd., 1-8, Doshomachi 3-chome, Chuo-ku, 541-0045, Japan.

1.29 "**Stringent Regulatory Authority**" means a regulatory authority which was a member or observer of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**"), or associated with an ICH member through a legally-binding mutual recognition agreement, in each case as before 23 October 2015.

1.30 "**Territory**" means all those countries as are set out in Appendix B, as may be amended from time to time in accordance with Clause 28.

1.31 "**Third Party(ies)**" means any party other than a party to this Agreement.

1.32 "**WHO**" means the World Health Organization.

1.33 "**WIPO Mediation Rules**" means the mediation rules adopted by the World Intellectual Property Organization from time to time.

1.34 References to "this Agreement" shall mean this licence agreement and shall include the Appendices.

1.35 Unless otherwise stated, references to "Clause(s)" and "Appendix(-ces)" are references to clauses and appendices of and to this Agreement and references to sub-clauses or paragraphs are references to sub-clauses or paragraphs of the Clauses or Appendices in which the reference appears.

1.36 Unless the context otherwise requires, the singular shall include the plural and vice versa and the masculine includes the feminine and neuter genders and vice versa.

1.37 The headings and sub-headings used in this Agreement are for convenience only and shall not affect the construction or the interpretation of this Agreement.

1.38 References to "party" or "parties" shall, unless otherwise stated or unless the context otherwise admits or requires, mean a party or parties to this Agreement.

2. GRANT OF SUBLICENCE

2.1 Subject to the terms and conditions of this Agreement and to the extent to which the Licensor has the right to grant a licence in respect of the Licensed Technology, the Licensor hereby grants to the Licensee a non-exclusive, non-transferable, royalty-bearing (in relation to the Royalty Countries), non-sublicensable (other than in accordance with Clauses 2.2 and 5.6) licence under the Licensed Technology to manufacture, have manufactured, use, offer for sale, sell, have sold, supply, import, or export the Compound and the Products anywhere in the world for ultimate use in the Field in the Territory.

2.2 Licensee may sublicense the rights set forth in this Agreement to its Approved Affiliates, for only so long as any such Approved Affiliate remains an Affiliate of Licensee and only where Licensees causes such Approved Affiliate to comply with the terms and conditions of this Agreement. Licensee agrees to be liable to Licensor and Roche for all acts and omissions by its Approved Affiliates which receive a sublicense hereunder; each such Approved Affiliate's acts and omissions will be deemed the acts and omissions of Licensee for the purposes of enforcement of Licensor's and Roche's rights pursuant to this Agreement. Except as explicitly permitted by this Clause 2.2 and by Clause 5.6, Licensee shall not further sublicense any of the rights set forth in this Agreement.

2.3 It shall not be a breach of this Agreement for Licensee to engage in any activity, inside or outside the Territory, that would not infringe any Patents or Non-Territory Patents granted and in force, including, without limitation, where a compulsory licence has been issued provided that such use is within the scope of the compulsory licence.

2.4 The Licensee's licence to have manufactured by a Third Party Compound and Products in accordance with Clause 2.1 shall be limited solely to manufacture on behalf of the Licensee of Compound and/or Product for supply to the Licensee (or to an Affiliate of the Licensee that has received a sublicence in accordance with Clause 2.2). Clause 2.1 shall not be construed as conferring any right for a Third Party to manufacture Compound and/or Products for supply to any party other than the Licensee and/or its Affiliate(s) (as applicable). The Licensee shall procure that any Third Party manufacturer shall comply with the terms of this Agreement as if it were the Licensee and shall remain fully liable for the acts and omissions of such Third Party manufacturer.

2.5 Notwithstanding the limitations in Clause 2.1, Licensee may sell or otherwise supply appropriate quantities of Product for use in clinical trials subject to the following conditions:

(a) no Product may be supplied under this Clause prior to receiving WHO prequalification or Regulatory Approval from a Stringent Regulatory Authority or WHO-Listed Authority in respect of Product; and

(b) no Product may be supplied under this Clause unless and until the clinical trial protocol in which Product is intended to be used has received ethical approval from a competent authority, as well as all other permissions and/or approvals required under the laws and regulations of the country in which the trial is to be conducted.

2.6 Other than the rights expressly granted in Clauses 2.1, 2.2 and 2.5, this Agreement does not confer any intellectual property rights on the Licensee nor any rights to manufacture, sell or supply Compound or Products inside or outside the Territory. Without prejudice to the generality of the foregoing, other than as expressly granted in Clauses 2.1, 2.2 and 2.5, no licence is granted to the Licensee to perform any acts or omissions which infringe any rights (including, but not limited to, patent rights) of the Licensor, Roche and/or any of their Affiliates and/or their sublicensees inside or outside the Territory.

2.7 The licence granted under this Agreement is subject to the intellectual property rights of any Third Party anywhere inside or outside the Territory. Without prejudice to the generality of the foregoing, no licence is granted to the Licensee to perform any acts or omissions which infringe any rights of any Third Party (including, without limitation, Roche and its Affiliates) inside or outside the Territory (including without limitation any rights relating to any active ingredient, other than the Compound, used in the Products).

2.8 The Licensee shall, acting in compliance with all applicable laws and regulations, use its best endeavours to maximise access to the Products in the Territory for use in the Field. Without prejudice to the generality of the foregoing, in the event that the Territory is amended by Licensor to include high-income economies (as defined by the World Bank) ("**HICs**"), Licensee shall prioritise those countries within the Territory that are low-, lower-middle- or upper-middle-income economies (as defined by the World Bank) ("**LMICs**"). If, in the reasonable opinion of Licensor, Licensee's supply of Products to HICs adversely affects its supply of Products to LMICs, Licensor shall give notice to the Licensee requiring it cure such defect. If in the opinion of the Licensor, the Licensee fails to report reasonable progress within 180 days after receiving written notice with respect to the defect, the Licensor shall have the

right to terminate this Agreement with immediate effect by giving written notice to the Licensee. Without limitation to the generality of this Clause, in exercising its reasonable opinion, the Licensor shall take into account the period within which the relevant authorities provide the necessary approvals as referred to in Clauses 5.2 and 5.3, normal development lead time for the Products, and progress reported by Licensee in its quarterly reports provided under Clause 13.2.

2.9 Notwithstanding the Effective Date of this Agreement, the Licensee undertakes not to sell or offer for sale a Product in a jurisdiction of the Territory prior to the relevant Approval Date for that Product for that jurisdiction (unless the sale or offer for sale is pursuant to an Import Waiver in that jurisdiction).

2.10 Where this Agreement requires the Licensee to obtain approval from Roche, the Licensee shall request such approval through the Licensor.

3. SOURCING OF RAW MATERIALS FROM ROCHE SUPPLIERS

3.1 Subject to Roche's compliance with Clause 7.8 of the Head Licence, Licensor shall provide to Licensee a list of Roche Suppliers within thirty (30) days of the Effective Date.

3.2 Prior to entering into any agreement with a Roche Supplier for the sale or supply of raw materials to be used in the manufacture of Compound and/or Product (including, without limitation, any chemical precursors or reagents), Licensee shall provide reasonable written notice to Licensor and Roche of its intention to source such materials from the Roche Supplier. Roche shall have the right to require, in good faith, reasonable conditions to ensure that the Roche Supplier's supply to Licensee does not adversely affect the Roche Supplier's ability to meet Roche's forecasted or actual supply requirements, and Licensee must take all reasonable steps to incorporate such conditions in its agreement with the Roche Supplier.

3.3 In any event and without prejudice to the foregoing, Licensee will endeavour to take commercially reasonable steps to diversify its own supply chain in relation to Compound and/or Product(s), so as to avoid over-reliance on any supplier or group of suppliers.

4. ROYALTIES

4.1 In consideration for the grant of the licence set out in Clause 2 in relation to the Royalty Countries the Licensee agrees to pay, subject to Clauses 4.2 to 4.8, the following royalties to Roche:

(a) five per cent (5%) of the Net Sales Value of all Products supplied in Royalty Countries classified by the World Bank as "Lower-Middle Income Economies" at the time of supply;

(b) ten per cent (10%) of the Net Sales Value of all Products supplied in Royalty Countries classified by the World Bank as "Upper-Middle Income Economies" at the time of supply; and

(c) forty per cent (40%) of the Net Sales Value of all Products supplied in Royalty Countries classified by the World Bank as "High-Income Economies" at the time of supply (to the extent that any such countries become included within the Territory, including as a result of the reclassification of a Royalty Country by the World Bank or

an expansion of the Territory in the event of a pandemic pursuant to Clause 2.6 of the Head Licence).

4.2 Royalty payments shall be paid to Roche on a Product-by-Product and country-by-country basis starting on the date of first sale of a Product in the relevant Royalty Country and continuing until the expiration of the last-to-expire Patent granted and in force in such country containing a valid claim covering the manufacture, use, import, offer for sale or sale of Compound and/or the Product in such country. For the avoidance of doubt:

(a) royalties shall be payable only once with respect to the same unit of Product, and

(b) nothing in this Agreement shall be construed as requiring Licensee to pay royalties in relation to the supply of Product into a country of the Territory where such supply would not infringe a Patent granted and in force in such country.

4.3 For the purposes of calculating royalties in accordance with this Clause 4, if Licensee sells in a particular country Product that includes active pharmaceutical ingredient(s) other than the Compound (hereafter, "**Combination Product**"), the Net Sales Value of such Product in such country will be calculated by multiplying the actual Net Sales value by the fraction **A/B**, where "**A**" is the mean invoice price invoiced by Licensee in such country during the relevant Agreement Quarter for Products in which the Compound is the sole active pharmaceutical ingredient ("**Mono Product**"), and "**B**" is the mean invoice price invoiced by Licensee in such country during the relevant Agreement Quarter for the Combination Products. If, on a country-by-country and Agreement Quarter-by-Agreement Quarter basis, the Licensee does not sell Mono Product in such country, "**A**" shall be replaced by the fair market value of Mono Product in such country, as such fair market values are provided (where applicable) in a statement by the Licensor on an annual basis and based on the average generic cost of the Mono Product.

4.4 When providing the information specified in Clause 13.3, the Licensee shall also provide to Licensor (or its nominee) its calculation of royalties payable to Roche pursuant to this Clause 4 in relation to the relevant Agreement Quarter. For Product sales in currencies other than Swiss Francs (CHF), royalties shall first be determined in the relevant foreign currency and then converted into CHF at the exchange rate published on *<www.oanda.com/currency-converter/en>* on the last Business Day of the relevant Agreement Quarter.

4.5 The Licensor shall supply the Licensee with an invoice from Roche in CHF in each Agreement Quarter for any royalty fee payable for the Agreement Quarter immediately preceding such Agreement Quarter. The Licensee shall, within thirty (30) days following the receipt of said invoice, pay to Roche (or to such other person as Roche may nominate in writing) in CHF, by way of wire transfer to such bank account as Roche shall nominate in writing, the amount due under that invoice.

4.6 In the event of any delay in the Licensee paying to Roche any sum due under this Clause 4 on the relevant due date, the Licensee shall pay to Roche interest (calculated on a daily basis) on the overdue payment from the date such payment was overdue to the date of actual payment at the annual rate of 2% above the Swiss National Bank (SNB) base rate as reported by SNB at *<snb.ch/en/the-snb/mandates-goals/statistics/statistics-pub/current_interest_exchange_rates>* on the due date of payment (or on the next Business Day if the due date is not a Business Day), on a daily basis using a three hundred and sixty-five (365) day year and such annual rate, compounded monthly.

4.7 If an inspection pursuant to Clause 13 reveals an underpayment by Licensee, Licensee shall promptly, and in any event within 30 days of the determination of such shortfall, pay to Roche the amount of such shortfall (including any interest payable pursuant to Clause 4.6 hereof) together with all costs incurred by Roche and/or Licensor in carrying out the inspection.

4.8 All amounts payable pursuant to this Agreement shall be made subject to withholding or deduction of, or in respect of, any tax, levy, impost, duty, charge or fee, as required by law. If any such withholding or deduction is required by law, the Licensee shall, when making the payment to which the withholding or deduction relates, pay to Roche (or to such other person as Roche may nominate in writing) the net amount and provide a certificate equivalent to the amount withheld.

5. DEVELOPMENT AND REGISTRATION

5.1 **Development generally**. As of the Effective Date and subject always to Roche's retained rights to the Licensed Technology (and that of its licensees), the Licensee shall have full control, responsibility (financial and otherwise) and authority over development, registration, importation, manufacture and commercialisation of the Products to be sold or supplied by the Licensee in the Territory under this Agreement.

5.2 **Manufacturing obligations**. Licensee agrees that it will manufacture Compound and Product in a manner consistent with (i) WHO pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority or WHO-Listed Authority. Where such standards are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable. Licensor may, in exceptional circumstances and in accordance with Article 4(e) of its Statutes, approve alternative manufacturing standards for the purposes of complying with this Clause.

5.3 **Regulatory approvals**. The Licensee will obtain from the relevant authorities in the Territory and maintain in force, as appropriate, all health registrations, permissions, consents and regulatory authorisations relating to the importation, manufacture and sale of the Products which are necessary to enable the Products to be sold or supplied in the Territory in accordance with this Agreement. Licensee shall submit a complete file for Regulatory Approval of a Product before at least one Relevant Regulatory Authority (including, but not limited to, the WHO pre-qualification programme) or one Stringent Regulatory Authority or WHO-Listed Authority not later than 36 months from the Effective Date, or such other period as agreed in writing by Licensor and Licensee, and will diligently pursue such applications following submission. Licensee shall also, upon Licensor's reasonable request, file for Regulatory Approval before the Relevant Regulatory Authority for any subsequent Products within a reasonable time.

5.4 **No supply prior to approval**. The Licensee shall not sell or otherwise supply Products in a country of the Territory prior to (a) Regulatory Approval from Relevant Regulatory Authority in that country, unless the sale or supply is made pursuant to Import Waiver; and (b) WHO prequalification, Regulatory Approval from a Stringent Regulatory Authority or WHO-Listed Authority, WHO Expert Review Panel approval, any provisional authorisations available through WHO, a Stringent Regulatory Authority or a WHO-Listed Authority, or any alternative mechanism approved by Licensor pursuant to Clause 5.2 above.

5.5 **Termination right**. If the Licensee sells, supplies or otherwise disposes of any Product otherwise than in compliance with Clauses 5.2 to 5.4 the Licensor shall be entitled to immediately terminate this Agreement by providing written notice to the Licensee.

5.6 **Local Distributors**. The Licensor acknowledges that in some countries of the Territory, for Product to be lawfully sold or supplied, Regulatory Approval must be held in the name of a local entity registered in such country ("**Local Distributor**"). Where Product can only be lawfully sold or otherwise supplied in a country of the Territory by a Local Distributor, the Licensee may use an Affiliate (or, where no Affiliate of the Licensee can act as such Local Distributor, another Third Party) as a Local Distributor in that country. In such cases, Licensee must provide Licensor with prior written notice of its intent to use an Affiliate or other Third Party as a Local Distributor in that country, accompanied by appropriate supporting documentation that demonstrates the need to use a Local Distributor in that country. The Licensee shall have the right to sublicence to the Local Distributor such of its rights under this agreement as are strictly necessary for the Local Distributor to obtain Regulatory Approval and/or sell or otherwise supply the Licensed Product in the relevant country of the Territory.

5.7 **Compliance**. The Licensee will manufacture and sell the Products in accordance with all laws and regulations relevant to the manufacture and sale of the Products and in accordance with good industry practice.

5.8 **Pandemic preparedness**. Within three (3) months of submitting its first complete file for Regulatory Approval pursuant to Clause 5.3 above, Licensee will confer in good faith with the WHO's Pandemic Influenza Preparedness Framework ("**PIP Framework**") Secretariat regarding the possibility of commitments under section 6.8 of the PIP Framework or other contributions to pandemic preparedness. If requested by Licensee, Licensor will provide any necessary assistance to facilitate these discussions

6. REFERENCE PRODUCT AND DATA PACKAGE

In the event that Licensee:

(a) wishes to procure Roche Product directly from Roche for use in bioequivalence studies required to obtain Regulatory Approval and/or in *in vitro* research related to Licensee's Product; and/or

(b) wishes to obtain a data package from Roche to expedite developing and filing for Regulatory Approval,

Licensee shall submit a written request to Licensor (which shall, for any request to procure Roche Product, indicate the proposed use of said Product). Upon receipt of such request, Licensor shall forward the request to Roche for consideration under Clause 4.1 and/or 4.2 of the Head Licence (as applicable) and shall keep Licensee informed of progress and outcome of the request.

7. SUPPLY, DISTRIBUTION AND LABELLING

7.1 The Licensee shall be solely responsible for providing its own clinical, promotional and commercial infrastructure to support the manufacture and sale of the Products in the Territory. The Licensee agrees, where applicable and to the extent that it is able: (a) to not seek; and (b) to waive, regulatory exclusivity in the Territory in relation to any data relating to the Products.

7.2 The Licensee shall be solely responsible for the distribution in the Territory of all Products to be sold in the Territory under this Agreement.

8. EXCHANGE OF INFORMATION AND CONFIDENTIALITY

8.1 During the term of this Agreement and for five (5) years thereafter, the Parties shall not use, reveal or disclose to any Third Party, or to any of their Affiliates save for those of its Affiliates who need to know such information to exercise the Party's rights under this Agreement, any Confidential Information received from the other Party or Roche and/or any of their Affiliates or otherwise developed by any Party in the performance of activities in furtherance of this Agreement, except as may be otherwise provided herein or as may be required for the purposes of securing essential authorisations in respect of the performance of this Agreement from governmental agencies in the Territory, or as may be required to be disclosed under law or regulation in the Territory. This confidentiality obligation shall not apply to such information which:

(a) the receiving party can prove, by written records, is or has become a matter of public knowledge other than through any breach by or at the instigation of the receiving party, or any of its Affiliates, of this Agreement;

(b) is already legitimately in the possession of the receiving party;

(c) is disclosed to the receiving party by a Third Party (other than the disclosing party or Roche and/or its Affiliates) having the right to do so;

(d) is subsequently and independently developed by employees of the receiving party or its Affiliates who had no knowledge of the Confidential Information disclosed;

(e) in the case of the Licensor, is required to be disclosed to Roche under the terms of the Head Licence; or

(f) a Party is required by law to disclose, provided that the disclosing Party is promptly notified of any such requirement, and the receiving Party otherwise complies with the provisions of this Clause 8.

8.2 The Parties shall ensure that no unauthorised use or disclosure is made by others to whom access to such Confidential Information is granted, by binding such persons on like terms to this Agreement which are enforceable by each of the Licensor and Roche.

8.3 If a receiving Party becomes obligated by law to disclose Confidential Information received under or in connection with this Agreement, or any portion thereof, to any Third Party, governmental authority or court, that Party shall immediately notify the disclosing Party of each such requirement and identify the Confidential Information to be disclosed so that such disclosing Party (or Roche or its Affiliates where the Confidential Information relates to or belongs to Roche or its Affiliates) may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and, to the extent necessary, waive the receiving Party’s compliance with the confidentiality obligations of this Agreement.

8.4 The Parties acknowledge that disclosure of any Confidential Information in breach of this Agreement could give rise to irreparable injury to the non-breaching Party and that such injury will not be adequately compensated by damages. Accordingly, the non-breaching Party, and Roche and its Affiliates where the non-breaching Party is the Licensor, shall be entitled to seek the remedies of specific performance and injunctive relief or other equitable relief for any threatened or actual breach of this Clause 8. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.

8.5 All Confidential Information shall remain the property of the disclosing party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a party to this Agreement, based on the insolvency or bankruptcy of such party (or based on any other analogous or similar status of that party under foreign laws), the bankrupt or insolvent party shall promptly notify the court or other tribunal:

(a) that Confidential Information remains the property of the disclosing party; and

(b) of the confidentiality obligations under this Agreement.

In addition, the bankrupt or insolvent party shall, to the extent permitted by law, take all steps necessary or desirable to maintain the confidentiality of such Confidential Information and to ensure that the court, other tribunal or appointee maintains such information in confidence in accordance with the terms of this Agreement.

8.6 Prior to submitting for written or oral publication any manuscript, abstract or the like which includes data or other information generated and provided under the terms of, or in relation to, this Agreement or relating to Products, the Licensee shall provide a copy of such Publication to Roche and shall take into account Roche's reasonable comments in connection therewith.

8.7 Nothing in this Agreement shall be construed as preventing or in any way inhibiting the Licensee from complying with statutory and regulatory requirements relating to, or arising out of, its rights under this Agreement.

9. PHARMACOVIGILANCE AND RISK MANAGEMENT

9.1 The Parties shall comply with the provisions of Appendix E to this Agreement.

9.2 Notwithstanding and without prejudice to the Licensor's rights under Clause 13, the Licensor shall have the right to monitor compliance with this Clause 9. In connection with such monitoring, the Licensee shall promptly provide all reasonably requested information and shall grant access to relevant records, systems, personnel, and facilities as may be necessary to verify compliance, including where such monitoring occurs in the context of an audit. The Licensee shall promptly implement appropriate corrective and preventive actions in respect of any identified non-compliance.

10. NON-DIVERSION

10.1 Save as provided under this Agreement, and to the extent that such restrictions comply with applicable law, the Licensee shall not, directly or indirectly, sell or supply:

(a) Products or Compound outside the Territory where there is a Non-Territory Patent granted and in force;

(b) Compound to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Compound outside the Territory where there is a Non-Territory Patent granted and in force;

(c) Products to any Third Party in the Territory that the Licensee knows, believes or ought reasonably to suspect will sell or supply Products outside the Territory where there is a Non-Territory Patent granted and in force.

10.2 The Licensee shall ensure that packaging (whether external, intermediate or internal), data sheets and promotional materials for the Products to be sold or otherwise supplied by the Licensee under this Agreement shall, unless inclusion of such statement is prohibited by applicable law, national procurement policy or the Relevant Regulatory Authority, carry clear statements in bold type that the Products have been produced under a licence from the Medicines Patent Pool.

Where inclusion of any of these statements is prohibited, the Licensee shall inform the Licensor of the prohibition and provide appropriate supporting evidence in order to seek a waiver.

11. INTELLECTUAL PROPERTY

11.1 If at any time during the term of this Agreement the Licensee (or any of its employees, agents, or other persons acting under its authority) makes, develops, conceives, acquires, reduces to practice, becomes entitled to or secures control over any Improvement it shall communicate such Improvement to Licensor and Roche in full together with all available information concerning the mode of working and using the same. Licensor and Roche shall treat this information as Confidential Information.

11.2 Licensee hereby grants to Licensor, Roche and Shionogi a perpetual, irrevocable, worldwide, royalty-free, non-exclusive licence to use any Improvement, Improvement Patent and related know-how (and shall promptly execute such document as Licensor and/or Roche may reasonably request accordingly). Licensor shall not sublicense such rights to any Third Party, provided, however, that should Licensor desire to sublicense any such rights, Licensee and Licensor agree to enter in good faith negotiations regarding such sublicence. Roche shall be entitled to grant sublicences (without further right to sublicence) under such licence only to its:

(a) Affiliates; and/or

(b) contract manufacturers, distributors and service providers solely for use in connection with their engagement of commercialising Roche products.

11.3 Licensee shall have no rights in relation to the conduct of any matter relating to the filing, prosecution and maintenance of Patents or Non-Territory Patents.

11.4 If any suit or claim by a Third Party is instituted against the Licensor or the Licensee for patent infringement involving the Products and/or the Compound, the Party sued shall promptly notify the Licensor and Roche in writing. Roche shall have the right, but not the obligation, to defend or to conduct the defence of such suit or claim at its own expense. The Licensee shall assist Roche and co-operate in any such litigation at Roche's request and expense.

11.5 Roche (and in no circumstances the Licensee) shall be entitled to bring infringement action in relation to the Patents or Non-Territory Patents at its own expense. To the extent Roche decides not to bring any such infringement action, Roche shall not be liable to the Licensee in any respect for such decision. The Licensee shall assist Roche and co-operate in any such litigation at Roche's request without expense to the Licensee.

12. TRADE DRESS AND TRADE MARKS

12.1 Subject always to Clauses 12.2 and 12.4, the Licensee, at its expense, shall be responsible for the selection, registration and maintenance of all trade marks which it employs in connection with the Products to be sold by the Licensee in the Territory under this Agreement and shall

own and control such trade marks. Nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensor to use such trade marks for any purpose. Further, nothing in this Agreement shall be construed as a grant of rights, by licence or otherwise, to the Licensee to use the trade marks owned by the Licensor, Roche, and/or any of their Affiliates anywhere in the world for any purpose.

12.2 The Licensee shall not use or seek to register (or, where it is possible to do so, apply to use or register) any trade or service mark, trade dress (where applicable), symbol or device in relation to any Products or any of their packaging (whether external, intermediate or internal) or promotional material which incorporates or is identical or confusingly similar to (i) any trade or service mark, trade dress, symbol or device used by the Licensor, Roche, Shionogi and/or any of their Affiliates anywhere in the world, or (ii) an International Nonproprietary Name assigned by the WHO in respect of a Compound. If the Licensor and/or Roche become aware that the Licensee is in breach of this Clause 12.2, the Licensee shall immediately stop any such use and withdraw any such trade mark application and/or registration upon request by the Licensor and/or Roche. This clause shall be without prejudice to any legal rights the Licensee may have in relation to the use of a trade or service mark, trade dress, symbol or device which is identical or confusingly similar to any trade or service mark, trade dress, symbol or device used by the Licensor, Roche and/or any of their Affiliates anywhere in the world where that use by the Licensee pre-dates the rights of the Licensor, Roche and/or any of their Affiliates.

12.3 The Licensee shall ensure that any Product offered for sale or sold under this Agreement shall utilise a trade dress, including colour, and a trade name that are appropriately differentiated from the trade dress, colour, and trade name used by Roche and/or any of its Affiliates for the comparable product anywhere in the world, subject to the requirements of any applicable laws, regulations, or official guidance from Relevant Regulatory Authorities.

12.4 The Licensee shall obtain the prior written approval, such approval not to be unreasonably withheld or conditioned, of the Licensor and Roche for any trade name the Licensee proposes to use in relation to the Products and any trade dress that the Licensee proposes to use on any of the packaging thereof (whether external, intermediate or internal) before seeking to register any such trade marks, before offering to sell, selling or otherwise disposing of any Products, and before applying for government or relevant regulatory authorisation to do so. The Licensor and Roche shall respond to any request for approval from the Licensee within thirty (30) days of receipt by Roche (from the Licensor) of all the relevant documentation necessary to consider the Licensee's request, with an approval or a written statement of why the request is not being approved by Roche. The Licensor and Roche must approve the request unless they have reasonably formed the view that the proposed trade name and/or trade dress is in breach of Clause 12.2 or Clause 12.3.

12.5 For the avoidance of doubt, any approval provided by the Licensor and/or Roche under Clause 12.4 is not to be interpreted as acquiescence by the Licensor and/or Roche that any packaging and/or labelling complies with any local legal or regulatory requirements, which remains the Licensee's responsibility.

13. STATEMENTS AND REMITTANCES; REPORTING

13.1 **Record-keeping; Audit**. At all times the Licensee shall keep, and shall require its Affiliates and any Third Party manufacturers and Third Parties making sales on its behalf to keep, complete and accurate records for the previous two (2) years (or for the period from the Effective Date to the then current date if such period is less than two years) of all quantities of

Compound and Products manufactured and/or sold under the licences granted by this Agreement, together with that information contemplated by Clause 13.3 and such information of the type and in sufficient detail to determine the calculation of royalties payable under this Agreement. The Licensor and Roche shall each have the right (and the Licensee shall procure such right), at its expense, through a certified public accountant or like person appointed by it, to examine such records during regular business hours during the term of this Agreement and for six (6) months after its termination or expiry; provided, however, that such examination shall not take place more often than twice in any calendar year and shall not cover such records for more than the preceding two calendar years and provided further that such accountant or like person shall report to Roche only as to:

(a) the accuracy of the manufacturing, sales and royalty statements of the Licensee (and/or its Affiliates and/or its Third Party manufacturers contemplated by this Agreement) in relation to such manufacture and sales;

(b) the appropriateness of quantities of Compound and Products imported or manufactured pursuant to this Agreement by reference to what quantities of Compound and Products would reasonably be required to meet demand for actual sales made and sales forecasted by the Licensee;

(c) verification that all sales and other supplies of Products and Compound made by the Licensee have been made (i) in the Territory, except for Products and Compound made outside the Territory as expressly provided for in this Agreement and (ii) otherwise in accordance with Clause 10; and

(d) verification that all sales and other supplies of Products and Compound made by Third Party manufacturers contemplated by this Agreement have been made to the Licensee in accordance with this Agreement.

13.2 **Development and regulatory approval**. Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report on the status of development of the Compound and any regulatory filing regarding the Products in relation to that Agreement Quarter. Such reporting shall be made in accordance with the Reporting Guidance issued by the Licensor and should cover (a) Products in its development pipeline, (b) status of development of each Product in development, (c) regulatory filing plan for each Product, and (d) a list of countries for which such regulatory approvals or authorisations have been filed and/or obtained for any Product. The Parties agree to confer on a quarterly basis regarding such reports and also review development and filing status of Products. For avoidance of doubt, Roche and the Licensor agree that information contained in quarterly and other such reports shall be treated as Confidential Information.

13.3 **Sale and supply**. Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly written report of all Products (in terms of smallest units and patient packs for each formulation) sold or supplied by the Licensee under this Agreement during such Agreement Quarter. Such accounting shall be made in accordance with the Reporting Guidance issued by the Licensor and show smallest unit, pack size, gross sales and Net Sales Value in CHF on a Product-by-Product, country-by-country, month-by-month and purchaser-by-purchaser basis.

14. SANCTIONS

14.1 The Parties acknowledge that a number of organisations and countries have adopted sanctions legislation relating to the Territory and/or entities and individuals which or who are resident or operate in the Territory and that such sanctions are varied or amended from time to time. The Licensee represents and warrants to Licensor and Roche that neither the Licensee nor, to the knowledge of the Licensee, any Affiliate, director, officer, employee of the Licensee, is a target of any applicable sanctions laws.

14.2 The Licensee represents and warrants that it is aware of and, in carrying out its obligations under the Agreement, will comply with and not become exposed to penalties or other retaliatory measures under any applicable sanctions, export control, and anti-boycott laws, regulations, orders, directives, designations, licences, or decisions of any country (or, as applicable, group of countries) with jurisdiction over activities undertaken in connection with the Agreement, including, without limitation, those of the European Union, Japan, Switzerland, the United Kingdom, the United Nations, and the United States (together, "**Sanctions Controls**"). Licensee further represents and warrants that, in the performance of its obligations under the Agreement, it will not take any action that causes Licensor and/or Roche to violate or otherwise become exposed to penalties or other retaliatory measures under any of the Sanctions Controls.

Without prejudice to the generality of the foregoing, Licensee represents and warrants that it shall not provide Product directly to the military, military hospitals and armed forces as end-users of any countries in contravention of any Sanctions Controls.

14.3 Notwithstanding the requirements of Clause 14.2, nothing in this Agreement shall be construed to prevent the Licensee from benefiting from an exemption or general license for activities that would otherwise be sanctioned by a country with jurisdiction over activities undertaken in connection with this Agreement. This includes exemptions or general licenses authorising the distribution, sale, use, supply, import or export of the Product for humanitarian assistance. To the extent that such activities benefit from an exemption or general license, the Licensee shall only be required to notify the Licensor pursuant to the requirements of Clause 24 of this Agreement.

15. ANTI-TERRORISM

15.1 Licensee represents and warrants that it is not in any way involved with the manufacture or sale of arms or ammunition.

15.2 Licensee declares that it is not a terrorist organisation, nor does it finance, make items or funds available or otherwise assist in the commission of terrorist acts by any individual or entity designated under applicable counter-terrorism sanctions or other measures, including that of the UN Security Council, pursuant to Security Council Resolution 1267 (1999) and 1989 (2011) or any other terrorism-related resolutions, included those managed by the US Office of Foreign Assets Control.

16. TERM AND TERMINATION

16.1 This Agreement shall be deemed to come into effect on the Effective Date and shall continue thereafter subject to the further provisions of this Clause 16.

16.2 Unless otherwise terminated, this Agreement shall expire upon the expiration, lapse or invalidation of the last remaining Patent in the Territory. Upon such expiration, the licence

granted to the Sublicensee under Clause 2 shall become a perpetual, fully paid-up, royalty-free licence under the Licensed Know-How to develop, make, have made, use, sell, have sold, offer for sale, import and distribute Compound and/or Product.

16.3 Save as otherwise provided in this Agreement, if the Licensee breaches any provision of this Agreement and if such breach (i) is material and incapable of correction; or (ii) is capable of correction but is not corrected within sixty (60) days after receiving written notice with respect to such default, the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the party in default.

16.4 Save as otherwise provided in this Agreement, if the Licensee repeatedly and/or persistently (meaning more than once) breaches this Agreement (whether or not such breaches are material), the Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.

16.5 If:

(a) Licensor becomes aware of an actual or threatened claim that Licensee's use of the Patents in the Territory infringes the intellectual property rights of a Third Party; or

(b) Licensor receives notice from Roche that Roche's right to grant licences of the Patents is challenged,

Licensor shall (and Roche shall be entitled to) notify the Licensee in writing, detailing the nature of such claim or challenge. Licensee shall, within ten (10) Business Days of receipt of such notice, and without prejudice to any of the Licensee's other obligations or liabilities under this Agreement or the Licensor's rights (including without limitation under Clause 16.6), elect to:

(c) suspend the terms of this Agreement in respect of the relevant Patent(s) until such issue is resolved; or

(d) confirm in writing that it will indemnify Licensor and Roche against any Losses (as defined in Clause 18.5) incurred by Licensor and/or Roche in connection with Licensee's continued use of such Patent(s) pursuant to this Licence.

If Licensee does not so notify Licensor within ten (10) Business Days of receipt of Licensor's (or Roche's) initial notice, the Agreement shall be deemed suspended pending resolution of the issue.

16.6 Licensor may terminate this Agreement, either in whole or in relation to a particular Patent or Patents, with immediate effect by notice in writing to Licensee if:

(a) Licensee breaches any of the provisions of Clause 10 or Clause 14;

(b) it is determined that Licensee's use of the Patents in the Territory or Non-Territory Patents outside of the Territory infringes the intellectual property rights of a Third Party;

(c) Roche's right to grant licences of the Patents or Non-Territory Patents expires or is terminated;

(d) Roche or Licensor receives a Third Party claim or demand for royalty payments relating to sales of the Products or Compound by Licensee, unless Licensee agrees to satisfy the claim should such a claim or demand become payable;

(e) the legal or beneficial ownership or control of Licensee and/or any of its Affiliates changes in such a manner as Licensor shall in its sole discretion consider significant; or

(f) Licensee repeatedly fails to timely provide Licensor with any report or statement required under this Agreement including, without limitation, those contained in Clauses 13.2 and 13.3 of this Agreement.

16.7 The provisions of Clauses 16.6(a), 16.6(b) and 16.6(d) are without prejudice to the Licensor's or Roche's rights to claim all damage and loss suffered by the Licensor, Roche and/or any of their Affiliates arising out of, or in relation to, the event giving rise to termination. In respect of such damage or loss under Clauses 16.6(a), 16.6(b) and/or 16.6(d) the Licensee hereby agrees to indemnify the Licensor and Roche subject to the Licensor and Roche (each of which shall be entitled to conduct the defence of such claims against them) taking reasonable account of the Licensee's input in the conduct of the claim to which such loss or damage relates. For the avoidance of doubt, the provisions of Clause 32 apply to any dispute between the Parties, or between Roche and the Licensee, in relation to the indemnities given under this Clause 16.7.

16.8 Any Party may terminate this Agreement with immediate effect by providing a written termination notice to the other Parties if, at any time, the other Party shall compound or make arrangements with its creditors or be adjudicated bankrupt or have a receiver appointed over all or any part of its assets or go into liquidation (whether voluntary or otherwise) otherwise than as part of a bona fide amalgamation or reconstruction without insolvency or suffer any insolvency event or analogous process under foreign laws.

16.9 Any change in the legal or beneficial ownership or control of the Licensee shall be immediately notified in writing to the Licensor and Roche by the Licensee. For the purposes of this Clause 16.9, "control" shall mean the ability of a person, entity or corporation to ensure, whether through ownership of shares or otherwise, that the affairs of a party are conducted in accordance with the wishes of such person, entity or corporation.

16.10 If Licensee fails to file for Regulatory Approval before at least one Relevant Regulatory Authority (including, but not limited to the WHO pre-qualification programme), Stringent Regulatory Authority or WHO-Listed Authority within 36 months, or such other period as agreed in writing between Licensor and Licensee, or fails to respond to Licensor's reasonable request in respect of any subsequent Products, Licensor shall have the right to terminate this Agreement with immediate effect by giving written notice to the Licensee.

16.11 Unless notice to the contrary is given by Roche, this Agreement shall terminate immediately in the event that the Head Licence is terminated or expires. This Agreement shall, subject to the conditions specified at Clause 7.4 of the Head Licence, be converted into a licence between Roche and the Sublicensee.

16.12 Licensee may terminate this Agreement at any time by providing thirty (30) days' written notice to Licensor.

16.13 Licensee acknowledges that it was offered to enter into this Agreement on the basis of certain representations and projections that it made through Licensor's Expression of Interest system.

Licensee hereby warrants that information provided by Licensee to Licensor during the Expression of Interest and selection process is complete, truthful and accurate in all respects. In the event that MPP discovers any material misrepresentations made therein, or if Licensee fails to substantially meet its projections (including, without limitation, projections regarding the countries in which Licensee intends to commercialise the Product, the efforts and resources that Licensee intends to devote to the commercialisation of the Product, and the extent to which Licensee's supply is sufficient to meet demand), MPP shall have the right to terminate this Agreement upon thirty (30) days' written notice.

17. RIGHTS AND DUTIES UPON TERMINATION OR EXPIRY

17.1 Upon termination or expiry of this Agreement, in accordance with Clauses 16.6(e), 16.8, 16.10, 16.11 and/or 16.12 the Licensee shall immediately notify the Licensor and Roche of the amount of Product the Licensee then has available to it and, provided that such amount is, in the opinion of Roche, reasonable in all the circumstances, the Licensee shall be permitted to sell that amount of Product in the Territory. This provision shall only apply to the extent that such termination would deprive Licensee of legal rights with respect to Product and Compound.

17.2 Termination or expiry of this Agreement shall not affect those provisions of this Agreement which are expressed or intended to survive the termination or expiration of this Agreement in particular, but without limitation, Clauses 8, 13, 18.5, 18.6 and 18.7 and the relevant provisions of this Clause 17. In addition, any other provisions required to interpret and enforce the parties' rights and obligations under this Agreement shall also survive, but only to the extent that such survival is required for the full observation and performance of this Agreement by the Parties.

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

18. WARRANTIES AND INDEMNITIES

18.1 Each of the Parties warrants that, to the best of its knowledge and belief:

(a) it has power to execute and deliver this Agreement and to perform its obligations under it and has taken all action necessary to authorise such execution and delivery and the performance of such obligations; and

(b) this Agreement constitutes legal, valid and binding obligations of that Party in accordance with its terms.

18.2 Nothing in this Agreement shall be construed as a warranty that (a) the information set out in Appendix C or Appendix D accurately reflects the status of Roche's patents and patent applications relating to the Compound and/or Products, (b) any of the Patents or Non-Territory Patents are valid or enforceable, or (c) their exercise does not infringe any patent rights of any Third Parties.

18.3 The Licensee acknowledges that, in entering into this Agreement, the Licensee has independently evaluated any information supplied by the Licensor and Roche (including, but not limited to, such information related to the Products), as well as the viability of this Agreement, before making its decision to enter into this Agreement and to undertake the commitments and obligations set forth herein.

18.4 The Licensee acknowledges that the Licensor and Roche do not in any way endorse the use of any Products sold or manufactured by the Licensee containing the Compound or other active ingredient, whether as a single compound or in combination with other compounds.

18.5 The Licensee hereby agrees to indemnify the Licensor, Roche, their Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgements, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("**Losses**"), that arise in connection with (i) the Licensee's breach of this Agreement; or (ii) the Licensee's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt any product liability claim relating to the Products manufactured by or on behalf of Licensee pursuant to this Agreement), provided that the indemnification obligation established in this Clause shall not apply to the extent such Losses arise out of negligence or wilful misconduct by Roche, its Affiliates and their respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. Roche shall, or shall procure that the Indemnified Person shall, provide Licensee with prompt written notice of such claims. Subject to Clauses 11.4 and 16.7, the Indemnified Person and Licensee will agree on the appropriate party to assume control of the defence or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.

18.6 Clause 18.5 may be enforced directly by each Indemnified Person against the Licensee.

18.7 Immediately upon the first administration of a Product to a human in accordance with this Agreement, and for a period of ten (10) years after the expiration or earlier termination of this Agreement, the Licensee shall obtain and/or maintain, at its sole cost and expense, product liability insurance in amounts which are reasonable and customary in the pharmaceutical industry of the countries in which the Compound and Products are manufactured, distributed and sold (as relevant), subject always to a minimum limit equivalent to U.S.$10,000,000 per occurrence (or claim) and in the aggregate annually. Such product liability insurance shall insure against all liability, including product liability, personal liability, physical injury or property damage. The Licensee shall provide written proof of the existence of such insurance to the Licensor and Roche upon request from either therefor and shall monitor such policy on a monthly basis to ensure that any cover is revised to take account of any currency fluctuations.

19. FORCE MAJEURE

19.1 If the performance of any part of this Agreement by any Party, or of any obligation under this Agreement (other than those provisions which in any respect concern the payment under any indemnity or otherwise under this Agreement) is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform (an "**Event of Force Majeure**"), unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable endeavours to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If the Event of Force Majeure continues for a period of more than six (6) months, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party.

20. RIGHT OF SET OFF

20.1 All amounts due by the Licensee under this Agreement shall be paid in full in Swiss Francs (CHF) or such other currency as may be agreed in full without any set-off or counterclaim and free and clear of all taxes, deductions, withholdings and other charges of whatever nature other than as required by law and the Licensee shall not be entitled to assert any set off or counterclaim in order to justify withholding payment of any such amount in whole or in part.

20.2 The Licensor and Roche shall be entitled at any time, without notice to the Licensee, to set off any liability of the Licensor or Roche to the Licensee (for example, in connection with the purchase of stock in hand and/or Compound pursuant to Clause 17), against any liability of the Licensee to the Licensor or Roche and may for such purpose convert or exchange any currency. Any exercise by the Licensor or Roche of their rights under this Clause 20.2 shall be without prejudice to any other rights or remedies available to the Licensor or Roche under this Agreement.

21. THIRD PARTY RIGHTS

21.1 Except for Roche and Roche's Affiliates or as otherwise expressly provided under this Agreement, a person who is not a party to this Agreement shall not have any right to enforce any term of this Agreement.

21.2 Roche and/or any of its Affiliates have the right to enforce and rely on the terms of this Agreement. The Licensee expressly agrees that Roche or any of its Affiliates shall be entitled to enforce any of the provisions of this Agreement as if they were named as a party to this Agreement in place of the Licensor.

21.3 The rights of the Licensor under this Agreement shall be applicable to Roche to the same extent as for the Licensor and the Licensor shall exercise such rights on behalf of Roche if so requested by Roche.

22. SEVERABILITY

22.1 In the event that any portion of this Agreement is or is held by any court or tribunal of competent jurisdiction to be illegal, void, unenforceable or ineffective, the remaining portions hereof shall remain in full force and effect.

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

22.3 In the event that the terms and conditions of this Agreement are materially altered as a result of Clauses 22.1 and/or 22.2, the Parties and Roche will seek to renegotiate the terms and conditions of this Agreement to resolve any inequities. If the Parties cannot reach an agreement, they agree to submit their dispute to mediation in accordance with Clause 32 of this Agreement. In the event that the dispute remains unresolved, either Party may terminate this Agreement by providing a written termination notice to the other Party.

23. ENTIRE AGREEMENT

23.1 This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous writings and understandings between the parties relating to the transactions contemplated by this Agreement.

23.2 Subject to Clause 23.3, each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of any other party before the date of this Agreement. Each Party waives all rights and remedies which, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

23.3 Nothing in this Clause 23 limits or excludes any liability for fraud.

24. NOTICES

24.1 Any notice, document or other communication required to be given or served under, or in connection with, this Agreement:

(a) shall be in writing;

(b) shall be in the English language; and

(c) shall be:

(i) delivered personally;
(ii) sent by commercial courier;
(iii) sent by registered or certified mail (postage paid); or
(iv) sent by email (receipt confirmed).

24.2 The addresses for delivery of a notice or other communication are as follows:

(a) to **Licensor**, marked for the attention of General Counsel, at:

Medicines Patent Pool
Rue de Varembé 7, Fifth Floor
CH-1202 Geneva
Switzerland
E-mail: Legal@medicinespatentpool.org

(b) to **Licensee**, marked for the attention of […] at:

[…]

(c) to **Roche**, marked for the attention of Legal and Compliance, at:

124 Grenzacherstrasse
4070 Basel
Switzerland

24.3 If a notice or other communication has been properly sent or delivered in accordance with this Clause 24, it will be deemed to have been received as follows:

(a) if delivered personally—at the time of delivery;

(b) if sent by commercial courier—on the date and at the time of signature of the courier's delivery receipt;

(c) if sent by registered or certified mail (postage paid)—on the fifth Business Day after posting; or

(d) if sent by email—on the date of delivery (receipt confirmed),

24.4 The provisions of this Clause 24 shall not apply to the service of any proceedings or other documents in any legal action.

25. ASSIGNMENT AND SUBCONTRACTING

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

25.2 Save as expressly set out in Clauses 2.1 to 2.4, and subject to those Clauses, neither the Licensor nor the Licensee shall be entitled to subcontract any of its rights or obligations under this Agreement.

26. NO COMPENSATION

To the extent that such exclusion is permitted by applicable law, no compensation, whether for loss of profit or any other reason whatsoever, shall be payable by any Party arising from any lawful amendment or lawful termination or expiry of this Agreement.

27. COSTS

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

28. AMENDMENTS

28.1 The Parties agree that any amendment of this Agreement shall not be effective unless set out in writing, expressed to amend this Agreement and signed by authorised representatives of each of the Parties.

28.2 Notwithstanding Clause 28.1, the Licensor (pursuant to approval from Roche and without the Licensee's consent) shall have the right to amend: (a) Appendix C or Appendix D of this Agreement at any time without the Licensee's consent in order to include additional patents in those appendices; (b) Appendix B of this Agreement at any time provided such amendment is to expand the scope of the licence granted by this Agreement; (c) Appendix B of this Agreement to remove a country from the Territory where such country has been accepted as an official candidate for membership of the European Union and in Licensor's reasonable opinion there is a risk that the Product will become subject to free movement of goods within the European common market (also known as the European single market). In the event a country becomes part of the European common market, it shall automatically be removed from the Territory.

Nothing in this Licence shall be deemed as consent to place the Product on the European common market.

28.3 The Licensee acknowledges that Roche and Licensor may occasionally review and propose reasonable changes to Appendix E to ensure compliance with applicable laws and regulations. Without prejudice to Clause 28.1, in the event that Licensor notifies Licensee of such proposed changes, Licensee shall not unreasonably withhold its assent.

29. WAIVER

The rights of each Party under this Agreement: (a) may be exercised as often as necessary; (b) are cumulative and not exclusive of rights or remedies provided by law; and (c) may be waived only in writing and specifically. Delay in exercising or non-exercise of any such right is not a waiver of that right.

30. NO PARTNERSHIP OR AGENCY

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

31. EXECUTION IN COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

32. GOVERNING LAW AND JURISDICTION

32.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Switzerland.

32.2 The Parties wish to facilitate the resolution of any dispute arising out of or relating to this Agreement including but not limited to the breach, termination, interpretation or validity thereof (a "**Dispute**") in an expedient manner by mutual cooperation and agree to follow the procedures set forth in this Clause 32.

32.3 **Escalation**. If a Dispute cannot be resolved between the Parties within thirty (30) days of written notice by one Party to another, such Dispute shall be referred in writing to the Parties' respective executive officers or their designees for attempted resolution by good faith negotiations which shall take place within thirty (30) days after such referral (or within such other time period as may be agreed by the Parties in writing).

32.4 **Mediation**. Any Dispute remaining unresolved thirty (30) days (or such other time period as may be agreed by the Parties in writing) after referral to the Parties' executive officers pursuant to Clause 32.3 shall be submitted to mediation in accordance with the WIPO Mediation Rules.

32.5 **Arbitration**. Any Party may refer any Dispute not resolved by mediation within forty-five (45) days (or within such other time period as may be agreed by the Parties in writing) after the appointment of the mediator, for resolution by final and binding arbitration conducted in accordance with the Rules of Arbitration of the International Chamber of Commercial (the "**ICC Rules**") provided that, to the extent that any of the following provisions of this Clause conflict with the said ICC Rules, the following provisions shall prevail:

(a) the arbitration shall be conducted by three (3) arbitrators;

(b) the seat of the arbitration shall be Geneva, Switzerland;

(c) the language of the arbitration shall be English;

(d) the decision of the arbitrator shall be final and binding on the Parties;

(e) judgment upon the arbitration award may be entered by any court having jurisdiction thereover or having jurisdiction over the relevant Party and its assets; and

(f) all documents and proceedings in any arbitration pursuant to this Clause 32.5 shall be confidential and all hearings shall be held in private, save to the extent necessary to enforce any award or to comply with any requirement of any lawful authorities. No public statement shall be made with regard to any arbitral proceedings save to the extent agreed between the Parties in writing.

32.6 **Injunctive relief**. Nothing in this Agreement shall prevent or restrict either Party from seeking or obtaining injunctive 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 arbitration proceedings referred to at Clause 32.5 above.

[*Signatures appear on the following page*]

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

Signed for and on behalf of:
[***LICENSEE***]

_____
Signature

_____
Name

_____
Position

_____
Date

Signed for and on behalf of:
MEDICINES PATENT POOL FOUNDATION

_____
Signature

_____
Name

_____
Position

_____
Date

APPENDIX A

SPECIFIC CHEMICAL NAME AND STRUCTURE OF THE COMPOUND

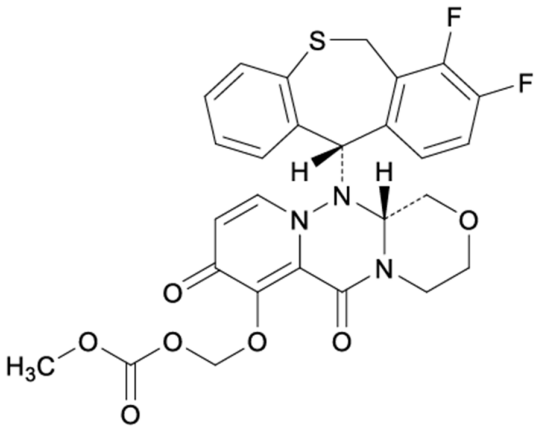
Common name

Baloxavir marboxil

Chemical name

({(12aR)-12-[(11S)-7,8-Difluoro-6,11-dihydrodibenzo[b,e]thiepin-11-yl]-6,8-dioxo-3,4,6,8,12,12a-hexahydro1H-[1,4]oxazino[3,4-c]pyrido[2,1-f][1,2,4]triazin-7-yl}oxy)methyl methyl carbonate

Chemical structure



APPENDIX B

LIST OF COUNTRIES FORMING THE TERRITORY

Afghanistan
Albania
Algeria
Angola
Argentina
Armenia
Azerbaijan
Bangladesh
Belarus
Belize
Benin
Bhutan
Bolivia
Bosnia and Herzegovina
Botswana
Brazil
Burkina Faso
Burundi
Cabo Verde
Cambodia
Cameroon
Central African Republic
Chad
Colombia
Comoros
Congo, Democratic Republic of
Congo, Republic of
Côte d'Ivoire
Cuba
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Eswatini
Ethiopia
Fiji
Gabon
Gambia
Georgia
Ghana
Grenada
Guatemala
Guinea
Guinea-Bissau
Haiti
Honduras
India
Indonesia
Iran
Iraq
Jamaica
Jordan
Kazakhstan
Kenya
Kiribati
Kosovo
Kyrgyz Republic
Lao People's Democratic Republic
Lebanon
Lesotho
Liberia
Libya
Madagascar
Malawi
Malaysia
Maldives
Mali
Marshall Islands
Mauritania
Mauritius
Mexico
Micronesia, Federated States of
Moldova
Mongolia
Montenegro
Morocco
Mozambique
Myanmar
Namibia
Nepal

Nicaragua
Niger
Nigeria
North Macedonia
Pakistan
Papua New Guinea
Paraguay
Peru
Philippines
Rwanda
Samoa
Saint Lucia
Saint Vincent and the Grenadines
São Tomé and Principe
Senegal
Serbia
Sierra Leone
Solomon Islands
Somalia
South Africa
South Sudan
Sri Lanka
Sudan
Suriname
Syrian Arab Republic
Tajikistan
Tanzania
Thailand
Timor-Leste
Togo
Tonga
Tunisia
Türkiye
Turkmenistan
Tuvalu
Uganda
Ukraine
Uzbekistan
Vanuatu
Venezuela
Vietnam
West Bank and Gaza
Yemen
Zambia
Zimbabwe

APPENDIX C

THE PATENTS

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
1	Türkiye	10789443.8	14-Jun-2010	28-Mar-2018	TR201808501	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Serbia	P-2018/0596	14-Jun-2010	10-Jul-2018	57244	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
2	Brazil	BR112013006722-5	21-Sep-2011	3-Nov-2020	112013006722-5	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	India	3057/CHENP/2013	21-Sep-2011	14-Aug-2019	318238	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Mexico	MX/a/2013/003139	21-Sep-2011	8-May-2014	319989	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Türkiye	11826859.8	21-Sep-2011	9-May-2018	TR201810736T4	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Serbia	11826859.8	21-Sep-2011	28-Sep-2018	57490	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
3	Brazil	BR112017022550-6	27-Apr-2016	3-Feb-2021	112017022550-62	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Colombia	NC2017/0010384	27-Apr-2016	27-Jan-2020	37003	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Indonesia	P-00201708399	27-Apr-2016	24-Jan-2020	IDP000066873	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	India	201747041390	27-Apr-2016	15-Sep-2020	346800	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Mexico	MX/a/2017/013809	27-Apr-2016	18-Aug-2021	385402	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Mexico	MX/a/2021/006404	31-May-2021	2-Aug-2022	394421	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Malaysia	PI2017703817	27-Apr-2016	28-Jan-2022	MY-189144-A	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Peru	2333-2017	27-Apr-2016	30-Dec-2021	11034	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Philippines	1-2017-501909	27-Apr-2016	3-Mar-2022	1-2017-501909	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Thailand	1701006387	27-Apr-2016			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Ukraine	A201710501	27-Apr-2016	26-May-2021	123725	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Viet Nam	1-2017-04705	27-Apr-2016	17-Apr-2024	39874	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	South Africa	2017/07111	27-Apr-2016	30-Jan-2019	2017/07111	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Albania	18189193.8	15-Aug-2018	6-Jan-2021	AL/P/21/00073	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Morocco	18189193.8	15-Aug-2018	6-Jan-2021	46300	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Serbia	18189193.8	15-Aug-2018	6-Jan-2021	P-2021/0119	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Serbia	SDZ-2023/0004	17-Jul-2023			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Türkiye	18189193.8	15-Aug-2018	6-Jan-2021	TR2021015556	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Morocco	16786500.5	27-Apr-2016	4-Jan-2023	41998	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Serbia	16786500.5	27-Apr-2016	4-Jan-2023	P-2023/0158	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Türkiye	16786500.5	27-Apr-2016	4-Jan-2023	2023/002709	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Serbia	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Türkiye	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
4	Argentina	P20170101679	19-Jun-2017	31-Jul-2025	AR108812	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Brazil	BR112018076600-3	19-Jun-2017			METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Mexico	MX/a/2018/016267	19-Jun-2017	1-Feb-2024	410205	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Türkiye	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
5	Brazil	BR1120190019 11-1	9-Aug-2017	29-Oct-2024	BR1120190 01911-1	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Indonesia	P-00201901329	9-Aug-2017	21-Jun-2021	IDP0000775 57	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Iran	1397501400030 09521	9-Aug-2017			A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Mexico	MX/a/2019/001 640	9-Aug-2017	28-Feb-2022	390287	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Mexico	MX/a/2021/010 629	3-Sep-2021	17-Nov-2023	408190	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Mexico	MX/a/2023/012 581	24-Oct-2023			A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Peru	351-2019	9-Aug-2017	5-Apr-2024	12483	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Thailand	1901000847	9-Aug-2017			A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
						PYRIDONE DERIVATIVES AND ITS PRODRUG
	Ukraine	a201901914	9-Aug-2017	2-Feb-2022	125218	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	South Africa	2019/00935	9-Aug-2017	30-Sep-2020	2019/00935	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	South Africa	2019/08427	18-Dec-2019	26-May-2021	2019/08427	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Türkiye	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
6	Argentina	P190101070	23-Apr-2019			SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Brazil	BR112020021059-5	23-Apr-2019	30-Aug-2022	112020021059-5	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Brazil	BR122022006356-0	23-Apr-2019	4-Oct-2022	122022006356-0	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Mexico	MX/a/2020/011130	23-Apr-2019	9-Sep-2022	395463	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Mexico	MX/a/2022/009094	22-Jul-2022	3-Sep-2025	427252	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
7	Argentina	P180103378	16-Nov-2018			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Brazil	BR1120200096 34-2	15-Nov-2018	30-Aug-2022	1120200096 34-2	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Mexico	MX/a/2020/004 680	15-Nov-2018	29-Mar-2023	401305	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Türkiye	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
9	Brazil	BR1120210144 21-8	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Mexico	MX/a/2021/010 834	26-Mar-2020	17-Jan-2024	409711	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Türkiye	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS

APPENDIX D

THE NON-TERRITORY PATENTS

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
1	Japan	2009-142166	15-Jun-2009			SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2011-519761	14-Jun-2010	1-May-2015	5737691	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2015-079299	8-Apr-2015	16-Sep-2016	6004552	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	China	201080036154.6	14-Jun-2010	10-Feb-2016	201080036154.6	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	EPO	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Taiwan	99119253	14-Jun-2010	11-Feb-2016	I520959	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	13/378334	14-Jun-2010	6-Jan-2015	8927710	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	14/536079	7-Nov-2014	18-Oct-2016	9469638	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	15/252791	31-Aug-2016	14-Nov-2017	9815835	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	WIPO	PCT/JP2010/060006	14-Jun-2010			SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Germany	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	France	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	United Kingdom	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Austria	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Belgium	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Bulgaria	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Switzerland	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Czech Republic	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Denmark	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Spain	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Finland	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Greece	10789443.8	14-Jun-2010	28-Mar-2018	3096629	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Croatia	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Hungary	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Ireland	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Italy	10789443.8	14-Jun-2010	28-Mar-2018	502018000018779	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Lithuania	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Netherlands	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Norway	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Poland	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Portugal	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Romania	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Sweden	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovenia	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovak Republic	10789443.8	14-Jun-2010	28-Mar-2018	2444400	SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
2	Japan	2010-213012	24-Sep-2010			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2012-535048	21-Sep-2011	6-Jun-2014	5553393	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2018-700121	11-May-2018	6-Feb-2019	5553393	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2018-700122	11-May-2018	6-Feb-2019	5553393	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2018-700448	5-Dec-2018	21-Aug-2019	5553393	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2021-700032	22-Feb-2021	22-Jun-2022	5553393	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2021-700033	22-Feb-2021	22-Jun-2022	5553393	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Japan	2014-104465	20-May-2014	17-Jul-2015	5777077	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Australia	2011307087	21-Sep-2011	23-Feb-2017	2011307087	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Canada	2812363	21-Sep-2011	2-Apr-2019	2812363	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	China	201180056716.8	21-Sep-2011	16-Mar-2016	201180056716.8	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	EPO	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Korea	10-2013-7010331	21-Sep-2011	24-Aug-2017	10-1773226	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Russia	2013114189	21-Sep-2011	19-Jan-2017	2608519	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Taiwan	100134256	23-Sep-2011	21-Jan-2016	I518085	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	13/824723	21-Sep-2011	24-Mar-2015	8987441	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	14/562117	5-Dec-2014	12-Sep-2017	9758515	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	15/676540	14-Aug-2017	12-Feb-2019	10202379	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	U.S.A.	18/230392	4-Aug-2023			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	WIPO	PCT/JP2011/071446	21-Sep-2011			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Germany	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	France	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	France	21C1012	15-Mar-2021	17-Feb-2023	21C1012	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	France	21C1012	18-Aug-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	United Kingdom	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	United Kingdom	SPC/GB21/036	18-Mar-2021	19-Oct-2023	SPC/GB21/036	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	United Kingdom	SPC/GB21/036	28-Aug-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Austria	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Austria	SZ7/2021	3-Mar-2021	16-May-2022	SZ 7/2021-3	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Austria	SZ7/2021	30-Jun-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Belgium	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Belgium	2021C/510	30-Mar-2021			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Bulgaria	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Bulgaria	BG/S/2021/9	16-Mar-2021	18-May-2022	2021/9	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Bulgaria	BG/S/2021/9	11-Jul-2025	1-Oct-2025	2021/9	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Switzerland	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Switzerland	C02620436/01	31-Jul-2020	24-Feb-2021	C02620436/01	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Czech Republic	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Czech Republic	2021-735	9-Mar-2021	8-Mar-2022	2620436/735	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Czech Republic	2021-735	25-Jun-2025	11-Dec-2025	2620436/735	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

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	Denmark	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Denmark	CA 2021 00004	2-Mar-2021	4-Oct-2021	CR 2021 00004	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Denmark	CA 2021 00004 EXT	21-Aug-2025	27-Oct-2025	CR 2021 00004 EXT	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Spain	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Spain	202130015	30-Mar-2021	19-Jan-2022	C202130015 (3)	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Spain	202130015	17-Jul-2025	13-Oct-2025	C202130015 (3)	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Finland	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Finland	C20210005	12-Mar-2021			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Greece	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Greece	20210800006	3-Mar-2021	5-Jul-2022	8000873	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

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	Greece	20250900010	25-Jun-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Croatia	11826859.8	21-Sep-2011	9-May-2018	P20181250	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Croatia	S20210006A	15-Mar-2021			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Hungary	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Hungary	S2100010	23-Mar-2021	12-May-2022	S000610	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Hungary	S2100010	21-Aug-2025	15-Oct-2025	S000610	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Ireland	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Ireland	2021/006	2-Mar-2021	18-Dec-2023	469/2009	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Ireland	2025/420	1-Jul-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Italy	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

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	Italy	132021000000038	24-Mar-2021	13-Apr-2021	132021000000038	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Italy	842025000131722	28-Aug-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Lithuania	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Lithuania	PA 2021 505	19-Mar-2021	27-Apr-2023	C 2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Lithuania	PA 2021 505	3-Jul-2025	21-Jul-2025	C 2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Netherlands	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Netherlands	301093	2-Mar-2021			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Norway	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Norway	2021011	8-Mar-2021	26-Sep-2024	2021011	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Norway	2025040	28-Aug-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

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	Poland	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Poland	DPO.0672	22-Mar-2021			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Portugal	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Portugal	1071	12-Mar-2021	21-Jan-2022	1071	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Portugal	1071	1-Jul-2025	18-Jul-2025	1071	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Romania	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Romania	C 2021 006	24-Mar-2021			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Sweden	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Sweden	2190007-1	16-Mar-2021	25-Sep-2025	2190007-1	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Sweden	2190007-1	27-Oct-2025			PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE

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	Slovenia	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovenia	C202140003	2-Mar-2021	28-May-2021	202140003	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovenia	C202140003	9-Jul-2025	26-Aug-2025	202140003	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovak Republic	11826859.8	21-Sep-2011	9-May-2018	2620436	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovak Republic	PDO 50005-2021	31-Mar-2021	16-Feb-2024	DO 516	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
	Slovak Republic	PDO 50005-2021	9-Jul-2025	27-Nov-2025	DO 516	PRODRUG OF SUBSTITUTED POLYCYCLIC CARBAMOYLPYRIDONE DERIVATIVE
3	Japan	2015-090909	28-Apr-2015			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2015-236844	3-Dec-2015			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Gulf Cooperation Council	2016/31213	26-Apr-2016	4-Sep-2024	GC0013219	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2016-535247	27-Apr-2016	22-Jul-2016	5971830	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2018-700104	23-Apr-2018	6-Feb-2019	5971830	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Japan	2018-700105	23-Apr-2018	6-Feb-2019	5971830	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2018-700449	5-Dec-2018	21-Aug-2019	5971830	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2021-700034	22-Feb-2021	22-Jun-2022	5971830	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2021-700035	22-Feb-2021	22-Jun-2022	5971830	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Japan	2016-135602	8-Jul-2016	28-Apr-2020	6697209	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Taiwan	105113329	28-Apr-2016	1-Jun-2018	I625330	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Taiwan	106145446	25-Dec-2017	11-Sep-2019	I671298	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Australia	2016256125	27-Apr-2016	14-May-2020	2016256125	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Canada	2984130	27-Apr-2016	20-Jul-2021	2984130	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Chile	02711-2017	27-Apr-2016	18-Apr-2023	66.997	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	China	202110162320.7	5-Feb-2021	2-Nov-2021	202110162320.7	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	China	202110303513.X	22-Mar-2021	18-Mar-2022	202110303513.X	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Costa Rica	2017-0530	27-Apr-2016	5-Sep-2023	4489	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	EPO	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	EPO	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	EPO	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	EPO	24172424.4	25-Apr-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Hong Kong	19101812.3	10-Apr-2018	21-May-2021	HK1259624	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Israel	255295	27-Apr-2016	30-Nov-2019	255295	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Korea	10-2017-7031140	27-Apr-2016	17-May-2019	10-1981880	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Korea	10-2018-7037812	27-Dec-2018	17-May-2019	10-1981912	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Korea	10-2019-7012391	29-Apr-2019	13-Jun-2022	10-2409779	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Macao	J/005732	18-Jan-2022	10-Mar-2022	J/005732	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Macao	J/006019	28-Apr-2022	26-May-2022	J/006019	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	New Zealand	736259	27-Apr-2016	7-Jan-2020	736259	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	New Zealand	757062	6-Sep-2019	31-Aug-2021	757062	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Russia	2017137518	27-Apr-2016	28-Jan-2020	2712275	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Singapore	11201708721X	27-Apr-2016	29-Apr-2020	11201708721X	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	U.S.A.	15/569191	27-Apr-2016	27-Aug-2019	10392406	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	U.S.A.	16/221733	17-Dec-2018	28-Apr-2020	10633397	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	U.S.A.	18/424022	26-Jan-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	WIPO	PCT/JP2016/063139	27-Apr-2016	-	-	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Germany	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	France	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	United Kingdom	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Austria	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Belgium	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Bulgaria	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Switzerland	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Cyprus	18189193.8	15-Aug-2018	6-Jan-2021	CY1123920	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Cyprus	2021006	4-Mar-2021	26-Apr-2021	SPCMCY2021006	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Cyprus	2021006	2-Jul-2025			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Czech Republic	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Denmark	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Estonia	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Estonia	C20210003	5-Mar-2021	17-Apr-2023	00390	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Estonia	C20210003	2-Jul-2025	17-Dec-2025	00390	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Spain	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Finland	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Greece	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Croatia	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Hungary	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Ireland	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Iceland	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Iceland	SPC328	9-Feb-2021	15-Jan-2022	SPC328	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Iceland	SPC328	2-Jul-2025	15-Oct-2025	SPC328	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Italy	18189193.8	15-Aug-2018	6-Jan-2021	502021000014597	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Lithuania	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Luxembourg	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Luxembourg	LUC00198	4-Mar-2021	4-Oct-2024	LUC00198	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Luxembourg	LUC00198	30-Jun-2025			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Latvia	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Latvia	CLV20210003	8-Mar-2021	20-Sep-2021	C/LV2021/0003/z	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Latvia	CLV20210003	14-Jul-2025	17-Sep-2025	C/LV2021/0003/z	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Monaco	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Macedonia	18189193.8	15-Aug-2018	6-Jan-2021	MK911846	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Malta	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Malta	182/2021	2-Mar-2021	1-Jun-2021	182/2021	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Malta	PEC 26/2025	26-Jun-2025	14-Jul-2025	PEC 26/2025	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Netherlands	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Norway	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Poland	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Portugal	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Romania	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Sweden	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Slovenia	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Slovak Republic	18189193.8	15-Aug-2018	6-Jan-2021	3428170	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	San Marino	18189193.8	15-Aug-2018	6-Jan-2021	SM-T-202100102	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Germany	16786500.5	27-Apr-2016	4-Jan-2023	602016077273.6	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	France	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	United Kingdom	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Austria	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Belgium	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Bulgaria	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Switzerland	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Czech Republic	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Denmark	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Spain	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Finland	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Greece	16786500.5	27-Apr-2016	4-Jan-2023	3112121	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Croatia	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Hungary	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Ireland	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Italy	16786500.5	27-Apr-2016	4-Jan-2023	502023000010518	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Lithuania	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Netherlands	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Norway	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Poland	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Portugal	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Romania	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Sweden	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Slovenia	16786500.5	27-Apr-2016	4-Jan-2023	3290424	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Slovak Republic	16786500.5	27-Apr-2016	4-Jan-2023	E41205	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Austria	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Belgium	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Belgium	2024C/542	7-Nov-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Bulgaria	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Switzerland	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Czech Republic	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Germany	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Germany	122024000036.2	6-Jun-2024	29-Sep-2025	122024000036	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Germany	122024000036.2	30-Jun-2025			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Denmark	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Spain	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Finland	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Finland	C20240038	12-Nov-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	France	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	United Kingdom	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Greece	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Croatia	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Croatia	S20240032A	23-Oct-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Hungary	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Ireland	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Italy	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Lithuania	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Netherlands	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Netherlands	301295	29-Oct-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Norway	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Poland	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Poland	DPO.0861	7-Nov-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Portugal	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Romania	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG

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	Romania	C/038/2024	11-Nov-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Sweden	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Sweden	2490314-8	14-Nov-2024			SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Slovenia	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
	Slovak Republic	23150186.7	3-Jan-2023	5-Jun-2024	4219508	SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVE AND ITS PRODRUG
4	Japan	2016-121453	20-Jun-2016			METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Japan	2017-538748	19-Jun-2017	22-Sep-2017	6212678	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Japan	2018-700125	15-May-2018	6-Feb-2019	6212678	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Japan	2018-700126	15-May-2018	6-Feb-2019	6212678	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Japan	2018-700450	5-Dec-2018	21-Aug-2019	6212678	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Japan	2021-700038	22-Feb-2021	2-Mar-2022	6212678	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF

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	Japan	2021-700039	22-Feb-2021	2-Mar-2022	6212678	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Japan	2017-170491	5-Sep-2017	11-Oct-2021	6959077	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Taiwan	106120359	19-Jun-2017	21-Dec-2021	I750188	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Australia	2017282305	19-Jun-2017	23-Sep-2021	2017282305	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Canada	3027840	19-Jun-2017	23-Sep-2025	3027840	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	China	201780038096.2	19-Jun-2017	16-Nov-2021	201780038096.2	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	China	202110909230.X	9-Aug-2021	7-Mar-2025	202110909230.X	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	EPC	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	EPC	22206730.8	10-Nov-2022			METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Hong Kong	19121836.1	3-Apr-2019	8-Apr-2022	1261892	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF

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	Hong Kong	42022048008.1	11-Feb-2022	5-Sep-2025	40057099	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Israel	263812	19-Jun-2017			METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Korea	2019-7001315	19-Jun-2017	22-Sep-2022	10-2447711	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Korea	2022-7019438	9-Jun-2022	4-Oct-2023	10-2586854	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Macao	J/005803	11-Feb-2022	10-Mar-2022	J/005803	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Macao	J/009420	24-Apr-2025			METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Singapore	11201810655Q	19-Jun-2017	27-Oct-2020	11201810655Q	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Singapore	10201912691S	19-Dec-2019			METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	U.S.A.	16/310897	19-Jun-2017	1-Mar-2022	11261198	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	U.S.A.	17/578743	19-Jan-2022	7-Nov-2023	11807648	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF

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	WIPO	PCT/JP2017/022478	19-Jun-2017	-	-	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Austria	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Belgium	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Switzerland	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Germany	17815337.5	19-Jun-2017	16-Nov-2022	602017063794.7	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Spain	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	France	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	United Kingdom	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Greece	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Croatia	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF

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	Ireland	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Italy	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Netherlands	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Poland	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Romania	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Sweden	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
	Slovenia	17815337.5	19-Jun-2017	16-Nov-2022	3473629	METHOD FOR PRODUCING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND CRYSTAL THEREOF
5	Japan	2016-157732	10-Aug-2016			A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2017-545688	9-Aug-2017	1-Dec-2017	6249434	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2018-700119	11-May-2018	6-Feb-2019	6249434	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC

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						PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2018-700120	11-May-2018	6-Feb-2019	6249434	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2018-700451	5-Dec-2018	21-Aug-2019	6249434	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2021-700036	22-Feb-2021	2-Mar-2022	6249434	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2021-700037	22-Feb-2021	2-Mar-2022	6249434	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2017-204957	24-Oct-2017	5-Jan-2018	6267397	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2018-700123	11-May-2018	6-Feb-2019	6267397	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2018-700118	11-May-2018	6-Feb-2019	6267397	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2018-700452	5-Dec-2018	21-Aug-2019	6267397	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Japan	2021-700040	22-Feb-2021	2-Mar-2022	6267397	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Japan	2021-700041	22-Feb-2021	2-Mar-2022	6267397	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Taiwan	106127161	10-Aug-2017	21-Jun-2019	I663172	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Taiwan	108115903	17-Apr-2019	1-Dec-2020	I711621	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Australia	2017310774	9-Aug-2017	20-Jul-2023	2017310774	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Australia	2023202350	17-Apr-2023	12-Dec-2024	2023202350	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Canada	3033180	9-Aug-2017	31-May-2022	3033180	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Chile	00325-2019	9-Aug-2017	14-Mar-2023	67.003	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Chile	02032-2020	4-Aug-2020	26-Dec-2023	68.689	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC

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						PYRIDONE DERIVATIVES AND ITS PRODRUG
	EPO	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	EPO	24190015.8	22-Jul-2024			A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Hong Kong	19126612.1	10-Jul-2019	18-Oct-2024	40003033	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Israel	264709	9-Aug-2017	2-Jan-2023	264709	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	New Zealand	750052	9-Aug-2017	3-Dec-2024	750052	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	New Zealand	791086	5-Aug-2022	2-Dec-2025	791086	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Russia	2019104987	9-Aug-2017	28-Jul-2020	2727962	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Singapore	11201900869Q	9-Aug-2017	9-Oct-2023	11201900869Q	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Singapore					A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	U.S.A.	16/323580	9-Aug-2017	1-Sep-2020	10759814	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	U.S.A.	16/937877	24-Jul-2020	19-Apr-2022	11306106	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	U.S.A.	18/891180	20-Sep-2024			A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	WIPO	PCT/JP2017/028923	9-Aug-2017	-	-	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Unitary Patent	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Switzerland	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Spain	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	United Kingdom	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
						PYRIDONE DERIVATIVES AND ITS PRODRUG
	Greece	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
	Poland	17839530.7	9-Aug-2017	28-Aug-2024	3498281	A PHARMACEUTICAL COMPOSITION COMPRISING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND ITS PRODRUG
6	Japan	2018-083006	24-Apr-2018			SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Gulf Cooperation Council	2019/37440	23-Apr-2019			SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Australia	2019259686	23-Apr-2019	7-Sep-2023	2019259686	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Australia	2023201826	23-Mar-2023	22-Feb-2024	2023201826	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Canada	3098006	23-Apr-2019			SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	China	201980038190.7	23-Apr-2019	15-Apr-2025	201980038190.7	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	EPO	19791663.8	23-Apr-2019			SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Hong Kong	62021026650.3	3-Mar-2021	11-Jul-2025	40036689	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Japan	2019-523143	23-Apr-2019	27-Sep-2019	6590436	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Japan	2021-700043	22-Feb-2021	10-Nov-2021	6590436	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Japan	2019-120378	27-Jun-2019	22-Nov-2019	6618099	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Japan	2021-700044	22-Feb-2021	10-Nov-2021	6618099	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Korea	10-2020-7033039	23-Apr-2019	14-Feb-2023	10-2501180	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Israel	278161	23-Apr-2019	4-Nov-2024	278161	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Macao	J/009549	12-Jun-2025	29-Jul-2025	J/009549	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	U.S.A.	17/077606	23-Apr-2019	12-Mar-2024	11925648	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	U.S.A.	18/435082	2-Jul-2024	30-Sep-2025	12427156	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	U.S.A.	19/317575	3-Sep-2025			SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Taiwan	108114338	23-Apr-2019	1-Jan-2023	I788557	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	Taiwan	111145705	29-Nov-2022	11-Nov-2023	I822498	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
	WIPO	PCT/JP2019/017146	23-Apr-2019	-	-	SOLID DOSAGE FORM HAVING EXCELLENT STABILITY
7	Japan	2017-222068	17-Nov-2017			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Gulf Cooperation Council	2018/36471	15-Nov-2018			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Australia	2018369241	15-Nov-2018	20-Apr-2023	2018369241	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Canada	3082522	15-Nov-2018			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	China	201880086457.5	15-Nov-2018			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	EPO	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	EPO	25206613.9	3-Sep-2025			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Hong Kong	62020019491	4-Nov-2020			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Japan	2019-549013	15-Nov-2018	13-Feb-2020	6660644	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Japan	2021-700042	22-Feb-2021	10-Nov-2021	6660644	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Japan	2020-018408	6-Feb-2020	27-Mar-2023	7251891	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Korea	10-2020-7016914	15-Nov-2018	28-Jul-2023	10-2562514	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Israel	274625	15-Nov-2018	3-Nov-2022	274625	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	U.S.A.	16/764067	15-Nov-2018	20-Aug-2024	12064438	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	U.S.A.	18/772892	24-Dec-2024			PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Taiwan	107140226	13-Nov-2018	11-Mar-2023	I795462	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	WIPO	PCT/JP2018/042220	15-Nov-2018	-	-	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Unitary Patent	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Switzerland	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Spain	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	United Kingdom	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Greece	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY
	Poland	18877429.3	15-Nov-2018	12-Nov-2025	3711767	PHARMACEUTICAL PREPARATION EXCELLENT IN LIGHT STABILITY AND DISSOLUTION PROPERTY

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
8	Taiwan	108108502	13-Mar-2019			TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Taiwan	109108050	11-Mar-2020	1-Feb-2024	I830882	TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Australia	2019433734	12-Mar-2019	11-Dec-2025	2019433734	TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Canada	3133189	12-Mar-2019			TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Japan	2021-553309	12-Mar-2019	14-Oct-2022	7158808	TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Korea	2021-7032268	12-Mar-2019			TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Malaysia	PI2021004656	12-Mar-2019	30-Oct-2025	MY-210958-A	TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
						SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	Singapore	11202109050W	12-Mar-2019			TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	U.S.A.	18/525177	30-Nov-2023			TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
	WIPO	PCT/IB2019/052012	12-Mar-2019	-	-	TREATING INFLUENZA USING SUBSTITUTED POLYCYCLIC PYRIDONE DERIVATIVES AND PRODRUGS THEREOF IN A SUBJECT HAVING INFLUENZA AND A COMPLICATION RISK FACTOR
9	EPO	19166228.7	29-Mar-2019			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Gulf Cooperation Council	2020/39438	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Taiwan	109110208	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Australia	2020254906	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Australia	2025252541	15-Oct-2025			COMPOUND AND METHOD FOR THE PREVENTION OF

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
						TRANSMISSION OF INFLUENZA VIRUS
	Canada	3129668	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	China	202080025834.1	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Hong Kong	62022050128.7	16-Mar-2022			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	EPO	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Israel	284990	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Japan	2021-557775	26-Mar-2020	29-Oct-2024	7579269	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Korea	2021-7035209	26-Mar-2020			COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Russia	2021128221	26-Mar-2020	9-Sep-2024	2826285	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	U.S.A.	16/830764	26-Mar-2020	19-Jul-2022	11389457	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	U.S.A.	17/560501	23-Nov-2021	27-Feb-2024	11911394	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	WIPO	PCT/EP2020/058573	26-Mar-2020	-	-	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Unitary Patent	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Switzerland	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Spain	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	United Kingdom	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Greece	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
	Poland	20713011.3	26-Mar-2020	27-Aug-2025	3946356	COMPOUND AND METHOD FOR THE PREVENTION OF TRANSMISSION OF INFLUENZA VIRUS
10	Taiwan	108128743	13-Aug-2019	11-Mar-2024	I834705	IMPROVED DOSAGE OF BALOXAVIR MARBOXIL FOR PEDIATRIC PATIENTS
	Australia	2019461218	13-Aug-2019			IMPROVED DOSAGE OF BALOXAVIR MARBOXIL FOR PEDIATRIC PATIENTS

Family	Country	Application No.	Filing Date	Issue Date	Patent No.	Title
	Canada	3146423	13-Aug-2019			IMPROVED DOSAGE OF BALOXAVIR MARBOXIL FOR PEDIATRIC PATIENTS
	U.S.A.	16/991451	12-Aug-2020			IMPROVED DOSAGE OF BALOXAVIR MARBOXIL FOR PEDIATRIC PATIENTS
	WIPO	PCT/EP2019/071699	13-Aug-2019			IMPROVED DOSAGE OF BALOXAVIR MARBOXIL FOR PEDIATRIC PATIENTS

APPENDIX E

PHARMACOVIGILANCE AGREEMENT

A. ESTABLISHMENT AND MAINTENANCE OF PHARMACOVIGILANCE SYSTEMS AND PROCEDURES

A.1 The Licensee shall, for the term of this Agreement (and thereafter as required to fulfil surviving obligations), establish, maintain and operate adequate pharmacovigilance and risk management systems, procedures, documentation and a safety database as required by applicable laws and regulations in the Territory. The Licensee shall be solely responsible for compliance with all applicable pharmacovigilance, drug safety and risk management requirements relating to the Products in the Territory, including without limitation the collection, evaluation and reporting of Adverse Event reports, literature monitoring, signal detection and fulfilment of regulatory reporting obligations.

A.2 The Licensee shall maintain appropriate business continuity and disaster recovery arrangements to ensure continuity of critical pharmacovigilance activities, including during periods of business disruption or force majeure.

A.3 The Licensee shall provide all reasonable cooperation and assistance requested by Roche or the Licensor in connection with their pharmacovigilance and risk management obligations under applicable law, the Head Licence, or this Agreement, including, by way of example and without limitation, responding promptly to any request for information or data required for the preparation of aggregate safety reports.

B. REQUIREMENTS FOR EXCHANGE OF PHARMACOVIGILANCE INFORMATION

B.1 The Licensee shall notify the Licensor and Roche in writing (by email addressed to <*global.pvpagreementmanagement@roche.com*>) of: (a) any enquiry received from a Relevant Regulatory Authority in the Territory relating to the Product that concerns a safety issue; and (b) any action that may be, will be, or has been taken by a Relevant Regulatory Authority for a safety reason in connection with the Product. Such notification shall be made immediately and in any event no later than twenty-four (24) hours after the Licensee's receipt of the relevant enquiry or notice, and shall include all available details.

B.2 The Licensee shall provide to Roche and the Licensor all safety and regulatory reports or information relating to the Products in accordance with the timelines, formats, methods of transmission and designated contact points specified in the table below (as may be updated from time to time in writing by the Parties).

Table 1: Requirements for exchange of safety and regulatory reports from Licensee to Licensor and Roche

Type of Report	**Timeline Calendar Days (CD) from Awareness Date**	**Format**	**Means of Exchange**	**Roche Contact**	**Licensor (MPP) Contact**
Serious AEs*	8 CD	CIOMS-I Form (English)	E-mail	intake.pds-pc@roche.com	pv@mppf.org
Non-Serious AEs & Special Situation/Scenario Reports*	30 CD	CIOMS-I Form (English)	E-mail	intake.pds-pc@roche.com	pv@mppf.org
Identified Signal	Within 5 calendar days after signal identification	N/A	E-mail	Contact_line.Drug_safety@roche.com	pv@mppf.org
Emerging Safety Issue (ESI)	Within 3 Business Days after internal decision to report as ESI	N/A	E-mail	Contact_line.Drug_safety@roche.com	pv@mppf.org
Urgent Safety Restriction (USR)	Within 1 Business Day after internal approval	N/A	E-mail	Contact_line.Drug_safety@roche.com	pv@mppf.org
Changes to local product information with potential impact on the Company Core Safety Information section of the Core Data Sheet (CDS)	Within 10 Business Days after receipt of regulatory approval	N/A	E-mail	Contact_line.Drug_safety@roche.com	pv@mppf.org
Post approval safety communications (E.g. Dear Healthcare Professional Letters or To Whom It May Concern Letters)	Within 5 business days after internal approval	N/A	E-mail	Contact_line.Drug_safety@roche.com	pv@mppf.org

**The Licensee shall continue to collect and report all Adverse Events to the Licensor and Roche until ninety (90) days after the expiry date of the last batch of the Product produced under the Agreement in the Territory. This obligation shall survive expiration or termination of this Agreement for any reason*.

B.3 Within ten (10) Business Days following the end of each Agreement Quarter, the Licensee shall provide the Licensor with a quarterly line listing of all Adverse Event reports submitted by the Licensee during the preceding quarter. Upon receipt, the Licensor shall consolidate Licensee listings and promptly provide such consolidated line listing to Roche. Roche shall review the line listing and verify receipt of the corresponding Adverse Event reports. Any Adverse Event reports identified as not received shall be transmitted within five (5) calendar days of Licensee's receipt of such request.

B.4 Roche shall provide the Licensor with all safety and regulatory reports or information relating to the Products in accordance with the timelines, formats, methods of transmission and designated contact points specified in the table below (as may be updated from time to time in writing by the Parties). Upon receipt, the Licensor shall provide the reports to the Licensee without undue delay.

Table 2: Requirements for exchange of safety and regulatory reports from Roche to Licensor.

Type of Report	**Timeline Calendar Days (CD) from Awareness Date**	**Means of Exchange**	**Licensor (MPP) Contact**
Effective version of Company Core Data Sheet (CDS) at time of the Agreement implementation	Within 30 calendar days of the Effective Date of the Head Licence	E-mail	pv@mppf.prg
Updated revisions of CDS	Within 5 Business Days after internal distribution	E-mail	pv@mppf.prg
Global Aggregate Reports* (i.e. PBRER to ICH E2C)	At least 5 days before submission deadline per ICH	E-mail	pv@mppf.prg
Effective Core Risk Management Plan (RMP) and Guided Questionnaires (GQs) at the time of Agreement implementation	Within 30 calendar days of the Effective Date of the Head Licence	E-mail	pv@mppf.prg
Updated revisions of Core Risk Management Plan (RMP) and Guided Questionnaires (GQs)	Within 10 Business Days after internal approval	E-mail	pv@mppf.prg
Emerging Safety Issue (ESI)	Within 3 Business Days after internal decision to report as ESI	E-mail	pv@mppf.prg

Type of Report	Timeline Calendar Days (CD) from Awareness Date	Means of Exchange	Licensor (MPP) Contact
Urgent Safety Restriction	Within 1 Business Day after internal approval	E-mail	pv@mppf.prg
Post approval safety communications (DHPC or TWIMCL)	Within 5 business days after internal approval	E-mail	pv@mppf.prg

**Roche shall not be responsible for the preparation, provision or submission of any Local Aggregate Safety Reports required under the Licensee's applicable local regulations.*

C. **DEFINITIONS**

C.1 All capitalised terms used but not defined in this Appendix E shall have the meaning given to them in the Agreement.

C.2 "**Adverse Event**" or "**AE**" means any untoward medical occurrence in a patient or clinical investigation subject administered a Product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a Product.

C.3 **"Awareness Date"** means the date the Licensee has first knowledge of the minimum data elements. For reports received from another contractual partner (e.g. licensing partner), the Awareness Date in relation to exchange of safety information under this Agreement is the date the report was made available to either Party.

The minimum data elements for a report are as follows:

- Identifiable patient (or group of patients for summary cases applicable to literature cases)
- Identifiable reporter
- AE or Special Situation/Scenario Report (refer to definition below)
- Product (generic or trade name)

With respect to relevant worldwide scientific and medical literature, the "Awareness Date" is the date of receipt of an abstract or full article relating to the Product.

With respect to internet or digital media channel that is owned, paid for and/or controlled by either Party, the Awareness Date is the date that safety relevant information (relating to the Product) is posted on the channel by an identifiable reporter (an individual that is privately contactable).

C.4 "**Emerging Safety Issue**" (or "**ESI**") means a safety issue considered to require urgent attention by the Relevant Regulatory Authority because of the potential major impact on the

risk-benefit balance of the medicinal product and/or on patients' or public health, and the potential need for prompt regulatory action and communication to patients and Healthcare Professionals (HCP). Examples include: Major safety issues identified in the context of ongoing or newly completed studies, (e.g., an unexpectedly increased rate of fatal or life-threatening adverse events); Major safety issues identified through spontaneous reporting or published in the scientific literature, which may lead to considering a contra-indication, a restriction of the use of the medicinal product or its withdrawal from the market; Major safety-related regulatory actions (e.g., a restriction of the use of the medicinal product or its suspension).

C.5 "**Identified Signal**" means information arising from one or multiple sources (e.g. individual case safety reports, studies, or literature) that suggests a new potentially causal association, or a new aspect of a known association, between a medicinal product and an adverse event, and has been judged by Licensee to be of sufficient likelihood to warrant further investigation and assessment.

C.6 "**Non-Serious AE**" means any Adverse Event that is not a Serious AE.

C.7 "**Safety Communication**" means a communication of important safety information on the Product to healthcare professionals, patients, and the public, with the objective of supporting the safe and effective use of the Product and minimising risks to patients and public health (e.g., Dear Investigator Letter [DIL], Urgent Safety Measures [USM], Direct Healthcare Professional Communication [DHPC], Safety To Whom It May Concern Letter [TWIMCL], Safety Memos).

C.8 "**Serious AE**" means an Adverse Event that: results in death; is life-threatening; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability or incapacity; or is a congenital anomaly or birth defect.

C.9 "**Special Situation**" means a situation associated with the use of the Product that may provide important safety information, even if no adverse reaction has occurred, and that therefore requires recording, evaluation and, where applicable, reporting for the purpose of ongoing benefit–risk assessment. For the avoidance of doubt, this only includes situations of which the Licensee receives knowledge or information in the performance of its obligations under Section A and, for the avoidance of doubt, this definition does not require Licensee to establish special systems or procedures additional to those required under Section A.

Special situations are defined as the following:

Special Situation Report	**Definition**	**Exchange without an AE?**
Abuse	This corresponds to the persistent or sporadic, intentional excessive use of a medicinal product, which is accompanied by harmful physical or psychological effects.	Yes
Breastfeeding (Lactation)	This refers to a situation in infants following exposure to a medicinal product from breast milk.	Yes

Special Situation Report	Definition	Exchange without an AE?
Intercepted medication error	This refers to situations where a medication error occurred, and an intervention caused a break in the chain of events in the treatment process before reaching the patient. The intervention has prevented actual harm being caused to the patient.	Yes
Lack of therapeutic efficacy	This refers to a situation of lack of therapeutic efficacy of a medicinal product.	Yes
Medication Error	A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient (including potential medication errors or intercepted medication errors).	Yes
Misuse	This refers to situations where the medicinal product is intentionally and inappropriately used not in accordance with the terms of the marketing authorization.	Yes
Occupational Exposure	This refers to the exposure to a medicinal product as a result of one's professional or non-professional occupation.	Yes
Off Label Use	This relates to situations where the medicinal product is intentionally used for a medical purpose not in accordance with the terms of the marketing authorization.	Yes
Overdose	This refers to the administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended dose according to the authorized product information. Clinical judgment should always be applied.	Yes
Pregnancy exposure	This refers to a situation where the embryo or fetus may have been exposed to a medicinal product(s), either through maternal exposure or transmission of a medicinal product via semen following paternal exposure.	Yes
Potential medication error	This refers to the recognition of circumstances that could lead to a medication error, and may or may not involve a patient. It refers to all possible mistakes in the prescribing, storing, dispensing, preparation for administration or administration of a medicinal product by all persons who are involved in the medication process.	Yes
Use of medicinal product in a paediatric or elderly population	Reasonable attempts should be made to obtain and submit the age or age group of the patient when a case is reported by a Healthcare Professional or consumer in	No Such report should be exchanged when associated with an AE

Special Situation Report	Definition	Exchange without an AE?
	order to be able to identify potential safety signals specific to a particular population.	
Accidental Exposure	Accidental exposure to medicines occurs if a medicinal product is used by someone other than the person the medicine was prescribed for, or if a person becomes inadvertently exposed. Some accidental exposures may also be occupational exposures.	Yes
Drug Dependence	This refers to a physical and / or psychological phenomenon making the repeated use of a drug compulsive.	Yes
Drug Interaction	This refers to the action of one drug upon the efficacy or toxicity of one or more other drugs. Drug interaction also includes drug or food, drug or device and drug or alcohol interactions.	No Such report should be exchanged when associated with an AE
Falsified medicinal products (Counterfeit) - whether suspected or confirmed	This relates to any medicinal product with a false representation of: ● its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; ● its source, including its manufacturer, its country of manufacturing, its country of origin or its Marketing Authorisation Holder; or ● its history, including the records and documents relating to the distribution channels used. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.	Yes
Unexpected Beneficial Effect	An unexpected beneficial effect not related to the indication for which the drug was used and not considered to be adverse in nature.	Yes

C.10 "**Urgent Safety Restriction**" means an urgent interim change, due to new information having a bearing on the safe use of the Product, to the product information concerning particularly one or more of the following items in the summary of product characteristics: the indications, posology, contraindications, special warnings and special precautions for use and undesirable effects. In rare cases the changes may also relate to quality problems requiring a change of the summary of product characteristics, labelling or package leaflet.