

## LICENSE AND TECHNOLOGY TRANSFER AGREEMENT

This License and Technology Transfer Agreement is made and entered into as of the 15th day of June, 2022 (**Effective Date**) by and between:

- (1) **Shionogi & Co., Ltd.**, registered under the laws of Japan, and having a principle place of business at 1-8 Doshomachi 3-chome, Chuo-ku, Osaka 541-0045, Japan (**Shionogi**); and
- (2) **GARDP Foundation**, a non-profit research and development organization registered under the laws of Switzerland, and having a principle place of business at 15 Chemin Camille-Vidart 1202 Geneva, Switzerland (**GARDP**)

Shionogi and GARDP are each referred to in this License Agreement as a **Party**. Shionogi and GARDP are collectively referred to in this License Agreement as the **Parties**.

### **Preliminary Statements**

The common objectives of the Parties are to enable Sublicensees (as defined below) to provide, with a sense of urgency, affordable and sustainable access to quality Licensed Product (as defined below) for patients in need in countries in the Territory (as defined below) while preserving the efficacy and appropriate use of the Licensed Product and encouraging good antimicrobial stewardship (the **Access and Stewardship Objectives**).

### **Whereas**

- (A) GARDP is a non-profit organization with an expertise in antibiotics with a mission to develop new treatments for drug-resistant infections that pose the greatest threat to health. GARDP works with partners and its international network to ensure sustainable access to treatments, promoting responsible use and affordability to all in need.
- (B) Shionogi, a Japanese pharmaceutical company with a global outreach, owns and/or Controls (as defined below) the Licensed Rights and Licensed Manufacturing Know-How (both, as defined below) with respect to the Licensed Compound (as defined below) and the Licensed Product with respect to the Territory.
- (C) GARDP desires to obtain a sublicensable license from Shionogi on these Licensed Rights and Licensed Manufacturing Know-How as set out in this License Agreement and Shionogi desires to grant such license to GARDP, all on the terms and conditions set out in this License Agreement, solely to manufacture Licensed Product for countries (including Low-to-Middle Income Countries (LMICs)) in the Territory and/or to obtain regulatory approvals for and commercialize Licensed Product in countries (including LMICs) in the Territory to achieve the humanitarian objectives of this License Agreement.
- (D) The Parties desire to provide for certain technology transfer arrangements as set out in this License Agreement to assist **Sublicensees** (as defined below) to manufacture the Licensed Product in the Territory.

- (E) In parallel with this License Agreement, the Parties are entering into a three-party **Collaboration Agreement** (as defined below) with Clinton Health Access Initiative (CHAI), that will govern the operational (as opposed to licensing) activities to be conducted by the Parties and CHAI to enable and facilitate Sublicensees to provide access to the Licensed Product in countries (including LMICs) in the Territory to achieve the humanitarian objectives of these agreements. The provisions of this License Agreement shall be read consistently with the provisions of the Collaboration Agreement.

Now, **therefore**, in consideration of the foregoing and the mutual agreements set out in this License Agreement, the Parties agree as follows.

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## 1. DEFINITIONS AND INTERPRETATION

### 1.1 Definitions

For the purposes of this License Agreement, the following definitions shall apply:

**Affiliate**, of a Person, means any Person which, directly or indirectly, is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term **control** as used with respect to a Person shall mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

**Business Day** means a day other than Saturday, Sunday, or any day on which commercial banks located in New York, New York, U.S.A., Tokyo, Japan or Geneva, Switzerland are authorized or obligated by law to remain closed.

**Clinical Data** has the meaning given to it in Section 8.3(a)(ii).

**Collaboration Agreement** means the three-party Collaboration Agreement being entered into in parallel with this License Agreement (and executed on the same date) by Shionogi, GARDP and CHAI, to govern the operational (as opposed to licensing) activities to be conducted by the Parties and CHAI to enable and facilitate Sublicensees to provide access to Licensed Product in countries in the Territory, as such may be amended from time to time in accordance with its terms. The provisions of this License Agreement shall be read consistently with the provisions of the Collaboration Agreement.

**Commercialization** or **Commercialize** means any and all activities directed at obtaining pricing and reimbursement approvals, obtaining and maintaining regulatory approvals to commercialize, marketing, promoting, distributing, importing, or more generally commercializing or selling a Licensed Product, including any related scientific and medical affairs and pharmacovigilance activities. Commercialization shall also include the preparation and submission of regulatory filings and regulatory affairs activities with respect to the foregoing. For the avoidance of doubt, Commercialization and Commercialize do not include the Manufacture or Development of the Licensed Product (even if such activities are required to obtain or maintain regulatory approvals for the Commercialization or Manufacture of the Licensed Product).

**Compassionate Use** means the use of Licensed Product outside of a clinical trial in a country where it has not been approved for commercialization and in accordance with applicable laws or regulations that allow such use to treat a patient with a serious or life-threatening disease or condition who has no comparable or satisfactory alternative treatment options.

**Confidential Information** means all proprietary technical, commercial or other information, including trade secrets, processes, formulae, data, know-how, improvements, unpublished inventions, techniques, methods, marketing plans, strategies, customer lists and sales information, that are disclosed directly or indirectly by a Party or any of its Affiliates or agents to the other Party or any of its Affiliates or agents, as well as any other information and materials that are deemed confidential or proprietary to or by a Party or any of its Affiliates (including all information and materials of a Party's (or its Affiliates') customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic or electronic form. Confidential Information will include the Licensed Manufacturing Know-How.

**Controlled** or **Controls**, when used in relation to any intellectual property rights or proprietary or trade secret information, means that a Party (or any of its Affiliates) has the legal authority and right to grant a license or sublicense of such intellectual property rights to the other Party, or to otherwise disclose such proprietary or trade secret information to the other Party in accordance with the terms of this License Agreement, without breaching the terms of any agreement with a Third Party, infringing upon the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

**Cost Recoupment Fee(s)** has the meaning given to it in Section 3.1.

**Cost Recoupment Period** has the meaning given to it in Section 3.1.

**Designated Officers** has the meaning given to it in Section 13.1(d).

**Development** and **Develop** means any and all non-clinical and clinical drug development activities related to or involving the Licensed Product, including without limitation those conducted for the purposes of the development and submission of information to a Regulatory Authority, including toxicology, microbiology, pharmacology and other discovery efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, and clinical studies (including pre- and post-approval studies).

**Development Results** has the meaning given to it in Section 8.3(a).

**Dispute** has the meaning given to it in Section 13.1(a).

**Effective Date** has the meaning set forth in the preamble hereto.

**Field** means, with respect to the Licensed Compound and/or Licensed Product, the treatment of infections due to aerobic Gram-negative organisms in adults (and, if approved by applicable Regulatory Authorities, children) with limited treatment options, it being understood that regulatory agencies within the Territory that approve the Licensed Product may grant approvals with indications that are more specific (e.g., for site-specific infections).

**Force Majeure** has the meaning given to it in Section 14.3.

**GARDP Contractor(s)** has the meaning given to it in Section 2.12.

**GARDP Indemnitee** has the meaning given to it in Section 11.2.

**Good Manufacturing Practice** or **GMP** means the current good manufacturing practices applicable from time to time to the manufacturing of a Licensed Product or any intermediate thereof pursuant to applicable laws.

**Indemnified Party** has the meaning given to it in Section 11.3.

**Indemnifying Party** has the meaning given to it in Section 11.3.

**License Agreement** means this License and Technology Transfer Agreement, together with all attached Schedules, as the same may be amended or supplemented from time to time.

**Licensed Compound** means the compound cefiderocol as described in Schedule A.

**License Management Subcommittee** has the meaning given to it in Section 2.8(a).

**Licensed Manufacturing Know-How** means all technical information and know-how owned and/or Controlled by Shionogi or its Affiliates as of the Effective Date (including all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control, and testing procedures) that is identified by Shionogi, in its good faith judgment, as reasonably necessary for the Manufacture of the Licensed Compound and/or Licensed Product in substantially the same manner that such Licensed Compound and/or Licensed Product have been Manufactured by or for Shionogi as of the Effective Date.

**Licensed Product** means any human pharmaceutical product or products produced under license from GARDP and/or Shionogi in the Field and containing the Licensed Compound as an active ingredient, in finished form. Notwithstanding anything to the contrary contained herein, the Parties acknowledge and agree that the license granted hereunder shall be limited to a license to rights relative to cefiderocol (for injection) in the form, presentation, dose and formulation approved by the United States Food and Drug Administration and/or European Medicines Agency as of the Effective Date, as described in Schedule A, and do not include rights to any other form, presentation, dose or formulation of cefiderocol.

**License Results** means any results and know-how and inventions, patentable or not, developed or generated by or for GARDP and/or a Sublicensee in the performance of any activities conducted pursuant to this License Agreement and/or a Sublicense Agreement. This includes all Process Results and all Development Results.

**Licensed Rights** means:

- (a) the patents and patent applications owned or Controlled by Shionogi in the Territory related to the Licensed Compound or Licensed Product or their Manufacturing or use listed on Schedule B. Should it appear that Shionogi or its Affiliates own or Control other patents or patents applications in the Territory that are necessary for GARDP or its Sublicensees to exercise the licenses granted pursuant to this Agreement, GARDP may request that such be added to Schedule B by amendment, and Shionogi shall not unreasonably refuse such request; for clarity, any changes to Schedule B must be documented in a written amendment to this License Agreement signed by both Parties;
- (b) any continuation, continuation-in-part (but only to the extent that such application includes new data in support of claims previously submitted in a prior originally filed application), divisional, and continued-prosecution applications of any patent applications included in paragraph (a); and
- (c) any patents issuing from any patent applications included in the paragraphs (a) and (b),

in each case, including any renewals, extensions, patents of addition, supplementary protection certificates, revivals, re-examinations, and reissues thereof; and

- (d) the data, information, and documentation that are owned or Controlled by Shionogi that are necessary to Develop, obtain regulatory approvals for, Manufacture and Commercialize the Licensed Product in the Field in the Territory, all as set forth in Schedule D, which Schedule may be updated from time to time by mutual agreement of the Parties. For clarity, the Licensed Rights include the Licensed Manufacturing Know-How.

**Losses and Claims** has the meaning given to it in Section 11.1.

**Manufacture** and **Manufacturing** mean any and all activities related to the production, packaging, testing and labeling of pharmaceutical products, including stability testing, quality control, quality assurance testing and release, post-marketing validation testing, storage and inventory control.

**Market Access Plan** has the meaning given to it in Section 2.1(a).

**Net Sales** means, with respect to any Licensed Product, the gross amounts invoiced for sales or other dispositions of such Licensed Product by or on behalf of GARDP or any Sublicensee, as applicable, to Third Parties less the following deductions to the extent included in the gross invoiced sales price for such Licensed Product or otherwise directly

paid or incurred by GARDP or any Sublicensee, as applicable, with respect to the sale or other disposition of such Licensed Product:

(i) normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of such Licensed Product (provided that such discounts are not applied disproportionately to such Licensed Product when compared to the other products of GARDP or the Sublicensee, as applicable);

(ii) credits or allowances given or made for rejection of or return of previously sold Licensed Product or for retroactive price reductions and billing errors;

(iii) rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers;

(iv) costs of freight, insurance, and other transportation charges directly related to the distribution of such Licensed Product;

(v) taxes, duties, customs duties or other governmental charges (including any tax such as a value added or similar tax, other than any taxes based on income) levied on or measured by the billing amount for such Licensed Product, as adjusted for rebates and refunds; and

(vi) the lesser of (a) ten percent (10.0%) of the aggregate gross amount billed or invoiced on sales of a Licensed Product in the relevant country (provided the amount deducted is consistent with generally accepted accounting practices in the relevant country), or (b) the actual amount of any write-offs for bad debt relating to such sales during the period in which GARDP has the obligation to pay a Cost Recoupment Fee.

Upon any sale or other disposition of any Licensed Product that should be included within Net Sales for any consideration other than exclusively monetary consideration on bona fide arm's-length terms, then for purposes of calculating Net Sales under this License Agreement, such Licensed Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Licensed Product in the country in which such sale or other disposition occurred when such Licensed Product is sold alone and not with other products.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales. Sales of Licensed Product between GARDP and any Sublicensee for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Licensed Product to a Third Party shall be included within the computation of Net Sales. Any free-of-charge disposal or use of a Licensed Product for development, regulatory or marketing purposes, such as clinical trials, compassionate use or indigent patient programs, shall not be deemed a sale or disposition for purposes of calculating Net Sales.

In the event of changes to a Party's or a Sublicensee's accounting rules as the result of merger or by operation of law, or should the above not be consistent with a Sublicensee's accounting rules, the Parties will engage in good faith negotiations with respect to possible amendments to the definition of Net Sales as applicable to such Party or Sublicensee. For the avoidance of doubt, any change to the definition of Net Sales must be made by a written amendment to this License Agreement signed by both Parties.

**Person** means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association, or other entity or other form of business organization.

**Process Results** has the meaning given to it in Section 8.2(a)(i).

**Product Trademark** means the trademarks set out in Schedule E.

**Regulatory Authority** means any national or supranational governmental authority that has responsibility in any one or more countries in the Territory over the Development, Manufacture and/or Commercialization of the Licensed Compound and/or Licensed Product.

**Sanctions** shall have the meaning given in the definition of "Sanctions Target".

**Sanctions Authorities** shall have the meaning given in the definition of "Sanctions Target".

**Sanctions Target** shall mean an individual or entity that is, or is owned or controlled by, one or more individuals or entities that are: (i) the target of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control (**OFAC**), the U.S. Department of State, Her Majesty's Treasury, the United Nations Security Council, the European Union or its Member States, or another sanctions authority with jurisdiction over either Party (together, the **Sanctions Authorities**) (collectively **Sanctions**); or (ii) located, organized, or resident in a country or territory that is the target of country-wide or territory-wide Sanctions; or (iii) listed on OFAC's Consolidated Sanctions List or any equivalent list of parties designated by the European Union.

**Shionogi Indemnitee** has the meaning given in Section 11.1.

**Shionogi Sole Inventions** has the meaning given in Section 8.1(a).

**Stringent Regulatory Authority** or **SRA** means any Regulatory Authority that is a member, observer, or associate of the International Conference of Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time, together with any other national Regulatory Authorities that are designated by the World Health Organization as a WHO Listed Authority with Maturity Level (ML) 3 (stable, well-functioning and integrated regulatory systems) or Maturity Level (ML) 4 (regulatory systems operating at advanced level of performance and continuous improvement).

**Sublicense Access Plan** has the meaning given to it in Section 2.3(d).

**Sublicense Agreement** has the meaning given to it in Section 2.3(c).

**Sublicense and Sublicensee** have the respective meanings given to them in Section 2.3(c).

**Technical Transfer Package** has the meaning given to it in Section 4.2.

**Term** has the meaning given to it in Section 12.1.

**Territory** means the countries listed in Schedule C and such other or different countries as the Parties may agree in writing.

**Third Party** means any Person other than Shionogi and GARDP and their respective Affiliates.

**WHO** means World Health Organization.

## 1.2 Interpretation

In this License Agreement:

- (a) Section headings are for convenience only and are not intended to affect the interpretation of this License Agreement;
- (b) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;
- (c) words in the singular include the plural and vice versa;
- (d) any reference to “includes” or “including” are to be construed as indicative and non-exhaustive lists;
- (e) unless otherwise specified or prevented by applicable laws, reference to “writing” includes faxes, email, letters, digital signatures or certificates, or any other legible form of writing;
- (f) if a period of time is specified and dates from a given day or the day of an act or event, it is to be calculated exclusive of that day;
- (g) whenever this License Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days; and
- (h) except to the extent expressly specified to the contrary, in the event of any inconsistency between any clause, any attachment, or other document incorporated by reference, the clauses override the attachments, and the attachments override any other incorporated documents incorporated by reference, to the extent of any inconsistency.



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## 2. LICENSE GRANT

### 2.1 Licensed Rights and Licensed Manufacturing Know-How

- (a) The Parties have agreed on a Market Access Plan (the **Market Access Plan**, the initial version of which is set forth in a schedule to the Collaboration Agreement), which plans and tracks the various activities to be conducted by GARDP and Shionogi (and CHAI, where applicable) pursuant to the Collaboration Agreement in pursuit of the Access and Stewardship Objectives, including notably the activities of GARDP and Shionogi (and CHAI, where applicable) to enable and facilitate the Sublicensees to supply, develop, register, and distribute the Licensed Product in countries in the Territory. Each of Shionogi and GARDP shall use reasonable best efforts to conduct the activities and achieve the objectives for which it is responsible in the Market Access Plan. The Market Access Plan shall be managed and updated from time to time in accordance with the Collaboration Agreement, which provides that either Party (or CHAI) may propose changes to the Market Access Plan, and that all such changes shall require the approval of both Parties and, if applicable, of CHAI except as otherwise specifically set forth in the Collaboration Agreement.
- (b) Upon the terms and subject to the conditions set out in this License Agreement, Shionogi hereby grants to GARDP, and GARDP hereby accepts, a non-exclusive, non-transferable license, with the right to grant sublicenses (subject to Shionogi's consent rights pursuant to the provisions of this License Agreement) under the Licensed Rights and the Licensed Manufacturing Know-How, to: (i) register, or have registered, the Licensed Product in the Field in the Territory, and (ii) Commercialize, or have Commercialized, the Licensed Product in the Field in the Territory, together with a non-exclusive, non-transferable, and sublicensable (subject to Shionogi's consent rights and limited to the agreed scope of the Sublicense Agreement), license to use and practice the Licensed Rights and Licensed Manufacturing Know-How, (iii) Develop, or have Developed, the Licensed Product, as may be approved by Shionogi, and (iv) Manufacture, or have Manufactured, the Licensed Compound and Licensed Product for distribution in the Territory, in each case (i) through (iv) strictly in accordance with the requirements of and as otherwise contemplated by this License Agreement and, for GARDP, the Collaboration Agreement and the Market Access Plan, and for each Sublicensee, the relevant Sublicense Agreement and Sublicense Access Plan. For clarity, the license to Manufacture, or have Manufactured, the Licensed Compound and Licensed Product for distribution in the Territory may include the right to Manufacture, or have Manufactured, the Licensed Compound and Licensed Product in a country outside the Territory, so long as the Manufactured Licensed Compound and Licensed Product are Commercialized exclusively in the Territory; for the purposes of this Manufacturing license, the Parties shall discuss and agree whether any licenses to any patents or patent applications owned or Controlled by Shionogi are necessary for such Manufacture in the relevant country(ies) of Manufacture outside the Territory, and if agreed, shall enter into an amendment to

this License Agreement to include a nonexclusive license to such patent in the Manufacturing license granted hereunder.

- (c) The license granted by Shionogi to GARDP includes a license to use and practice the Licensed Rights as may be required for GARDP to conduct all the activities for which it is responsible under this License Agreement or the Collaboration Agreement. The License Rights granted to GARDP pursuant to this License Agreement shall be strictly limited to conducting the activities contemplated in this License Agreement and to those set out in the Market Access Plan. GARDP will not have any right to practice the license granted under this Section 2.1 or otherwise exploit the Licensed Rights and Licensed Manufacturing Know-How for any other purpose.

## **2.2 Term of license grant**

The license granted to GARDP in Section 2.1 with respect to Licensed Rights will expire upon the expiry of the Term, subject to an earlier termination in accordance with Section 12.

## **2.3 Sublicenses**

- (a) Shionogi shall, for so long as GARDP is expending reasonable best efforts to pursue the Access and Stewardship Objectives in accordance with the Market Access Plan, refer to GARDP all enquiries received by Shionogi from potential partners for countries in the Territory, and such potential partners shall be evaluated by GARDP in accordance with the Market Access Plan. Notwithstanding the foregoing, should the Parties agree, or Shionogi reasonably determine after consulting with GARDP, that it would be preferable for the Access and Stewardship Objectives to grant a Third Party a direct license to the Licensed Product for one or more countries in the Territory where access is not being addressed by GARDP or its Sublicensees, Shionogi shall be free to grant such license directly to the Third Party.
- (b) The Parties shall evaluate in good faith the capacities and proposals of each potential Third-Party Sublicensee to perform its obligations in accordance with the Access and Stewardship Objectives in countries within the Territory. Each Sublicensee shall be approved by Shionogi prior to the grant of any Sublicense, and Shionogi shall have the right to withhold approval of any Sublicensee proposed by GARDP for reasonable concerns.
- (c) The Parties acknowledge and agree that potential Sublicensees of the license granted by Shionogi to GARDP in Section 2.1 shall be identified by GARDP and/or CHAI in accordance with the Collaboration Agreement. These Sublicensees may be involved in Manufacturing the Licensed Product (and/or Licensed Compound), in Commercializing the Licensed Product, or both. GARDP shall grant sublicenses to these Sublicensees according to the terms of a sublicense agreement to be entered into with at least the provisions attached as Schedule F to this License Agreement,

except to the extent these provisions are not relevant for the Sublicensee given the nature of the rights granted to them (each such executed sublicense agreement being a **Sublicense Agreement**, the sublicense granted pursuant thereto being a **Sublicense**, and each Third Party with which a Sublicense Agreement is entered into being a **Sublicensee**).

- (d) Each Sublicense Agreement will include an agreed Commercialization plan (the **Sublicense Access Plan**), including specific target dates for Commercialization objectives in the portion of the Territory covered by such Sublicense Agreement and means by which the Sublicensee will adhere to, and promote Third Party adherence to, the Access and Stewardship Objectives. The Sublicensee shall have an obligation to devote commercially reasonable efforts to achieving the objectives and target dates of their Sublicense Access Plan. The Sublicense Access Plan for each Sublicensee shall be agreed to by Shionogi, and progress under the Sublicense Access Plan for each Sublicense Agreement will be routinely discussed with Shionogi in the License Management Subcommittee. Shionogi shall also have the right to review and approve each Sublicense Agreement to ensure that it is consistent with the terms and conditions of this License Agreement (including the provisions attached as Schedule F), and may refuse to approve any proposed Sublicense Agreement that is not consistent. Shionogi shall promptly provide its feedback to any first and final draft of each Sublicense Agreement proposed by GARDP.
- (e) GARDP may include in each Sublicense Agreement a covenant by GARDP not to seek another market access partner for the country(ies) covered by such agreement, together with a confirmation that Shionogi has agreed to refer to GARDP all enquiries from potential market access partners for such country(ies), in each case for so long as the Sublicensee is complying with its diligence obligations. For the avoidance of doubt, the license granted herein is non-exclusive and nothing herein shall restrict Shionogi or its agents' Development, Manufacture, or Commercialization (including registration) of any product containing cefiderocol within the Territory.
- (f) Any Sublicense Agreement will be entered into subject to the following:
  - (i) it will refer to this License Agreement and will be subject to and subordinate to this License Agreement;
  - (ii) the Sublicensees will confirm in writing that it has reviewed the terms and conditions of this License Agreement and agree to not perform any acts or omissions that would place GARDP in breach of this License Agreement;
  - (iii) the sublicense rights granted to each Sublicensee will be non-sublicensable and non-transferable except as may be expressly provided under the Sublicense Agreement;

- (iv) each Sublicensee will be entitled, limited to the activities described in its Sublicensee Access Plan and subject to the express rights granted as set forth in the applicable Sublicense Agreement, to make, have made, offer for sale, have sold, export or import the Licensed Compound, whether inside or outside of the Territory, exclusively for use in the Field in the Territory;
  - (v) each Sublicensee shall be required to enter into a Safety Data Exchange Agreement, as contemplated by Section 6.1;
  - (vi) the Sublicensees will be entitled, limited to the activities described in its Sublicensee Access Plan and subject to the express rights granted as set forth in the applicable Sublicense Agreement, to offer for sale, sell, and have sold the Licensed Product to customers outside of the Territory solely to the extent that such Licensed Product will be exclusively imported (as applicable) and used in the Field in the Territory and not exported outside of the Territory; and
  - (vii) before entering into a Sublicense Agreement, GARDP and/or CHAI, as applicable in accordance with the Collaboration Agreement, will perform due diligence of the proposed Sublicensees in order to ensure compliance with applicable laws relating to corruption (including anti-bribery laws and the U.S. Foreign Corrupt Practices Act and the Unfair Competition Prevention Act and Penal Code Act in Japan); and if applicable relevant national and international quality and good manufacturing practices. No Sublicense Agreement may be entered into before the satisfactory completion of such due diligence by GARDP and/or CHAI, and the approval of such proposed Sublicensee by Shionogi.
- (g) GARDP will procure that:
- (i) each applicable Sublicensee has demonstrated capability to Manufacture the Licensed Product it intends on Manufacturing; and
  - (ii) each applicable Sublicensee will file for registration of the Licensed Product in at least one country in the Territory within four (4) years of the start of technical transfer pursuant to Section 4.2 to the Sublicensee, or if there is no technical transfer to the Sublicensee, within four (4) years of the Effective Date of the applicable Sublicense Agreement.
- (h) GARDP will coordinate execution of the Sublicense Agreement between GARDP and each Sublicensee.
- (i) GARDP will not modify the terms and conditions of any executed Sublicense Agreement (including the provisions as attached as Schedule F) without Shionogi's prior written consent. Shionogi may refuse to consent to any proposed Sublicense Agreement amendment that is not consistent with the terms of this License Agreement (including the provisions as attached as Schedule F). Shionogi shall

promptly provide its feedback to any draft Sublicense Agreement amendment proposed by GARDP.

- (j) GARDP will remain jointly and severally liable with any Sublicensee to Shionogi for any failure by any Sublicensee to comply with the terms and conditions of this License Agreement applicable to the Sublicensee or with the terms and conditions of its Sublicense Agreement that would cause GARDP to be in breach of its obligations pursuant to this License Agreement or that would otherwise cause damages to Shionogi.
- (k) GARDP will diligently monitor and enforce each Sublicensee's compliance with its Sublicense Agreement, including, without limitation, diligently reviewing the progress reports received from such Sublicensee, and monitoring compliance with the applicable Sublicense Access Plan. GARDP shall provide unredacted copies of any and all such progress reports to Shionogi within ten (10) Business Days of receipt.
- (l) If GARDP becomes aware of any act or omission of a Sublicensee which constitutes a breach of the relevant Sublicense Agreement, GARDP will:
  - (i) if the breach is capable of correction and does not give rise to an immediate right of termination under the Sublicense Agreement, direct the relevant Sublicensee in writing to cure the breach, with a copy of that writing to Shionogi; and
  - (ii) if the breach remains uncured at the end of the specified period, or if there are otherwise grounds for termination under the Sublicense Agreement, in consultation with Shionogi, take all actions to procure the termination of the relevant Sublicense Agreement in accordance with its terms.
- (m) GARDP agrees that it will not grant sublicenses to entities other than Sublicensees approved by Shionogi and will not enter into any Sublicense Agreement under this License Agreement without the prior written consent of Shionogi. Any purported sublicense not entered into in compliance with the foregoing will be null and void ab initio and without effect. Notwithstanding the foregoing, licenses contemplated in Section 2.1 may be further sublicensed by Sublicensees through multiple tiers (each further tier sublicensee also being considered a Sublicensee for the purposes hereof) for the purpose of Commercializing the Licensed Product in the Territory that is Manufactured by or for the relevant Sublicensee; provided that all such further tier Sublicensees shall be subject (i) to the approval of both Shionogi and GARDP; and (ii) to all other applicable conditions applicable to Sublicensees. For the avoidance of doubt, Third Parties selling finished product Manufactured and Commercialized under the principal Sublicensee's name shall not be considered further tier Sublicensees.

- (n) The Sublicense Agreements will prohibit Sublicensees from Manufacturing and selling the Licensed Compound and/or Licensed Product in combination with other active pharmaceutical ingredients in the Territory or outside of the Territory.
- (o) Without limiting the foregoing, Shionogi has the right to review and comment on any and all proposed Development activities (other than Development relating to Manufacturing / chemistry, Manufacturing and controls (CMC) / process development conducted as part of the technical transfer described in Section 4.2(a)) to be conducted by any Sublicensee (or GARDP, as applicable) relating to the Licensed Product or the Licensed Compound, and whether to conduct, and the design and performance of, all such Development activities by any Sublicensee (or GARDP, as applicable) shall be subject to Shionogi's prior approval. Shionogi shall use its reasonable best efforts to promptly respond to any such proposed Development activities. For the avoidance of doubt, GARDP and/or Sublicensees would be responsible for the cost of any such Development work, including clinical trials.
- (p) Each Sublicensee shall be solely responsible at its expense for making or procuring from a Sublicensee that Manufactures Licensed Product, as applicable, all of its respective requirements for the Licensed Compound and Licensed Product in conformity with all applicable specifications in the countries of the Territory where it Commercializes the Licensed Product and will hold all relevant authorizations and permits required by the applicable Regulatory Authority(ies) in this respect. In addition, each Sublicensee shall adhere to, and promote Third Party adherence with, the obligations relating to the Access and Stewardship Objectives set forth in the applicable Sublicense Agreement.
- (q) Each Sublicensee that will Manufacture the Licensed Compound and Licensed Product for use and sale in the Territory will (i) do so in strict conformity with the applicable conditions specified in this License Agreement and their Sublicense Agreement, and (ii) use commercially reasonable efforts in accordance with the applicable Sublicense Access Plan to provide a sufficient supply thereof to meet the needs in the countries of the Territory. Without limiting the foregoing and to the extent applicable, each Sublicense Agreement with a Sublicensee that Manufactures Licensed Product shall require the Sublicensee to Manufacture the Licensed Product: (a) in a manner consistent with and in accordance with standards validated by a World Health Organization prequalification (**WHO PQ**) or by any applicable Stringent Regulatory Authority (if the manufacturing site has already been approved by a Stringent Regulatory Authority) or, if neither WHO PQ or an SRA has assessed and confirmed compliance with such manufacturing standards, by a Third Party audit (including relative to GMP) to confirm adherence with WHO PQ and/or SRA standards, such third party to be agreed by both Parties; and (b) any applicable industry standards for responsible Manufacture of antibiotics.

## 2.4 No trademark license

- (a) No right or license, express or implied, is granted to GARDP or the Sublicensees either under this License Agreement or the Sublicense Agreement to use the Product Trademark or any trademark, trade name, logo, trade dress, or service mark owned or Controlled by Shionogi or any of its Affiliates. Notwithstanding the above, if GARDP or any Sublicensee, as applicable, believes applicable law or regulation would require that GARDP or such Sublicensee use or reference any Product Trademark or any trademark, trade name, logo, trade dress, or service mark owned or Controlled by Shionogi or any of its Affiliates, GARDP shall provide Shionogi with documentation supporting its interpretation of the applicable law or regulation, and Shionogi and GARDP shall discuss in good faith the matter and use reasonable best efforts to reach an amicable resolution thereof.
- (b) The relevant Sublicensee(s) shall, at their sole cost and expense, be responsible for the selection, registration, and maintenance of all trademarks and trade dress which they employ in connection with their activities conducted pursuant to their Sublicense Agreement, and will own and control such trademarks and trade dress.
- (c) Shionogi shall have the right to review all trademarks and trade dress used in the Commercialization of the Licensed Product in the Territory, and shall have the right to refuse all trademarks and trade dress for reasonable concerns, in particular, if it considers the proposed trademarks or trade dress may be confusingly similar with any Product Trademark or other trademarks or trade dress, or if the proposed trademarks or trade dress are immoral, deceptive, or scandalous, or if the proposed trademarks or trade dress disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs, or national symbols, or bring them into contempt or disrepute. Shionogi shall provide its feedback for any proposed trademark or trade dress promptly following receipt of all information requested in order to fully evaluate such request. If Shionogi reasonably objects to the Sublicensee's proposal within the foregoing time period, the Parties and the Sublicensee shall discuss in good faith Shionogi's concerns, and the Sublicensee will agree to make such modifications to the Sublicensee's proposed trademark, trade dress or product markings as are necessary to address Shionogi's concerns.
- (d) Without limiting the foregoing, GARDP and its Sublicensees will not use (or allow their distributors to use) the Product Trademark or any trademark or trade dress or product marking used by Shionogi or any of its Affiliates or licensees in any manner or any trademark or trade dress that is confusingly similar to the Product Trademark or any trademark or trade dress used by Shionogi or any of its Affiliates.
- (e) GARDP will require that its Sublicensees cause the product markings, packaging and related features of each Licensed Product to be distinctive from that which is used by Shionogi with cefiderocol products.

## **2.5 No implied license**

No license or other right is or will be created or granted under this License Agreement by implication, estoppel, or otherwise. All licenses and rights are or will be granted only as expressly provided in this License Agreement. For the avoidance of doubt, Shionogi has entered into this License Agreement subject to the express understanding between the Parties that GARDP would not obtain any licenses or rights other than those expressly provided in this License Agreement.

## **2.6 Retained rights**

- (a) All rights not expressly granted under this License Agreement are reserved by Shionogi and Shionogi's use thereof for any purpose is not restricted by this License Agreement.
- (b) Without limiting the foregoing, Shionogi retains any and all rights under the Licensed Rights and Licensed Manufacturing Know-How to make, have made, use, offer for sale, sell, have sold, export, import, license, or exploit:
  - (i) the Licensed Compound and any product containing the License Compound for any use whether within or outside the Territory and whether within or outside the Field; and
  - (ii) compounds other than the Licensed Compound covered by one or more claims in the patents included in the Licensed Rights, for any use.
- (c) Shionogi also expressly reserves and retains the right to make or have made, and use, the Licensed Compound and any product containing the Licensed Compound for any internal research purpose.

## **2.7 Non-diversion**

- (a) GARDP acknowledges that the license to use and sell the Licensed Compound and Licensed Product granted under Section 2.1 is granted solely under and with respect to the Licensed Rights and Licensed Manufacturing Know-How for the purposes of supplying Licensed Product in the Territory.
- (b) Nothing in this License Agreement will be construed as granting GARDP or its Sublicensees any rights under any patents, know-how, or otherwise to use or sell the Licensed Compound or any Licensed Product for ultimate use outside of the Field and/or outside of the Territory.
- (c) Subject to any applicable competition law, each Sublicense Agreement will include provisions to prevent and prohibit the Licensed Product intended for distribution in the Territory from being diverted outside the Territory, including for use outside the Territory. Shionogi shall refer to GARDP (or as applicable the relevant Sublicensee) all requests for any Licensed Product in a country in the Territory where a commercial Sublicensee is actively supplying the Licensed Product, and



Shionogi shall consult with GARDP as to how to respond to any request for the Licensed Product in a country in the Territory where the Licensed Product is not being supplied by a commercial Sublicensee. For the avoidance of doubt, nothing herein or in any Sublicense Agreement shall restrict or limit Shionogi or its agents' rights or ability to Develop, Manufacture, or Commercialize the Licensed Product in the Territory.

## **2.8 License Management Subcommittee**

- (a) The Parties shall form a License Management Subcommittee, composed of an equal number of representatives from Shionogi and GARDP, which shall meet at least once per quarter to oversee and manage the licensing activities conducted pursuant to the License Agreement, and in particular, but not limited to:
  - (i) Review the management of Sublicense Agreements granted pursuant thereto.
  - (ii) Discuss any other matters that may arise in connection with the License Agreement.
- (b) Any decisions made by the License Management Subcommittee shall require unanimous approval of all members of the License Management Subcommittee. If the License Management Subcommittee cannot reach consensus on a particular issue within its authority, such issue will be subject to an initial dispute resolution process involving escalation to the Joint Steering Committee formed pursuant to the Collaboration Agreement (it being understood that, although CHAI is a member thereof, CHAI shall not have any decision-making right in relation to matters relating to the management of this License Agreement or any Sublicense Agreement), and if the Joint Steering Committee is unable to resolve the issue, to senior executives of both Parties for negotiation and resolution. If the senior executives are unable in good faith to resolve the issue within sixty (60) days of it being submitted to them, then either Party may: (i) if the issue concerns a question of interpretation of this Agreement or of the Parties' rights and obligations hereunder, demand resolution of the issue by binding arbitration pursuant to Section 14.6 of this License Agreement; or (ii) for strategic or other issues that cannot be resolved through interpretation of this Agreement or of the Parties' rights and obligations hereunder, request a mediation procedure to assist in resolving the issue through appointment of a neutral, independent third party with appropriate expertise mutually agreed by the Parties, or if the Parties are unable to agree on such neutral third party within thirty (30) days following the request, by a neutral third party mediator with appropriate expertise appointed by the ICC. For the avoidance of doubt, this Section 2.8(b) shall not apply to any issues outside the authority of the License Management Subcommittee, including any matters that would involve amending the terms and conditions of this License Agreement.

## 2.9 OFAC Licenses

- (a) GARDP represents that neither GARDP nor, to the knowledge of GARDP, any Affiliate, director, officer, or employee of GARDP, is a Sanctions Target.
- (b) GARDP agrees that it will not, with respect to the licensed intellectual property (including the Licensed Rights and the Licensed Manufacturing Know-how), Licensed Compound and Licensed Product, engage in any transactions or dealings with or involving a Sanctions Target or a country or territory that is the target of US or EU country-wide or territory-wide Sanctions absent a license or other authorization from the relevant governmental authority, should such a license or other authorization be required. GARDP shall convey such license or other authorization, if required and obtained, to Shionogi prior to any such transactions or dealings.

GARDP also agrees that prior to, directly or indirectly,

- (i) making any Licensed Compound or any Licensed Product available to, or contracting for Licensed Product Manufacture with, any Sanctions Target; or
- (ii) making any Licensed Compound or any Licensed Product available to, or contracting for Licensed Product Manufacture in, a country or territory that is the target of country-wide or territory-wide Sanctions;

it will obtain a license or other authorization, if required, either directly from the relevant government authority or cooperate with Shionogi to obtain such a license or other authorization in each case to permit GARDP, its Sublicensee, and Shionogi (as the ultimate licensor of the Licensed Product) to engage in transactions with a Sanctions Target or involving a country or territory that is the target of country-wide or territory-wide Sanctions. If Shionogi is in agreement with the decision to try to obtain such license or other authorization (such decision to be made in Shionogi's sole discretion), Shionogi shall provide reasonable assistance as requested by GARDP and as may be reasonably necessary to obtain the license or other authorization; and

in the event that performance of the License Agreement or any Sublicense Agreement by GARDP or its Sublicensee would (or might), in the reasonable opinion of Shionogi, breach, or expose Shionogi to potential liability under, any Sanctions or export control regime or any other similar laws of any jurisdiction (whether or not such Sanctions, controls, or laws were in existence at the date of this License Agreement, and whether or not there have been any other changes in circumstance from those that existed at the Effective Date of this License Agreement or execution date of any Sublicense Agreement), Shionogi shall be entitled to immediately request that GARDP or its Sublicensees (i) cease all shipments of Licensed Compound or Licensed Product into any country or territory that is the target of countrywide or territory-wide Sanctions, or (ii) if the Licensed

Compound or Licensed Product is already in such country or territory but still within the custody and control of GARDP, its Sublicensees or its respective agents or representatives, to use its reasonable best efforts to remove such Licensed Compound or Licensed Product from the country or territory, or (iii) suspend the operation of such provisions of the License Agreement or relevant Sublicense Agreement(s) (including any supply provisions) which require or permit performance by either Party or the Sublicensee which, in the reasonable opinion of Shionogi, would result in a breach of, or expose Shionogi to potential liability under, any such Sanctions, controls, or laws, until, in the reasonable discretion of Shionogi, such time as all necessary approvals or licenses have been obtained to enable the License Agreement to continue in a lawful and compliant manner and without exposure to liability for Shionogi. Notwithstanding any provision of the License Agreement or the relevant Sublicense Agreement(s), Shionogi shall not be obliged to pay any compensation to GARDP or any Sublicensee or otherwise indemnify them in respect of any losses or costs which they may suffer or incur as a result of such suspension and/or termination.

- (c) GARDP and its Sublicensees shall not be required pursuant to this License Agreement or any Sublicense Agreement to conduct any activities or engage in any transactions or dealings that would be contrary to any, or expose them to any potential liability under, any Sanctions or export control regime or any other similar laws of any jurisdiction.

## **2.10 Limitation on GARDP's rights to assign**

GARDP acknowledges that Shionogi has carefully selected GARDP to participate in the arrangements contemplated in this License Agreement. It is intended that Shionogi should not be obligated to participate in such arrangements with a party not of its choosing. Accordingly, this License Agreement includes limitations on the right of GARDP to sublicense to Third Parties, and to assign and delegate its rights and obligations under this License Agreement without the prior consent of Shionogi. For clarity, GARDP's use of collaborators, consultants, agents or other contractors for which it remains entirely responsible to perform its obligations under this License Agreement in accordance with Section 2.12 and to whom it has not granted a Sublicense shall not be considered a delegation by GARDP of its rights and obligations under this License Agreement.

## **2.11 Shionogi Affiliates**

GARDP agrees that Shionogi may perform its obligations under this License Agreement through one or more of its Affiliates, Shionogi remaining entirely responsible for such performance in accordance with the terms and conditions of this License Agreement as if such obligations had been performed by Shionogi.

## **2.12 GARDP Contractors**

GARDP may perform its obligations under this License Agreement or the Sublicense Agreements through one or more collaborators, consultants, agents or other contractors

**(GARDP Contractors)** acting on behalf of GARDP; provided that: (a) the activities of such GARDP Contractors would not require a Sublicense to the Licensed Rights (it being understood that the fact that a GARDP Contractor has had access to use Confidential Information in and of itself shall not require a Sublicense for the purposes hereof); (b) GARDP remains entirely responsible for such performance in accordance with the terms and conditions of this License Agreement as if such obligations had been performed directly by GARDP, and (c) GARDP shall have entered into a written agreement with such GARDP Contractors ensuring that GARDP shall be able to comply with its obligations under this License Agreement applicable to the activities conducted by the GARDP Contractor, including confidentiality obligations in accordance with Section 10.2(a)(iv) and, if applicable, obligations requiring the GARDP Contractor to assign to GARDP all intellectual property rights in and to any results generated by them in a manner that enables GARDP to comply with its obligations in relation thereto as set out in Section 8.2 and/or 8.3. For clarity, GARDP may not grant to GARDP Contractors any sublicense rights to Develop, Manufacture or Commercialize Licensed Product for their own account or benefit, or any right to produce, make or sell Licensed Product, and GARDP Contractors shall not be considered Sublicensees for the purposes of this License Agreement.

### 2.13 Compassionate Use

The Parties agree that after the Effective Date of this License Agreement, Shionogi shall retain all rights to initiate and conduct a Compassionate Use or comparable early access program using Licensed Product Manufactured by Shionogi in all countries in the Territory. Once Licensed Product manufactured by a Sublicensee (including Licensed Product from the initial validation batch) can be used for such purposes under applicable laws and regulations, the conduct of Compassionate Use or comparable early access programs shall be transitioned to GARDP and/or applicable Sublicensee(s) for the Territory; provided that Shionogi may, in coordination with GARDP, choose to continue to conduct Compassionate Use or comparable early access programs for one or more countries in the Territory. Notwithstanding the foregoing, Shionogi and GARDP may agree on a case-by-case basis on an alternative approach for one or more countries in the Territory taking into account relevant criteria, such as the sustainable availability of sufficient quantities of Licensed Product for the applicable country(ies) (Manufactured by Shionogi), the agreement of Sublicensees to conduct such activities, and relevant regulatory considerations.

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## 3. RECOUPMENT OF COSTS

- 3.1 In consideration of the rights and licenses granted under this License Agreement, GARDP shall pay Shionogi a fee (**Cost Recoupment Fee**) equal to a percentage of all Net Sales of the Licensed Product within the Territory by or on behalf of all Sublicensees as follows, which fee is intended to reimburse Shionogi for its costs of implementation

and maintenance related to the activities conducted pursuant to this License Agreement and/or the Collaboration Agreement:

- (a) High Income Countries (as identified in Schedule C): nine percent (9%) with no minimum threshold of sales (inclusive of royalties that may be due by Shionogi to Third Parties *i.e.* Shionogi shall remain responsible for paying such royalties).
- (b) Upper Middle Income Countries (as identified in Schedule C): five percent (5%) with no minimum threshold of sales (inclusive of royalties that may be due by Shionogi to Third Parties *i.e.* Shionogi shall remain responsible for paying such royalties).
- (c) Low Middle Income Countries and Low Income Countries (as identified in Schedule C): no Cost Recoupment Fees.

Cost Recoupment Fees are payable to Shionogi until the later of, on a country by country basis: (i) the expiration of the last-to-expire patent set forth on Schedule B in the country (if any) that covers the Licensed Product, and (ii) twelve (12) years from the first sale of Licensed Product in the relevant country in the Territory (**Cost Recoupment Period**). After the expiration of this period in any given country, the Sublicense granted to the Sublicensee shall survive on a fully-paid up basis for so long as the applicable Sublicense Agreement is valid and in effect, after which such Sublicense shall immediately terminate.

- 3.2 GARDP shall report Net Sales on Licensed Product sales in the Territory and the corresponding Cost Recoupment Fees due to Shionogi on a calendar quarter basis in accordance with Section 9.1, and shall pay the Cost Recoupment Fees due within thirty (30) days of receiving the corresponding invoice from Shionogi. Net Sales shall be reported and Cost Recoupment Fees shall be paid in Euros. In addition, GARDP shall promptly provide to Shionogi any reports and other information regarding Net Sales requested by Shionogi to facilitate Shionogi's compliance with third party obligations, as detailed more specifically in Section 4 of the Collaboration Agreement.

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## 4. TECHNICAL ASSISTANCE

### 4.1 Documentation and Assistance; Regulatory Filings in the Territory

- (a) Upon GARDP's request, Shionogi will provide GARDP or its Sublicensees, as applicable, with access to the content of the regulatory filings included within the Licensed Rights and described on Exhibit D (collectively, the **Regulatory Approvals**) to the extent reasonably required for the Manufacture or Commercialization of Licensed Product(s) in one or more countries in the Territory, all for use in accordance with the license granted pursuant to this License Agreement. Upon GARDP's request, Shionogi will also provide GARDP or its Sublicensees, as applicable, with regulatory filing reference rights (including promptly providing to GARDP or its Sublicensees or any relevant Regulatory Authorities any letters of authorization or comparable documents that may be required) pursuant to which the applicable Regulatory Authority could access the

content of the Regulatory Approvals and regulatory exclusivity waivers (*i.e.* waivers of any rights Shionogi or its Affiliates may have under any applicable regulatory or data exclusivity regulations that would prevent GARDP or its Sublicensees from Commercializing Licensed Product in any country(ies) in the Territory, or using or referencing the Regulatory Approvals for such purpose, all in accordance with the license granted pursuant to this License Agreement), in each case to the extent reasonably required by the applicable Regulatory Authorities for the Manufacture, or Commercialization of Licensed Product(s) in the Territory.

- (b) The documentation provided by Shionogi (including the Regulatory Approvals) will not be used by GARDP or any of its Sublicensees for any purpose other than the Development, Manufacture and Commercialization of the Licensed Compound and Licensed Product in accordance with this License Agreement and the relevant Sublicense Agreement, and constitutes Confidential Information and trade secrets of Shionogi. For the avoidance of doubt, each Sublicensee shall have the responsibility to seek regulatory approvals for the Manufacture and Commercialization of the Licensed Product in the countries in which it conducts such activities pursuant to its Sublicense Agreement, which regulatory approvals shall be in the Sublicensee's name and in respect of which the Sublicensee shall have all rights and responsibilities. Each Sublicensee shall be responsible to maintain its own regulatory documentation, provided that, if Shionogi has provided documentation to the Sublicensee, that the Sublicensee shall use such documentation as it maintains its own regulatory documentation. Each Sublicensee will assume full responsibility and liability to Shionogi for any unauthorized use or disclosure of any Confidential Information of Shionogi. Any and all such documents and materials delivered to GARDP or Sublicensees pursuant to this Section 4 are and will remain the sole property of Shionogi.
- (c) Shionogi will be responsible for providing one set of electronic copies only, subject to Section 4.1(a). Shionogi will respond to reasonable requests from GARDP or its Sublicensees for clarification on the documents and information provided under this Section 4.1, where responses to such requests are reasonably necessary to clarify the Manufacture and registration (in the manner Manufactured by or for Shionogi and registered by Shionogi on the Effective Date) of the Licensed Compound or a Licensed Product.
- (d) Notwithstanding the foregoing, Shionogi does not represent any Licensed Product is equivalent to any product containing cefiderocol (including but not limited to cefiderocol sulfate tosylate) which is Manufactured or sold by Shionogi, and no regulatory exclusivity waiver granted by Shionogi shall be understood to make any such representation.
- (e) Shionogi shall have the right to review and comment on the content of all preclinical and clinical data portions of all regulatory filings for the approval of the Licensed Product in the Territory as well as all proposed product labels, package inserts and Company Core Data Sheets (CCDS) (including a list prepared by GARDP and/or the relevant Sublicensee of deviations between the proposed CCDS

and the then-existing CCDS of Shionogi) proposed to be submitted to Regulatory Authorities for the Licensed Product in the Territory. Copies of all such documents shall be provided to Shionogi in English. Shionogi shall have the right to oppose any proposed regulatory filing in the Territory for failure to comply with the foregoing requirements, or based on reasonable concerns relating to the accuracy and quality of the data included therein, and the proposed filing may not proceed until Shionogi's opposition has been resolved as set forth herein. Any disagreement regarding proposed regulatory filings contemplated by this Section shall be escalated for resolution to the Joint Steering Committee (JSC) formed pursuant to the Collaboration Agreement; a representative of the Sublicensee will be invited to the JSC if the Parties deem appropriate. Shionogi shall use reasonable best efforts to provide feedback to any such documents submitted to Shionogi for review within thirty (30) days.

- (f) Shionogi shall not be responsible for the performance of additional studies or submission of additional data for the grant of the regulatory approval of a Licensed Product in the Territory. Sublicensees shall agree not to seek any further regulatory exclusivity in the country(ies) governed by their Sublicense Agreement.

#### **4.2 Technical Transfer and Technical Transfer Package**

- (a) Shionogi shall be responsible at GARDP's request for providing one technical transfer of its Manufacturing process to a Manufacturing Sublicensee in accordance with the Collaboration Agreement and the Market Access Plan (which technical transfer may, depending on the circumstances, involve a separate technical transfer of the Licensed Compound Manufacturing process to one entity and of the final Licensed Product Manufacturing process to another). This technical transfer shall include a transfer of a package of documentation to be prepared and provided by Shionogi for such Sublicensees' use (the **Technical Transfer Package**) that contains all the Licensed Manufacturing Know-How reasonably necessary for the effective technical transfer thereof, and a technical transfer process pursuant to which Shionogi or its contractors will provide reasonable assistance to enable the understanding and implementation of the Licensed Manufacturing Know-How. Shionogi will provide the Technical Transfer Package for the first Sublicensee set to Manufacture the Licensed Product in accordance with Shionogi's Licensed Manufacturing Know-How pursuant to this License Agreement. Shionogi shall be responsible for providing one set of electronic copies of the Technical Transfer Package to the relevant Manufacturing Sublicensee; GARDP and/or CHAI shall also receive a set of electronic copies of the Technical Transfer Package. Any subsequent Sublicensee will be provided the Technical Transfer Package and all other assistance and support necessary to effect the transfer thereto by GARDP and/or CHAI and/or by the Manufacturing Sublicensee that received the initial technical transfer. The Technical Transfer Package and all information and materials provided by or on behalf of Shionogi in connection therewith are trade secrets of Shionogi.

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## 5. COMMERCIALIZATION

- (a) Any Sublicensee to which GARDP grants a Sublicense for the Commercialization of the Licensed Product must be selected in accordance with the Collaboration Agreement.
- (b) Each commercial Sublicensee will be responsible, at its own expense, for Commercialization of the Licensed Product in the countries of the Territory covered by its Sublicense Agreement.
- (c) Each Licensed Product Commercialized by a Sublicensee under this License Agreement and a Sublicense Agreement will be marked with all markings and notices as may be required by applicable law, including in relation to patent and other intellectual property; provided, however, that if GARDP or any Sublicensee believes applicable law or regulation requires the use of the Shionogi name, such as, for example, a notice that the Licensed Product is sold under a license from Shionogi and/or GARDP, or any Shionogi trademark in connection with the Commercialization of the Licensed Product in any country within the Territory, the Parties shall discuss the matter in accordance with Section 2.4(a) above.
- (d) Each Sublicense Agreement will contain an obligation for the Sublicensee to use commercially reasonable efforts in accordance with the applicable Sublicense Access Plan to provide an adequate supply of the Licensed Product to meet the therapeutic needs in the countries of the Territory covered by their Sublicense.
- (e) In recognition of the humanitarian objectives of this License Agreement, GARDP also will use reasonable best efforts to promote the affordable access to the Licensed Product through its Sublicensees in the Territory.

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## 6. PHARMACOVIGILANCE AND QUALITY MATTERS

### 6.1 Pharmacovigilance

- (a) GARDP will require that its Sublicensees, in accordance with their standard protocols, maintain effective and reliable systems for receiving and tabulating any reports of adverse reactions to the Licensed Product and to report such information on a timely basis to the relevant Regulatory Authorities in the countries of the Territory included in their respective Sublicenses in accordance with local laws and regulations. GARDP will require that its Sublicensees be responsible for fulfilling all required pharmacovigilance reporting responsibilities under applicable laws and regulations within the countries in the Territory included in their respective Sublicenses. The responsibilities of the Parties and of the Sublicensees for safety related or Licensed Product related inquiries will be performed in accordance with applicable local laws and regulations. Shionogi will be responsible for maintaining the global pharmacovigilance database for the Licensed Product, and GARDP shall: (i) cause each Sublicensee to enter into a safety data exchange agreement (SDEA) with Shionogi and GARDP on terms reasonably acceptable to Shionogi



and based on a first draft proposed by Shionogi, governing the exchange of Licensed Product safety information among Sublicensee, Shionogi and GARDP that is consistent with applicable regulations and global pharmacovigilance standards; and (ii) use reasonable best efforts to monitor the activities and duties of the Sublicensees to ensure the Sublicensees' compliance with their respective pharmacovigilance obligations set forth in the Sublicense Agreement. Should GARDP propose to engage directly in any activities under this Sublicense Agreement for which Shionogi reasonably believes a SDEA would be necessary or prudent, GARDP shall enter into a SDEA agreement in a form reasonably acceptable to Shionogi relative to such activities.

## **6.2 Quality**

GARDP will require its Sublicensees to Manufacture the Licensed Compound and Licensed Product in accordance with standards validated by:

- (a) a WHO prequalification; or
- (b) any Stringent Regulatory Authority (if the manufacturing site of the Sublicensee has already been approved by a Stringent Regulatory Authority); or
- (c) if neither of WHO PQ or an SRA has assessed, by a Third Party GMP audit agreed by both Parties, which audit shall confirm the Sublicensee's compliance with WHO pre-qualification standards or a Stringent Regulatory Authority's standards.

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## **7. REPRESENTATIONS AND WARRANTIES**

### **7.1 General**

Each Party hereby represents, covenants, and warrants to the other that:

- (i) it is duly organized and validly existing under the applicable law of the jurisdiction of its incorporation or organization, and has full corporate or institutional power and authority to enter into this License Agreement and to carry out the provisions hereof;
- (ii) it is qualified to do business and is in good standing in each jurisdiction in which it conducts business;
- (iii) it is duly authorized to execute and deliver this License Agreement and to perform its obligations hereunder, and the Person executing this License Agreement on its behalf has been duly authorized to do so by all requisite corporate or institutional action; and
- (iv) this License Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery, and performance of this License Agreement by such Party does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable law;
- (v) the performance of this License Agreement by either Party does not create a breach or default under any other agreement to which it is a party; and

- (vi) it will comply with all applicable laws and regulations, including all applicable anti-bribery and corruption laws (including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010, as applicable).

## **7.2 Representations and warranties of Shionogi**

Shionogi represents and warrants to GARDP that, with respect to the Licensed Compound:

- (i) Shionogi owns or otherwise Controls the Licensed Rights (including the Licensed Manufacturing Know-How) and the Licensed Compound described in Schedule A, free and clear of any liens, charges and encumbrances, and has the right to grant to GARDP the license to the Licensed Rights granted hereunder; and
- (ii) as of the Effective Date, Shionogi has not received written notification of, any claim pending, threatened, or previously made, alleging that the use or practice of the Licensed Rights (including the Licensed Manufacturing Know-How) or the Manufacture, use or Commercialization of the Licensed Compound or Licensed Product infringes or misappropriates any patent, trade secret, or other intellectual property right of any Third Party.

## **7.3 Representations, warranties and covenants of GARDP**

GARDP represents, warrants, and covenants to Shionogi that:

- (i) Sublicensees will be selected in accordance with the Collaboration Agreement and the Market Access Plan;
- (ii) it will have and maintain suitable mechanisms in order to comply with all applicable laws (including the U.S. Foreign Corrupt Practices Act and the UK Bribery Act), in particular, it will not, directly or indirectly, offer, promise, or give any financial or other advantage and/or pay money or anything of value to government officials, political parties, candidates, and any other person for the purposes of corruptly obtaining or retaining business; each Party will certify to the other in writing, at the frequency requested by the other Party (and at least once annually), compliance with its obligations under this License Agreement (including compliance with the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010);
- (iii) it will, during the Term, perform regular internal due diligence to ensure ongoing compliance with all applicable laws and the terms of this License Agreement and its compliance under all Sublicense Agreements;
- (iv) all of its activities related to the use of the Licensed Rights and Licensed Manufacturing Know-How and the Development and Commercialization of the Licensed Compound and Licensed Product by its Sublicensees pursuant to this License Agreement and the Sublicense Agreements will comply with all applicable legal and regulatory requirements;

- (v) it will not engage in any activities that use the Licensed Rights and/or Licensed Manufactured Know-How in a manner that is outside the scope of the license rights granted to it under this License Agreement;
- (vi) any modifications to the Manufacturing process or compound technology will be undertaken at the Sublicensees' sole risk and in no event will Shionogi indemnify, hold harmless, or defend GARDP or any Sublicensees for any consequences of such modifications; and
- (vii) as between Shionogi and the GARDP, and between Shionogi and any Sublicensees, GARDP acknowledges and agrees that Shionogi will have no liability whatsoever in relation to any infringement of the intellectual property rights of any Third Party arising out of the Development, Manufacture, and Commercialization of the Licensed Product by the Sublicensees, subject to Section 7.2.

#### **7.4 "AS IS" license**

- (i) Notwithstanding any other provision of this License Agreement but subject to Sections 7.1 and 7.2, GARDP acknowledges and agrees that the Licensed Rights and Licensed Manufacturing Know-How are licensed to GARDP "as is".
- (ii) Notwithstanding any other provision of this License Agreement but subject to Sections 7.1 and 7.2, Shionogi makes no representation or warranty of non-infringement or any representation or warranty that the Licensed Rights or Licensed Manufacturing Know-How is suitable for any purpose for which it may be used by GARDP or its Sublicensees.

#### **7.5 Disclaimer**

Except for Sections 7.1 and 7.2, Shionogi makes no representations or warranties of any kind, either express or implied, including any express or implied warranties of merchantability or fitness for a particular purpose, with respect to the Licensed Rights or Licensed Manufacturing Know-How or any license granted by Shionogi under this License Agreement or any Sublicense Agreement, or with respect to any compounds or products. FURTHERMORE, NOTHING IN THIS LICENSE AGREEMENT OR THE SUBLICENSE AGREEMENT WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE LICENSED RIGHTS ARE VALID OR ENFORCEABLE, OR SUBJECT TO SECTION 7.2 THAT GARDP'S OR ANY SUBLICENSEES' USE OF THE LICENSED RIGHTS AND LICENSED MANUFACTURING KNOW-HOW CONTEMPLATED UNDER THIS LICENSE AGREEMENT OR ANY SUBLICENSE AGREEMENT DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

#### **7.6 Limitation of liability**

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES ARISING FROM OR

RELATING TO ANY BREACH OF THE LICENSE AGREEMENT OR THE ACTIVITIES CONDUCTED BY SUCH PARTY PURSUANT TO THE LICENSE AGREEMENT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES ARISING OUT OF ANY BREACH OF THE LICENSE AGREEMENT OR THE ACTIVITIES CONDUCTED BY SUCH PARTY PURSUANT TO THE LICENSE AGREEMENT. THE FOREGOING LIMITATIONS DO NOT APPLY TO CLAIMS BASED ON: (1) THE BREACH OF ITS CONFIDENTIALITY OBLIGATIONS, (2) A PARTY'S GROSS NEGLIGENCE, FRAUD, OR WILLFUL MISCONDUCT, OR (3) A PARTY'S INDEMNIFICATION OBLIGATION UNDER SECTION 11.

NOTWITHSTANDING THE FOREGOING, ANY AMOUNTS DUE TO GARDP FROM SHIONOGI AND/OR ITS AFFILIATES WITH RESPECT TO THE ACTIVITIES CONTEMPLATED BY THE LICENSE AGREEMENT, WHETHER BY MEANS OF INDEMNIFICATION OR OTHERWISE, SHALL BE LIMITED TO THE GREATER OF (A) THE AGGREGATE TOTAL AMOUNT OF COST RECOUPMENT FEES RECEIVED BY SHIONOGI PURSUANT TO THE LICENSE AGREEMENT, AND (B) THE INSURANCE PROCEEDS ACTUALLY RECOVERED BY SHIONOGI FROM ITS INSURERS FOR THE CORRESPONDING CLAIM(S). For the avoidance of doubt, the fact that no amount will be due to GARDP unless insurance proceeds are received by Shionogi may not be used as a justification not to pay the corresponding insurance proceeds to Shionogi that would otherwise be due by the insurer.

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## **8. INVENTIONS, PATENT MAINTENANCE, INFRINGEMENT**

### **8.1 Inventions**

- (a) Shionogi (or its Affiliates) will own the entire right, title and interest in and to any and all inventions conceived solely by its employees and agents before, on and after the Effective Date relating to the Licensed Compound or any Licensed Product, including the Licensed Rights and any such inventions that constitute an adaptation of any Manufacturing process or proprietary drug delivery or formulation technology of Shionogi or its Affiliates for the production of the Licensed Compound or any Licensed Product, and any patents covering such invention (**Shionogi Sole Inventions**), subject to the license grant to GARDP set out in Section 2.

### **8.2 Manufacturing Process Results**

- (a) To the extent a Sublicensee accepts a Technical Transfer Package, or otherwise has access to any Shionogi non-public proprietary information or Confidential Information relating to the Manufacturing process used by Shionogi to Manufacture Licensed Compound and Licensed Product (not including the specifications of the Licensed Compound or Licensed Product that are required for a Sublicensee to demonstrate that the Licensed Compound or Licensed Product Manufactured by the Sublicensee using its process are pharmaceutically equivalent to the Licensed

Compound or Licensed Product Manufactured using the Shionogi Manufacturing process):

- (i) Shionogi shall own (and shall have the sole right to patent or not to patent) all inventions and results developed or generated by the Sublicensee related to the process to Manufacture Licensed Compound or Licensed Product (**Process Results**) (whether or not patentable) that are specific to the Licensed Product and/or that incorporate any Shionogi non-public proprietary information or Confidential Information or intellectual property; and
  - (ii) GARDP or the Sublicensee, as applicable, shall own (and shall have the sole right to patent or not to patent) all Process Results (whether or not patentable) solely to the extent separable from the Licensed Product (i.e., that such can be used to Manufacture products other than the Licensed Product) and that do not incorporate any Shionogi non-public proprietary information or Confidential Information.
- (b) If a Sublicensee has not accepted a Technical Transfer Package, and has not had access to any Shionogi non-public proprietary information or Confidential Information relating to Shionogi's Manufacturing process (not including the specifications of the Licensed Compound or Licensed Product that are required for a Sublicensee to demonstrate that the Licensed Compound or Licensed Product Manufactured by the Sublicensee using its process are pharmaceutically equivalent to the Licensed Compound or Licensed Product Manufactured using the Shionogi Manufacturing process):
- (i) GARDP or the Sublicensee, as applicable, shall own (and shall have the sole right to patent or not to patent) all Process Results (whether or not patentable) developed or generated by or for them that do not incorporate any Shionogi non-public proprietary information or Confidential Information.
- (c) The Process Results shall be considered Confidential Information of the party who owns the results, provided in any case that each of Shionogi, GARDP and the Sublicensee that developed or generated the Process Results shall have the right to access and use all Process Results in accordance with the licenses set forth in Section 8.4.

### 8.3 Development Activity License Results

- (a) With respect to any inventions, know-how or results (whether or not patentable) developed or generated by or for GARDP and/or a Sublicensee in the performance of any Development activities conducted pursuant to this License Agreement or any Sublicense Agreement other than Development activities relating to Manufacturing (the results of which are governed by Section 8.2) (**Development Results**):

- (i) Shionogi shall own (and shall have the sole right to patent or not to patent) all Development Results that are specific to the Licensed Product and/or that incorporate any Shionogi non-public proprietary information or Confidential Information or intellectual property.
- (ii) notwithstanding the above, GARDP shall own the clinical data associated with or arising from clinical studies conducted by or for GARDP and/or a Sublicensee pursuant to this License Agreement and/or the Collaboration Agreement or any Sublicense Agreement (**Clinical Data**), but may use such Clinical Data only for the purposes consistent with this License Agreement and/or the Collaboration Agreement; provided that Shionogi shall have the right to access and use all such Clinical Data in accordance with the licenses set forth in Section 8.4; and GARDP shall provide, at a minimum and at its expense, at least one copy of the Clinical Data to Shionogi upon completion of each applicable clinical study.
- (iii) Each Party or as applicable the Sublicensee shall have the right to publish for scientific purposes Development Results developed or generated by or for such party (subject if applicable to the rights of one or more other parties that may also have participated in the development or generation thereof), subject to, with respect to any such Development Results that relate to the Licensed Product or any Shionogi proprietary or confidential information: (A) Shionogi's prior review of any such proposed publication, (B) Shionogi's right to remove Shionogi Confidential Information (but not the Development Results themselves) from any such proposed publication, and (C) any reasonable delay in publication requested by Shionogi for Shionogi to file any related patent applications. Shionogi shall have the right to oppose any such proposed publication for failure to comply with the foregoing requirements, or any objection based on reasonable concerns relating to the accuracy and/or quality of the data referenced therein, and the publication may not proceed until Shionogi's opposition based on the above has been resolved as set forth herein. Any disagreement regarding proposed publications contemplated by this Section 8.3(a)(iii) shall be escalated for resolution to the Joint Steering Committee (**JSC**) formed pursuant to the Collaboration Agreement; a representative of the Sublicensee will be invited to the JSC meeting if the disagreement concerns a publication containing Development Results generated by the Sublicensee.
- (iv) GARDP shall have the right to use all Development Results not owned by it only for regulatory filings, or otherwise to enable or facilitate access to Licensed Product, in the Territory, including by granting Sublicenses to such Development Results, all in accordance with the requirements of this License Agreement.
- (v) Each Sublicensee shall have the right to use Clinical Data developed or generated by the Sublicensee only for Development, Manufacture or Commercialization in the country(ies) in the Territory for which it has a

license, as applicable, all in accordance with this License Agreement and the applicable Sublicense Agreement.

- (vi) Shionogi shall have the sublicensable right to use all Development Results, including any and all Clinical Data, not owned by it for development, regulatory filings, manufacturing, commercialization or otherwise to enable or facilitate access to cefiderocol, or any product containing cefiderocol, worldwide.

#### **8.4 General Conditions Applicable to all License Results**

- (a) Each Party, including any Sublicensees, shall grant the other Party a free, nonexclusive, nontransferable, sublicensable license to use its License Results and any intellectual property rights thereon to conduct the activities for which they are responsible pursuant to the Collaboration Agreement.
- (b) GARDP and the Sublicensees shall grant Shionogi a free, perpetual, nonexclusive, sublicensable (including to all Sublicensees in the Territory) license to use License Results, including any and all Clinical Data, owned by them (including any intellectual property rights thereon) for the development, regulatory filings, manufacture, commercialization or otherwise to enable or facilitate access to cefiderocol, or any product containing cefiderocol, worldwide.
- (c) Each Sublicensee shall grant GARDP a free, nonexclusive, sublicensable (including to all Sublicensees in the Territory) license to use License Results owned by them (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization of the Licensed Product in the Territory pursuant to the License Agreement.
- (d) All License Results owned by Shionogi (including any intellectual property rights thereon) shall be included in the sublicensable License Rights granted to GARDP for the Territory pursuant to this License Agreement.

#### **8.5 Patent maintenance and abandonment**

Shionogi will be responsible (at its own expense and discretion) for, and will control, the prosecution (including any interferences, reissue proceedings, and reexaminations) and maintenance of all Licensed Rights in the Territory. GARDP and any applicable Sublicensee will, at Shionogi's cost but only limited to actual and reasonable out-of-pocket costs for Sublicensee's assistance, provide reasonable assistance to Shionogi, as may be required, for such prosecution.

#### **8.6 Enforcement of Licensed Rights**

- (a) Information

In the event that GARDP becomes aware of a suspected or actual infringement of any patents included in the Licensed Rights, GARDP will notify Shionogi promptly, and following such notification, the Parties will confer.

(b) Enforcement of Licensed Rights

Shionogi (and/or its Affiliates) will have the right, but will not be obligated, to bring an infringement action against any Third Party at its own expense, in its own name and entirely under its own direction and control, subject to the following:

- (i) GARDP and each Sublicensee will reasonably assist Shionogi (at Shionogi's expense but only limited to actual and reasonable out-of-pocket costs for GARDP's and Sublicensee's assistance) in any action or proceeding being prosecuted if so requested by Shionogi and such reasonable assistance is necessary for Shionogi to fully exercise its rights under such proceeding;
  - (ii) GARDP will have the right, but will not be obligated, to participate and be represented in any such suit by its own counsel at its own expense; and
  - (iii) Shionogi may enter into a settlement of any such action or proceeding to restrict the scope of the Licensed Rights at its sole discretion.
- (c) The Parties agree to keep the other Party reasonably informed of all such material developments in connection with any infringement proceedings and of any matters coming to such Party's attention that may materially affect the preparation, filing, prosecution, or maintenance of any patents included in the Licensed Rights.
- (d) If the making, import, use, offer for sale, or sale of the Licensed Compound or the Licensed Product by or on behalf of GARDP or a Sublicensee infringe on the intellectual property rights of a Third Party in the Territory, GARDP or as applicable the Sublicensee will be solely responsible for such infringement, and Shionogi will not have any obligation to defend or indemnify GARDP or a Sublicensee with respect to any such claim, subject to Section 7.2.

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## 9. AUDIT AND REPORTS

### 9.1 Reports

GARDP will send to Shionogi, within sixty (60) days following the end of each calendar quarter, the number of units of Licensed Product sold by strength by applicable stock keeping unit (SKU) or other applicable delineation by country, and the number of units of Licensed Product Manufactured by each Sublicensee, and current inventory reports. GARDP shall also provide Shionogi with a quarterly written report setting forth each Sublicensee's: (a) Licensed Product in its portfolio; (b) status of Development of each Licensed Product in Development; (c) regulatory filing plan for each Licensed Product, by country; (d) a list of countries within the Territory for which such regulatory approvals or authorizations have been obtained for any Licensed Product; (e) any rejection, withdrawal,



expiration, or other significant regulatory development for any Licensed Product; and (f) a description of activities performed by GARDP relating to filing, obtaining, or maintaining regulatory approvals or authorizations in the Territory for the Licensed Product and/or Licensed Compound. GARDP and Shionogi agree to confer on a quarterly basis regarding such reports and also to review development and filing status of Licensed Product. GARDP further agrees that Shionogi may share all such information and reports with its Affiliates at any time (subject to confidentiality and non-use obligations substantially similar to those set out in Section 10.1 hereof) and with third parties as contemplated by the Collaboration Agreement (including Section 4 thereof).

## **9.2 Audit**

- (a) GARDP grants Shionogi the right, upon reasonable notice of not less than forty-five (45) days, to inspect and audit, at its own cost:
  - (i) the performance of, and compliance with, this License Agreement and the Sublicense Agreements and applicable laws;
  - (ii) all documents and other records relating to the performance of this License Agreement and the Sublicense Agreements; and
  - (iii) all documents, records, and any other information required to determine the calculation of Cost Recoupment Fees owed under this License Agreement and any Sublicense Agreement.
- (b) GARDP shall require its Sublicensees to keep and maintain at least ten (10) years of records of quantities of Licensed Product, and raw materials used to make Licensed Product, Manufactured and/or sold under each Sublicense Agreement, as well as any other information required to determine the calculation of Cost Recoupment Fees owed under the Sublicense Agreement. Shionogi and GARDP shall have the right to audit these Sublicensee records.
- (c) Subject to execution of a confidentiality agreement with GARDP, Shionogi may choose to nominate an independent Third-Party auditor or consultant to exercise, or assist with the exercise of, its rights set out in this Section 9.
- (d) GARDP will cooperate with and provide all reasonable assistance to Shionogi, its officers, employees, agents, advisors, representatives, or contractors exercising their rights under this Section 9.

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## **10. NON DISCLOSURE OF CONFIDENTIAL INFORMATION**

### **10.1 Non disclosure**

- (a) Each Party agrees that, for so long as this License Agreement is in effect and for a period of ten (10) years thereafter, or indefinitely with respect to all Confidential Information that constitutes trade secrets (including the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the

content of the Shionogi European Union and United States and all other cefiderocol regulatory filings, and any other Shionogi trade secrets, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), for so long as the relevant trade secrets do not become publicly available other than as a result of a fault attributable to the receiving Party or its agents or sublicensees, a Party receiving Confidential Information of another Party (or that has received any such Confidential Information from such other Party prior to the Effective Date) will:

- (i) maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value;
- (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the relevant other Party, except for disclosure expressly permitted under this License Agreement; and
- (iii) not use such Confidential Information for any purpose except those permitted by this License Agreement (it being understood that this Section (iii) will not create or imply any rights or licenses not expressly granted under Section 2 of this License Agreement).

(b) Exceptions

The obligations under Section 10.1(a) will not apply with respect to any portion of the Confidential Information that the receiving Party can show by written evidence:

- (i) is or was publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party; or
- (ii) was known to the receiving Party or any of its Affiliates, without any obligations to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or
- (iii) is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in the possession thereof and without any obligation to keep it confidential or any restriction on its use; or
- (iv) is published by a Third Party or otherwise becomes publicly available, either before or after it is disclosed to the receiving Party; or
- (v) has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application, or use of Confidential Information of the disclosing Party.

## 10.2 Authorized disclosure

- (a) The receiving Party may disclose Confidential Information belonging to another Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
  - (i) regulatory filings;
  - (ii) prosecuting or defending litigation;
  - (iii) complying with applicable governmental laws and regulations (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange or laws or regulations) and with judicial process, if in the reasonable opinion of the receiving Party's counsel, such disclosure is necessary for such compliance; and
  - (iv) disclosure, in connection with the receiving Party's performance of its obligations or exercise of its rights under this License Agreement and solely on a "need-to-know basis", to Affiliates, potential Sublicensees and Sublicensees, potential donors and donors, research collaborators, employees, consultants, contractors, including GARDP Contractors, or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 10 (the duration of such obligations being at least for the duration of the agreement with such other Person and a period of ten (10) years thereafter, or indefinitely with respect to all Confidential Information that constitutes trade secrets (including the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of the Shionogi European Union and United States and all other cefiderocol regulatory filings, and any other Shionogi trade secrets, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), for so long as the relevant trade secrets do not become publicly available other than as a result of a fault attributable to the receiving Party or to such other Person; provided, however, that the receiving Party will remain responsible for any failure by any such Person who receives Confidential Information to treat such Confidential Information as required under this Section 10.
- (b) If and whenever any Confidential Information is disclosed in accordance with this Section 10.2, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this License Agreement). Where reasonably possible, the receiving Party will notify the disclosing Party of the receiving Party's intent to make such disclosure pursuant to this Section 10.2 sufficiently prior to making such disclosure so as to allow the

disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

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## 11. INDEMNITY

### 11.1 GARDP indemnity

GARDP will indemnify, defend and hold harmless Shionogi and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns, and representatives (**Shionogi Indemnitee**), from and against any and all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments, whether for money or equitable relief, of any kind from a Third Party (including Sublicensees) (**Losses and Claims**) arising out of or in connection with:

- (a) any activities conducted by GARDP, its Affiliates, or Sublicensees pursuant to this License Agreement, the Collaboration Agreement or a Sublicense Agreement;
- (b) any breach by GARDP of any of the provisions of this License Agreement or the Collaboration Agreement;
- (c) any negligence or willful misconduct by or on behalf of GARDP;
- (d) any breach of a Sublicense Agreement by GARDP or its Sublicensee;
- (e) GARDP's (or its Affiliates and its Sublicensee's) use and practice of the Licensed Rights and Licensed Manufacturing Know-How, including claims and threatened claims based on:
  - (i) any product liability, bodily injury, risk of bodily injury, death, or property damage;
  - (ii) infringement or misappropriation of Third-Party patents, copyrights, trademarks, or other intellectual property rights; or
  - (iii) the failure to comply with applicable laws related to the matters referred to in the foregoing with respect to the Licensed Compound and/or any Licensed Product.

except in any such case for Losses and Claims to the extent arising out of or in connection with (i) a material breach by Shionogi or its Affiliates of any of its representations and warranties set forth in Section 7.1 and 7.2 of this License Agreement, or (ii) any gross negligence or willful misconduct by Shionogi or its Affiliates or agents in connection with their performance of or activities conducted under this License Agreement.

In addition to the foregoing, as a condition to the grant of each Sublicense Agreement, GARDP shall obtain a direct indemnification undertaking by each Sublicensee to Shionogi

and its Affiliates requiring its Sublicensees to indemnify, defend and hold harmless Shionogi Indemnitees under the same terms as stated in this Section 11.1.

## 11.2 Shionogi indemnity

Shionogi will indemnify, defend and hold harmless GARDP and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns, and representatives (**GARDP Indemnitee**), from Losses and Claims to the extent arising out of or in connection with:

- (a) A material breach by Shionogi or its Affiliates of any of its representations and warranties set forth in Section 7.1 and 7.2 of this License Agreement; or
- (b) any gross negligence or willful misconduct by or on behalf of Shionogi or its Affiliates in connection with their performance of or activities conducted under this License Agreement,

except in any such case for Losses and Claims to the extent arising out of or in connection with (i) a material breach by GARDP or its Affiliates of any of its representations and warranties set forth in Section 7.1 and 7.3 of this License Agreement, or (ii) any gross negligence or willful misconduct of GARDP or its Affiliates or agents or any Sublicensee in connection with their performance of or activities conducted under this License Agreement or any Sublicense Agreement.

## 11.3 Indemnification Procedure

Each Party will promptly notify the other Party when it becomes aware of a Third Party claim (a **Claim**) for which indemnification may be sought hereunder. To be eligible to be indemnified for a Claim, a Person seeking indemnification (the **Indemnified Party**) shall (i) provide the Party required to indemnify such Person (the **Indemnifying Party**) with prompt written notice of the Claim giving rise to the indemnification obligation under this Section 11, provided that, the failure to provide such prompt notice shall not relieve the Indemnifying Party of any of its obligations under this Section 11 except to the extent the Indemnifying Party is actually prejudiced thereby; (ii) provide the Indemnifying Party with the exclusive ability to defend (with the reasonable cooperation of the Indemnified Party) against the Claim; and (iii) not settle, admit or materially prejudice the defense of the Claim, without the Indemnifying Party's prior written consent. The Indemnified Party shall reasonably cooperate with the Indemnifying Party, at the Indemnifying Party's expense, in the defense of any Claim. Notwithstanding the foregoing, the Indemnified Party shall have the right to participate in and have its own counsel participate in any action or proceeding for which the Indemnified Party seeks to be indemnified by the Indemnifying Party. Such participation shall be at the Indemnified Party's expense, unless (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. The Indemnifying Party's obligations under Section 11, as the case may be,

shall not apply to the extent of the Indemnified Party's failure to take reasonable action to mitigate any Losses. The Indemnifying Party shall not settle or compromise, or consent to the entry of any judgment with respect to, any Claim, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld or delayed.

#### **11.4 Insurance**

Throughout the Term, and for a period of five (5) years after the Term for policies on a claims-made basis, GARDP shall, at its sole cost and expense, obtain, pay for, and maintain in full force and effect, appropriate insurance in commercially reasonable and appropriate amounts that provides, at least, product liability coverage concerning the Licensed Product and contractual liability coverage for GARDP's defense and indemnification obligations under this License Agreement. Upon request by Shionogi, GARDP shall provide Shionogi with certificates of insurance or other reasonable written evidence of all coverages described in this Section 11.4. Additionally, GARDP shall provide Shionogi with written notice prior to GARDP cancelling, not renewing, or materially changing its insurance in a manner such that it would no longer be compliant with its obligations under this Section 11.4. Without limiting the foregoing, GARDP will require its Sublicensees to purchase and maintain appropriate insurance in order to cover their potential liabilities, including product liability, under the Sublicense Agreements.

Throughout the Term, and for a period of five (5) years after the Term for policies on a claims-made basis, Shionogi shall maintain appropriate insurance (including by means of self-insurance) consistent with market practice in respect of its obligations under the License Agreement.

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## **12. TERM AND TERMINATION**

### **12.1 Term**

This License Agreement will commence as of the Effective Date and, unless sooner terminated in accordance with the terms of this License Agreement or by mutual written consent, will expire upon the expiration of the last-to-expire of the patents set forth on Schedule B in the last country in the Territory in which there is such a patent; provided that, with respect to any and all countries in the Territory in which any Sublicensee is pursuing the Commercialization of Licensed Product at such expiry date, the License Agreement will survive for so long as the Commercialization of Licensed Product is being pursued in such country(ies) (the period from the Effective Date until such last patent expiry date or as applicable the date on which the Commercialization of Licensed Product is no longer being pursued, being the **Term**, subject to early termination as contemplated below).

### **12.2 Termination by either Party**

Either Party will have the right to terminate this License Agreement, at its sole discretion, upon delivery of written notice to the other Party, upon the occurrence of any of the following:

- (a) the other Party becomes bankrupt or insolvent, or cannot pay its debts when due; or
- (b) a material breach of this License Agreement by the other Party that is not cured within ninety (90) days after written notice of such breach is given.

### **12.3 Additional termination rights**

- (a) Shionogi has the right to terminate this License Agreement upon delivery of written notice to GARDP upon the occurrence of any of the following:
  - (i) the failure of GARDP to use reasonable best efforts to conduct the activities and achieve the objectives for which it is responsible in the Market Access Plan with the objective of promoting affordable access to the Licensed Product through its Sublicensees in the countries in the Territory selected pursuant to the Market Access Plan;
  - (ii) the failure of GARDP to comply with Shionogi's reasonable requests in connection with a breach under Sections 2.3(n) through (q);
  - (iii) any failure by GARDP of ensuring compliance with relevant OFAC regulations under Section 2.9 of this License Agreement; or
  - (iv) if, in the reasonable opinion of Shionogi, control (through ownership or otherwise) of GARDP changes.
- (b) GARDP will have the right to, and will at Shionogi's request, terminate any Sublicense Agreement, by delivery of written notice to the relevant Sublicensee(s) upon the occurrence of any of the following:
  - (i) the occurrence of any material safety issue that Shionogi reasonably believes makes it inadvisable to proceed or continue with the Commercialization of the Licensed Product in the Territory;
  - (ii) without prejudice to Section 2.7(c), a cross-border diversion of the Licensed Compound and/or Licensed Product whereby any Sublicensee (directly or indirectly or through a Third Party, located in or out of the Territory) uses, offers for sale, sells, or has sold Licensed Compound and/or Licensed Product for use in any country outside of the Territory;
  - (iii) any failure by the Sublicensee to comply with the quality requirements under Section 6.2 of this License Agreement for any Licensed Product that is Commercialized or intended for Commercialization;
  - (iv) the failure by the respective Sublicensee to file for registration of the Licensed Product in at least one country in the Territory within four (4) years of the start of technical transfer pursuant to Section 4.2 to the Sublicensee,

or if there is no technical transfer to the Sublicensee, within four (4) years of the Effective Date of the applicable Sublicense Agreement;

- (v) the occurrence of a direct or indirect change of control of Sublicensee (with control having the meaning set out in the definition of Affiliate in Section 1.1), unless Shionogi and GARDP have previously confirmed in writing that they would not terminate the Sublicense Agreement based on such change of control; and/or
  - (vi) in the event of any serious or intentional violation of any laws and regulations or intentional misappropriation of a Third Party's intellectual property rights by a Sublicensee anywhere in the world which, in Shionogi's and GARDP's judgment, may reflect unfavorably on Shionogi, GARDP, their reputation or the Licensed Product.
- (c) GARDP will have the right to terminate this License Agreement upon sixty (60) days advance written notice to Shionogi if it is unable despite its reasonable best efforts to raise required funding for the performance of GARDP's obligations under this License Agreement and the Collaboration Agreement, and such termination in and of itself shall not constitute a breach of GARDP's obligations under the Agreement or give rise to the payment of damages; provided, however, that the foregoing shall not relieve GARDP of liability in respect of any other breach or noncompliance with this Agreement or affect any other right or remedy available to Shionogi with respect thereto.

#### **12.4 Scope of termination**

Except as otherwise expressly provided in this License Agreement, any termination of this License Agreement pursuant to this Section 12 will be as to all Licensed Compound and Licensed Product.

#### **12.5 Effect of termination or expiration**

- (a) Upon termination or expiration of this License Agreement, all rights and licenses granted to GARDP under Section 2 will terminate, and all rights, licenses, and cross-references will revert to Shionogi, and GARDP will cease all use of the Licensed Rights and the Licensed Manufacturing Know-How; and
- (b) Upon termination of this License Agreement, Shionogi will, if requested by any Sublicensee that is in material compliance with its obligations under its Sublicense Agreement, negotiate in good faith with the intent to enter into a new and separate license agreement directly between Shionogi and the respective Sublicensee on terms reasonably acceptable to Shionogi and the Sublicensee, it being understood and agreed that Shionogi reserves its rights to require additional terms to be included in such licenses as may be needed to protect its interests.
- (c) Within sixty (60) Business Days after termination or expiration of this License Agreement, each Party shall at the other Party's request: (A) return to the other



Party or destroy Confidential Information of the other Party within its possession or control (which shall as concerns Shionogi's Confidential Information include without limitation the Licensed Rights, the Licensed Manufacturing Know-How, any unpublished Shionogi Sole Inventions or other non-public intellectual property otherwise owned by Shionogi); and (B) certify to the other Party in writing that it has complied with the requirements of this Section 12.5(c); provided that: (i) the receiving Party may retain one archival copy of the Confidential Information of the other Party but not of any Confidential Information that constitutes trade secrets of the other Party (including, without limitation, the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of the European Union and United States and all other cefiderocol regulatory filings, and any other Shionogi trade secrets, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), except for any of such that has become publicly available other than as a result of a fault attributable to the receiving Party or its agents or sublicensees, in a limited access file (meaning only accessible by such Party's Information Technology (IT) department and/or by such Party's legal personnel) to the extent that the receiving Party requires such Confidential Information for the purpose of performing any obligations or exercising any rights under this License Agreement that may survive such expiration or termination; (ii) the receiving Party may retain Confidential Information of the other Party to the extent that the receiving Party is required to retain such information for compliance purposes under applicable laws and regulations; and (iii) the above obligations shall not require either Party to delete any automatic electronic backup files maintained in accordance with its standard policies and to which access is limited and only accessible by such Party's IT department; subject in any case (i), (ii) or (iii) above to continued compliance by such Party of its confidentiality obligations as set out in Section 10 above.

- (d) Neither Party will be relieved of any obligation that accrued prior to the effective date of such termination. It is understood and agreed that either Party will be entitled to specific performance as a remedy to enforce the provisions of this Section 12.5, in addition to any other remedy to which it may be entitled by applicable law.

The Parties acknowledge that the right of either Party to terminate this License Agreement is not intended to be an exclusive right and shall not preclude the right to claim damages in accordance with the terms of the Agreement for any breach of this License Agreement that occurred prior to the termination (including the breach that gave rise to the termination), or affect any other right or remedy available under applicable law.

## **12.6 Survival**

The following provisions will survive termination or expiration of this License Agreement, as well as any other provisions which by their nature are intended to survive termination or expiration: Section 1 (as applicable), Section 3 (in respect of Cost Recoupment Fees

accrued before the termination), and Sections 7.5, 7.6, 8 (other than Section 8.6), 10, 11, 12.5, 12.6, 12.7, 13 and 14.

### **12.7 Termination cooperation**

Upon the termination or expiration of this License Agreement, the Parties will cooperate with one another to provide for an orderly wind-down of the transactions contemplated in this License Agreement, including as applicable an orderly management of any remaining inventory of Licensed Compound and Licensed Product.

### **12.8 Bankruptcy**

The Parties agree that in the event a Party becomes a debtor under Title 11 of the U.S. Code, this License Agreement will be deemed to be, for the purposes of Section 365(n) of such title, a license to rights to “intellectual property” as defined therein. Each Party as a licensee hereunder will have the rights and elections as specified in such Title 11. Any agreements supplemental to this License Agreement will be deemed to be “agreements supplementary to” this License Agreement for the purposes of Section 365(n) of such Title 11.

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## **13. DISPUTE RESOLUTION**

### **13.1 Resolution by senior executives**

- (a) All disputes, controversies, or claims between the Parties in connection with this License Agreement, its construction, or the rights, duties, or liabilities of either Party under this License Agreement (a **Dispute**) must be resolved pursuant to the following resolution process in this Section 13.1 and the binding arbitration process in Section 14.6. The Parties may alter or amend these procedures by agreement in writing.
- (b) To commence the resolution process, any Party may serve a notice on another Party identifying: (i) the nature of the Dispute; and (ii) if applicable, the amount in Dispute.
- (c) Once notice is received, the Parties must first attempt in good faith to resolve such Dispute by negotiation and consultation between their respective operational teams.
- (d) In the event that such Dispute is not resolved on an informal basis within thirty (30) days after such notice is received, either Party may, by written notice to the other Party, refer the Dispute to the Head of Shionogi’s Global Business Division and to GARDP’s Executive Director (together, the **Designated Officers**) for attempted resolution by good faith negotiation.
- (e) If any such Dispute is not resolved by the Designated Officers within thirty (30) days after the receipt of the notice referring such Dispute to the Designated Officers, then either Party may initiate binding arbitration proceedings as contemplated by Section 14.6.

## 13.2 Injunctive Relief

The Parties acknowledge and agree that the breach by either Party of the provisions of this License Agreement related to the protection of Confidential Information, including trade secrets, or the cross-border diversion of the Licensed Compound and/or Licensed Product may not be fully compensable by money damages and may result in irreparable harm to the other Party. Notwithstanding anything in this Section 13, each Party will have the right to seek injunctive or other equitable relief from a court of competent jurisdiction as may be necessary to avoid irreparable harm, maintain the status quo, including any breach or threatened breach of Section 10.1. Without limiting their right to seek such relief before any other competent court, the Parties agree that any such request for injunctive or equitable relief may be brought (a) in the federal court sitting in District for the Southern District of New York, U.S.A., or (b) to the Secretariat of the International Chamber of Commerce (“ICC”) International Court of Arbitration pursuant to the Emergency Arbitration Provisions of the ICC commercial arbitration rules, and the Parties irrevocably and unconditionally consent to the exercise of personal jurisdiction by either such institutions in such proceedings.

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## 14. MISCELLANEOUS

### 14.1 Severability

If any one or more of the provisions of this License Agreement is held to be invalid or unenforceable, the provision will be considered severed from this License Agreement and will not serve to invalidate any remaining provisions of this License Agreement. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this License Agreement may be realized.

### 14.2 Notices

14.2.1 Any notice required or permitted to be given under this License Agreement will be in writing and will be delivered by hand or internationally recognized express courier with tracking capabilities or mailed postage prepaid by first class, registered, or certified mail, in any case addressed as set forth below unless changed by notice so given. The Parties may also for information purposes provide a copy of any such notifications to the email addresses set forth below:

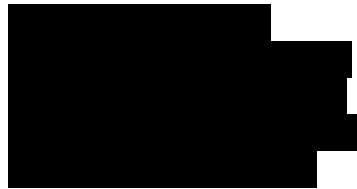
(i) If to Shionogi:

[REDACTED]

With a copy to:



(ii) If to GARDP:



14.2.2 Any such notice will be deemed delivered on the date received. A Party may add, delete, or change the person or address to whom notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 14.2.

### 14.3 Force Majeure

14.3.1 Neither Party will be liable for any failure to perform its obligations under this License Agreement (other than obligations to make payments of money) to the extent such performance has been delayed, interfered with, or prevented by any event of Force Majeure.

14.3.2 As used in this License Agreement, **Force Majeure** means any circumstances whatsoever which are not within the reasonable control of the Party affected thereby, including an act of God, war, terrorism, insurrection, riot, strike or labor dispute, shortage of materials, fire, explosion, flood, government requisition or allocation, breakdown of damage to plant, equipment or facilities, interruption or delay in transportation, fuel supplies or electrical power, embargo, boycott, order or act of civil or military authority. The Party who declares an event of Force Majeure will give prompt notice to the other Parties of such declaration.

14.3.3 If the performance of any obligation has been delayed, interfered with, or prevented by an event of Force Majeure, then the Party affected by such event will take such actions as are reasonably available to remove the event of Force Majeure or to mitigate the effect of such occurrence, except that labor disputes will be settled at the sole discretion of the Party affected thereby.

14.3.4 If an event of Force Majeure occurs, the obligations of the Parties under this License Agreement (other than the obligations to make payments of money) will be

suspended during, but not longer than, the continuance of the event of Force Majeure.

#### **14.4 Assignment**

14.4.1 Neither Party may assign this License Agreement, except as specifically permitted by this Section 14.4.

14.4.2 Shionogi may, without GARDP's consent, assign or transfer all of its rights and obligations under this License Agreement to any Affiliate of Shionogi or to any Person that acquires all or substantially all of its assets to which this License Agreement relates (including its rights in and to the Licensed Product, Licensed Compound, Licensed Manufacturing Know How and Licensed Rights), provided that such Affiliate or Person shall undertake directly in writing to GARDP to assume and comply with all of Shionogi's obligations under this License Agreement, including, without limitation, the grant of the license to GARDP pursuant to Section 2.1.

14.4.3 GARDP may not assign all or any part of its rights, or delegate all or any part of its obligations, under this License Agreement without Shionogi's prior written consent. For clarity, GARDP's use of GARDP Contractors for which it remains entirely responsible to perform its obligations under this License Agreement shall not be considered an assignment or delegation of its obligations under this License Agreement.

14.4.4 Any assignment or transfer in violation of the foregoing will be null and void ab initio and wholly invalid, the assignee or transferee in any such assignment or transfer will acquire no rights whatsoever, and the non-assigning non-transferring Party will not recognize, nor will it be required to recognize, such assignment or transfer.

14.4.5 Subject to the foregoing provisions of Section 14.4, this License Agreement will inure to the benefit of and be binding on the Parties' successors and assigns.

#### **14.5 Waiver and modifications**

The failure of any Party to insist on the performance of any obligation under this License Agreement will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision of this License Agreement will not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release, or amendment of any obligation under or provision of this License Agreement will be valid or effective unless in writing and signed by the Party(ies).

#### **14.6 Choice of law; Arbitration**

This License Agreement, and any dispute arising from the performance or breach thereof, will be governed, and will be construed and enforced in accordance with the laws of the

State of New York, without giving effect to the choice of laws provisions thereof that would require the application of the laws of any other jurisdiction.

If any Dispute is not resolved in accordance with Section 13.1, then either Party may submit such Dispute for final resolution by binding arbitration under the commercial arbitration rules of the International Chamber of Commerce (the “**ICC**”). The arbitration proceedings shall be conducted in the English language in (a) New York, New York or (b) another mutually agreed upon location. Nothing in this License Agreement shall limit the right of either Party to apply to the arbitration tribunal or any court of competent jurisdiction for any non-monetary interim relief or provisional remedy, including a temporary restraining order, preliminary injunction or other interim or conservatory relief that may be available under applicable law.

#### **14.7 Publicity**

The Parties agree that neither Party will issue a press release or public announcement concerning the transactions contemplated by this License Agreement without the prior written consent of the other Parties. If either Party intends to issue a press release, it will submit a draft of such proposed press release to the other Parties at least five (5) Business Days prior to the date such Party intends to issue the release and will agree to consider the comments of the other Parties to the press release. After any initial press release or public announcement is made, however, each Party may disclose to Third Parties or make public statements, by press release or otherwise, regarding the existence of this License Agreement, the identity of the Parties, and the terms, conditions, and subject matter previously disclosed about the License Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein. The Parties agree and acknowledge that nothing in this Section shall restrict the press releases or public announcements of any third party based on publicly available information.

#### **14.8 Anti-Corruption**

Each Party agrees to perform its respective obligations under this License Agreement in accordance with the principles set forth in Shionogi’s Anti-Corruption guidelines found here: <https://www.shionogi.com/global/en/company/policies/shionogi-group-anti-corruption-anti-bribery-policy.html>, as may be revised from time to time throughout the Term. Without limiting the foregoing, each Party shall fully comply at all times with the applicable laws and regulations, including, but not limited to, applicable anti-corruption laws of the Territory(ies) in which GARDP conducts business with Shionogi and/or grants Sublicenses.

#### **14.9 Relationship of the Parties**

Each Party is an independent contractor under this License Agreement. Nothing contained in this License Agreement is intended or is to be construed so as to constitute Shionogi and GARDP and/or any Sublicensees as partners, agents, or joint ventures. None of the Parties will have any express or implied right or authority to assume or create any obligations on

behalf of or in the name of the other Parties or to bind the other Parties to any contract, agreement, or undertaking with any Third Party.

#### **14.10 Headings**

Headings and captions are for convenience only and are not to be used in the interpretation of this License Agreement.

#### **14.11 Entire Agreement**

This License Agreement, together with the Collaboration Agreement, constitutes the entire agreement between the Parties as to the subject matter of this License Agreement, and supersedes and merges all prior negotiations, representations, agreements, and understandings regarding the same.

#### **14.12 Counterparts**

This License Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together, and will constitute one and the same instrument.

#### **14.13 Ambiguities**

Each of the Parties acknowledges and agrees that this License Agreement has been diligently reviewed and negotiated by and between them; that in such negotiations, each of them has been represented by competent counsel; and that the final agreement contained in this License Agreement, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this License Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this License Agreement or any such provision, and ambiguities, if any, in this License Agreement will not be construed against any Party irrespective of which Party may be deemed to have authored the ambiguous provisions.

#### **14.14 Business conduct and ethics**

Shionogi takes seriously its compliance and ethics responsibilities and seeks to do business only with Third Parties who share our high standards of ethical behavior. To that end, Shionogi has adopted Standards of Business Conduct and Ethics for Third Parties (**3P Standards**). Shionogi encourages GARDP and its Sublicensees to comply with the elements of the 3P Standards that apply to them. For your reference, the 3P Standards are available at Shionogi Group Business Partner Code of Conduct: <https://www.shionogi.com/global/en/company/policies/shionogi-group-business-partner-code-of-conduct.html> and Shionogi Group Anti-Corruption/Anti-bribery Policy: <https://www.shionogi.com/global/en/company/policies/shionogi-group-anti-corruption-anti-bribery-policy.html>.

(remainder of the page intentionally left blank)

IN WITNESS THEREOF the Parties have caused this License Agreement to be executed by their respective duly authorized officers.

[Redacted Signature]

\_\_\_\_\_  
[Redacted Name]

[Redacted Signature]

[Redacted Signature]

\_\_\_\_\_  
[Redacted Name]

[Redacted Signature]

[Redacted Signature]

[Redacted Signature]



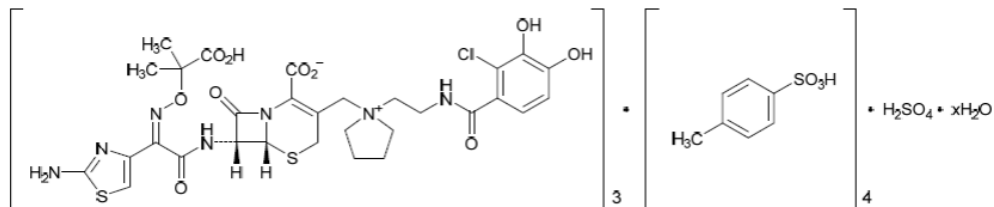
## Schedule A Licensed Compound and Licensed Product

### 11 DESCRIPTION

FETROJA is a cephalosporin antibacterial drug product consisting of cefiderocol sulfate tosylate for intravenous infusion. Cefiderocol functions as a siderophore [see *Microbiology (12.4)*].

The chemical name of cefiderocol sulfate tosylate is Tris[(6*R*,7*R*)-7-[(2*Z*)-2-(2-amino-1,3-thiazol-4-yl)-2-[(2-carboxypropan-2-yl)oxy]imino}acetamido]-3-(1-[2-(2-chloro-3,4-dihydroxybenzamido)ethyl]pyrrolidin-1-ium-1-yl)methyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate] tetrakis(4-methylbenzenesulfonate) monosulfate hydrate, and the molecular weight is 3043.50 (anhydrous). The molecular formula is  $3C_{30}H_{34}ClN_7O_{10}S_2 \cdot 4C_7H_8O_3S \cdot H_2SO_4 \cdot xH_2O$ .

**Figure 1 Chemical Structure of Cefiderocol Sulfate Tosylate**



FETROJA for injection is a white to off-white, sterile, lyophilized powder formulated with 1 gram of cefiderocol (equivalent to 1.6 grams of cefiderocol sulfate tosylate), sucrose (900 mg), sodium chloride (216 mg), and sodium hydroxide to adjust pH. The sodium content is approximately 176 mg/vial. The pH of the reconstituted solution of 1 gram cefiderocol (1 vial) dissolved in 10 mL water is 5.2 to 5.8.

**Schedule B Licensed Patent Rights**

Publication/ Application No.	Name	Filing date	Countries	
			Pending Application	Granted Patent
WO2010/050468	CEPHALOSPORIN  HAVING CATECHOL GROUP	2009-10-  27	DO	BR, CL, CO, CR, DZ, EG, EA (AM, AZ, BY, KG, KZ, MD, TJ, TM), EP (AL, BA, ME, MK, RS), IN, MA, MX, NG, PE, TT, UA, ZA
WO2016/035845	SALT OF CEPHALOSPORIN DERIVATIVE, ITS CRYSTALLINE SOLID AND A METHOD OF MANUFACTURING THEREOF	2015-09- 03	BR, IN	EA (AM, AZ, BY, KG, KZ, MD, TJ, TM), EP (AL, MK, RS), MX, ZA
WO2016/035847	INTERMEDIATE OF CEPHALOSPORIN DERIVATIVES AND METHOD FOR PRODUCING SAME	2015-09- 03		IN

## Schedule C Territory

High Income	Upper Middle Income		Lower Middle Income		Low Income
Antigua	Albania	Marshall Isl.	Algeria	Nepal	Afghanistan
Bahamas	Argentina	Mexico	Angola	Nicaragua	Burkina Faso
Barbados	Armenia	Montenegro	Bangladesh	Nigeria	Burundi
Chile	Azerbaijan	Namibia	Benin	Pakistan	Central African Republic
Mauritius	Belarus	N. Macedonia	Bhutan	Papua NG	Chad
Nauru	Belize	Paraguay	Bolivia	São Tomé	Dem. Rep. of Congo
Palau	Bosnia, Herz.	Peru	Cabo Verde	Senegal	Eritrea
Panama	Botswana	Samoa	Cambodia	Solomon Isl.	Ethiopia
Uruguay	Brazil	Serbia	Cameroon	Sri Lanka	Gambia
Seychelles	Colombia	South Africa	Comoros	Tanzania	Guinea
St. Kitts	Costa Rica	St. Lucia	Congo, Rep.	Timor-Leste	Guinea-Bissau
Trinidad/Tobago	Cuba	St. Vincent	Côte d'Ivoire	Tunisia	Haiti
	Dominica	Suriname	Djibouti	Ukraine	Dem. People's Rep. of Korea
	Dominican Rep	Tonga	Egypt	Uzbekistan	Liberia
	Ecuador	Turkmenistan	El Salvador	Vanuatu	Madagascar
	Eq. Guinea	Tuvalu	Eswatini	Zambia	Malawi
	Fiji	Venezuela	Ghana	Zimbabwe	Mali
	Gabon		Honduras		Mozambique
	Georgia		India		Niger
	Grenada		Kenya		Rwanda
	Guatemala		Kiribati		Sierra Leone
	Guyana		Kyrgyz Rep.		Somalia
	Iran		Lao PDR		South Sudan
	Iraq		Lesotho		Sudan
	Jamaica		Mauritania		Syrian Arab Republic
	Jordan		Micronesia		Tajikistan
	Kazakhstan		Moldova		Togo
	Lebanon		Mongolia		Uganda
	Libya		Morocco		Yemen
	Maldives		Myanmar		

## **Schedule D**












### **Licensed Rights**








- EU MAA for cefiderocol, initial date of submission 04 March 2019
- NDA 209445 for the United States
- the Licensed Manufacturing Know-How

### Schedule E Product Trademark

Trademark	Country branch No.	Country Name	Reference No.	Deadline
FETROJA	AL01		M2016-00001	01/08/2026
FETROJA	AM01	Armenia	M2016-00001	01/08/2026
FETROJA	AU01		M2016-00001	01/08/2026
FETROJA	BR01	Brazil	M2016-00001	05/06/2028
FETROJA	AZ01		M2016-00001	01/08/2026
FETROJA	BA01		M2016-00001	01/08/2026
FETROJA	BY01	Belarus	M2016-00001	01/08/2026
FETROJA	CA01		M2016-00001	18/06/2029
FETROJA	CH01		M2016-00001	01/08/2026
FETROJA	CN01		M2016-00001	01/08/2026
FETROJA	DZ01	Algeria	M2016-00001	01/08/2026
FETROJA	EG01		M2016-00001	01/08/2026
FETROJA	HK01		M2016-00001	26/07/2026
FETROJA	ID01		M2016-00001	
FETROJA	IL01		M2016-00001	01/08/2026
FETROJA	IS01		M2016-00001	01/08/2026
FETROJA	JP01		M2016-00001	12/08/2026
FETROJA	KG01	Kyrgyz Rep.	M2016-00001	01/08/2026
FETROJA	KR01		M2016-00001	01/08/2026
FETROJA	KZ01	Kazakhstan	M2016-00001	01/08/2026
FETROJA	LI01		M2016-00001	01/08/2026
FETROJA	MA01	Morocco	M2016-00001	01/08/2026
FETROJA	MC01		M2016-00001	01/08/2026
FETROJA	MD01	Moldova	M2016-00001	01/08/2026
FETROJA	MK01		M2016-00001	01/08/2026
FETROJA	MX01	Mexico	M2016-00001	01/08/2026
FETROJA	MY01		M2016-00001	03/02/2026
FETROJA	NO01		M2016-00001	01/08/2026
FETROJA	NZ01		M2016-00001	01/08/2026
FETROJA	PH01		M2016-00001	01/08/2026
FETROJA	RS01	Serbia	M2016-00001	01/08/2026
FETROJA	RU01		M2016-00001	01/08/2026
FETROJA	SG01		M2016-00001	01/08/2026
FETROJA	SM01		M2016-00001	01/08/2026
FETROJA	TJ01	Tajikistan	M2016-00001	01/08/2026
FETROJA	TM01		M2016-00001	01/08/2026
FETROJA	TR01		M2016-00001	01/08/2026

FETROJA	TW01		M2016-00001	15/03/2027
FETROJA	UA01	Ukraine	M2016-00001	01/08/2026
FETROJA	VN01		M2016-00001	01/08/2026
NEXFIDRO	JP01		M2016-00002	Abandoned
INBACIO	JP01		M2016-00003	Abandoned
ENBACEO	JP01		M2016-00004	12/08/2026
FETROJA	US01		M2016-00005	19/09/2027
NEXFIDRO	US01		M2016-00006	Abandoned
INBACIO	US01		M2016-00007	Abandoned
ENBACEO	US01		M2016-00008	19/09/2027
FETROJA	EM01		M2016-00009	28/01/2026
FETROJA	GB01		M2016-00009	28/01/2026
NEXFIDRO	EM01		M2016-00010	Abandoned
INBACIO	EM01		M2016-00011	Abandoned
ENBACEO	EM01		M2016-00012	28/01/2026
ENBACEO	GB01		M2016-00012	28/01/2026
LIMZEFO	EM01		M2016-00036	01/12/2026
LIMZEFO	GB01		M2016-00036	01/12/2026
LIMZEFO	US01		M2016-00036	08/08/2027
LIMCEFRO	EM01		M2016-00037	01/12/2026
LIMCEFRO	GB01		M2016-00037	01/12/2026
LIMCEFRO	US01		M2016-00037	08/08/2027
KYDELTIS	EM01		M2016-00038	Abandoned
KYDELTIS	US01		M2016-00038	Abandoned
フェトロージャ	JP01		M2016-00057	22/12/2026
フェトロジャ	JP01		M2016-00058	22/12/2026
FETAROJA	EM01		M2017-00003	23/01/2027
FETAROJA	GB01		M2017-00003	23/01/2027
FETEROJA	EM01		M2017-00004	23/01/2027
FETEROJA	GB01		M2017-00004	23/01/2027
FETCROJA	EM01		M2017-00005	23/01/2027
FETCROJA	GB01		M2017-00005	23/01/2027
PHEROY	EM01		M2017-00006	23/01/2027
PHEROY	GB01		M2017-00006	23/01/2027
TROFETRA	EM01		M2017-00007	23/01/2027
TROFETRA	GB01		M2017-00007	23/01/2027
FETROYER	EM01		M2017-00008	23/01/2027
FETROYER	GB01		M2017-00008	23/01/2027
TROYFETRO	EM01		M2017-00009	23/01/2027
TROYFETRO	GB01		M2017-00009	23/01/2027
TROYFETRA	EM01		M2017-00010	23/01/2027
TROYFETRA	GB01		M2017-00010	23/01/2027

JANFETRO		EM01		M2017-00011	23/01/2027
JANFETRO		GB01		M2017-00011	23/01/2027
logo		AU01		M2017-00013	01/06/2027
logo		CH01		M2017-00013	01/06/2027
logo		CN01		M2017-00013	01/06/2027
logo		EM01		M2017-00013	01/06/2027
Logo		GB01		M2017-00013	01/06/2027
logo		IN01	India	M2017-00013	01/06/2027
logo		IS01		M2017-00013	01/06/2027
logo		JP01		M2017-00013	25/08/2027
logo		KR01		M2017-00013	01/06/2027
logo		LI01		M2017-00013	01/06/2027
logo		MX01	Mexico	M2017-00013	01/06/2027

logo		NO01		M2017-00013	01/06/2027
logo		RU01		M2017-00013	01/06/2027
logo		SG01		M2017-00013	01/06/2027
logo		TR01		M2017-00013	01/06/2027
logo		US01		M2017-00013	01/06/2027
フィトロージャ		JP01		M2018-00017	07/06/2029
エフロージャ		JP01		M2018-00018	07/06/2029
FETCROJA		US01		M2019-00014	Abandoned
FETEROJA		US01		M2019-00015	Abandoned
FETAROJA		US01		M2019-00016	Abandoned
FETROYER		US01		M2019-00017	Abandoned
JANFETRO		US01		M2019-00018	Abandoned
logo		TW01		M2019-00027	31/10/2029
FETROJA		PH01		M2019-00032	26/12/2029
logo		MX01	Mexico	M2022-00011	To be filed in 2023
FETROJA		PH01		M2022-00012	To be filed in 2022



## Schedule F Provisions for Sublicense Agreement

This Sublicense Agreement (“**Sublicense Agreement**” or “**Agreement**”), effective as of [DATE] (the “**Effective Date**”), is by and between **GARDP Foundation**, a non-profit research and development organization registered under the laws of Switzerland, and having a principle place of business at 15 Chemin Camille-Vidart 1202 Geneva, Switzerland (“**Sublicensor**”), and [SUBLICENSEE], a [STATE OF ORGANIZATION] [ENTITY TYPE] (“**Sublicensee**”). Sublicensor and Sublicensee may be referred to herein collectively as the “**Parties**” or individually as a “**Party**”.

WHEREAS, Sublicensor is a party to the License and Technology Transfer Agreement, dated as of [DATE] (“**License Agreement**”), with Shionogi & Co., Ltd. (“**Licensor**”), under which Licensor granted Sublicensor a license under certain rights of Licensor; and

WHEREAS, Sublicensee desires to obtain, and Sublicensor agrees to grant, a sublicense under Sublicensor’s rights in and to the Sublicensed Rights, on the terms and conditions of this Agreement and subject to all applicable restrictions and limitations on the rights granted to Sublicensor under the License Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms, and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Sublicensee Commitment. Sublicensee hereby agrees to use commercially reasonable efforts to implement an agreed registration and commercialization plan (the **Sublicense Access Plan**), that includes specific target dates for various registration and commercialization objectives, and that furthers the Access and Stewardship Objectives. The Sublicense Access Plan shall be agreed to by Licensor, Sublicensor and Sublicensee.

2. License Agreement. Sublicensor has provided to Sublicensee, attached as Exhibit [LETTER], a true and complete copy of the License Agreement in effect as of the Effective Date, including all amendments thereto, except those terms and conditions that have been redacted as reasonably necessary to protect Licensor’s commercially sensitive information. Sublicensee acknowledges and agrees that this Agreement and Sublicensee’s rights and obligations under it are subject to, and Sublicensee shall comply with, all terms and conditions of the License Agreement applicable to Sublicensor’s sublicensees. To the extent that the License Agreement explicitly requires that any terms or conditions be included in any agreement granting a sublicense under the License Agreement, such terms and conditions are deemed to be incorporated by reference in this Agreement. For the avoidance of doubt, any right of Sublicensor under the License Agreement not expressly sublicensed to Sublicensee under this Agreement remains the right of Sublicensor and is not implicitly sublicensed to Sublicensee.

3. Sublicensee Acknowledgement. Sublicensee hereby acknowledges that Licensor has made no representations or warranties to Sublicensee regarding the Licensed Rights or the Licensed Product, and that the Sublicensee has independently evaluated any information supplied by or on behalf of Licensor or Sublicensor before making its decision to enter into the Sublicense Agreement and undertake the commitments and obligations set forth herein.

4. Sublicensor Commitment [OPTIONAL]. So long as Sublicensee is complying with its diligence obligations, Sublicensor hereby agrees not to seek another market access partner for the country(ies) covered by this Agreement. For the avoidance of doubt, nothing herein shall restrict Licensor or its agents' development, manufacture, registration, or commercialization of the Licensed Product in the Territory.

5. Adverse Event Reporting. Sublicensee shall, in accordance with its standard protocols, maintain effective and reliable systems for receiving and tabulating any reports of adverse reactions to the Licensed Product commercialized by Sublicensee and to report such information on a timely basis to the relevant regulatory authorities in accordance with applicable laws and regulations in the countries in which it is commercializing Licensed Product. Sublicensee shall be responsible for fulfilling all required pharmacovigilance reporting responsibilities, and managing inquiries related to the safety of Licensed Product, in accordance with applicable laws and regulations in the countries in which it is commercializing Licensed Product. Sublicensee acknowledges that Licensor is responsible for maintaining the global pharmacovigilance database for Licensed Product. Simultaneously with the execution of this Agreement, Sublicensee and Licensor are entering into a safety data exchange agreement on terms reasonably acceptable to Licensor (the "SDEA") governing the exchange of Licensed Product safety information between Sublicensee and Licensor and the conduct of inquiries relating to adverse events reported by Sublicensee as set forth in Schedule X attached hereto. Any breach by Sublicensee of its obligations under the SDEA shall be deemed to constitute a breach by the Sublicensee of its obligations under this Sublicense Agreement.

Sublicensee and Sublicensor will ensure that appropriate standard operating procedures regarding events are established, maintained and regularly reviewed to ensure compliance in accordance with the terms of this Agreement and Applicable Laws.

6. Intellectual Property. Licensor (or its Affiliates) will own the entire right, title and interest in and to any and all inventions conceived solely by its employees and agents before, on or after the Effective Date relating to the Licensed Compound or any Licensed Product, including the Licensed Rights and any such inventions that constitute an adaptation of any manufacturing process or proprietary drug delivery or formulation technology of Licensor or its Affiliates for the production of the Licensed Compound or any Licensed Product, and any patents covering such invention (**Licensor Sole Inventions**), subject to the license granted to Sublicensor.

#### **Manufacturing Process Results**

- (a) To the extent Sublicensee accepts a Technical Transfer Package, or otherwise has access to any non-public proprietary information or confidential information of Licensor relating to the manufacturing process used by Licensor to manufacture Licensed Compound and Licensed Product (not including the specifications of the Licensed Compound or Licensed Product that are required for a Sublicensee to demonstrate that the Licensed Compound or Licensed Product manufactured by the Sublicensee using its process are pharmaceutically equivalent to the Licensed Compound or Licensed Product manufactured using Licensor's manufacturing process):

- (i) Licensor shall own (and shall have the sole right to patent or not to patent) all inventions and results developed or generated by the Sublicensee related to the process to manufacture Licensed Compound or Licensed Product (**Process Results**) (whether or not patentable) that are specific to the Licensed Product and/or that incorporate any non-public proprietary information or confidential information or intellectual property of Licensor and Sublicensee will provide reasonable assistance to Licensor, as may be required, for such prosecution; and
  - (ii) Sublicensee shall own (and shall have the sole right to patent or not to patent) all Process Results (whether or not patentable) solely to the extent separable from the Licensed Product (i.e., that such can be used to manufacture products other than the Licensed Product) and that do not incorporate any non-public proprietary information or confidential information of Licensor.
- (b) If Sublicensee has not accepted a Technical Transfer Package, and has not had access to any non-public proprietary information or confidential information of Licensor relating to Licensor's manufacturing process (not including the specifications of the Licensed Compound or Licensed Product that are required for a Sublicensee to demonstrate that the Licensed Compound or Licensed Product manufactured by the Sublicensee using its process are pharmaceutically equivalent to the Licensed Compound or Licensed Product manufactured using Licensor's manufacturing process):
  - (i) Sublicensee shall own (and shall have the sole right to patent or not to patent) all Process Results (whether or not patentable) developed or generated by or for them that do not incorporate any non-public proprietary information or confidential information of Licensor.
- (c) The Process Results shall be considered confidential information of the party who owns the results, provided that each of Licensor, Sublicensor and Sublicensee shall have the right to access and use all Process Results in accordance with the licenses set forth in this Sublicense Agreement and the License Agreement.
- (d) Licensor shall have the sublicensable right to use all Process Results not owned by it for development, regulatory filings, manufacturing, commercialization or otherwise to enable or facilitate access to any product containing cefiderocol worldwide.

#### **Development Activity Sublicense Results**

- (a) With respect to any inventions, know-how or results (whether or not patentable) developed or generated by or for Sublicensor and/or Sublicensee in the performance of any Development activities conducted pursuant to this Sublicense Agreement other than Development activities relating to Manufacturing (the results of which are Process Results governed by the terms above) (**Development Results**):

- (i) Licensor shall own (and shall have the sole right to patent or not to patent) all Development Results that are specific to the Licensed Product and/or that incorporate any non-public proprietary information or confidential information or intellectual property of Licensor.
- (ii) notwithstanding the above, Sublicensor shall own the clinical data associated with or arising from clinical studies conducted pursuant to this Sublicense Agreement (**Clinical Data**), but may use such Clinical Data only for the purposes consistent with this Sublicense Agreement and the License Agreement; and Licensor and Sublicensor shall have the right to access and use all such Clinical Data in accordance with the licenses set forth in this Sublicense Agreement and the License Agreement, and Sublicensor or Sublicensee, as applicable, shall provide at least one copy of the Clinical Data to Licensor upon completion of each applicable clinical study.
- (iii) Each Party shall have the right to publish for scientific purposes Development Results developed or generated by or for such Party (subject if applicable to the rights of one or more other parties that may also have participated in the development or generation thereof), subject to, with respect to any such Development Results that relate to the Licensed Product or any proprietary or confidential information of Licensor, (i) Licensor's and Sublicensor's prior review of any such proposed publication, (ii) Licensor's right to remove its confidential information (but not of the Development Results themselves) from any such proposed publication, and (iii) Licensor's right to request a reasonable delay in publication for Licensor to file any related patent applications. Licensor shall have the right to oppose any such proposed publication for failure to comply with the foregoing requirements, or for any objection based on reasonable concerns relating to the accuracy and/or quality of the data referenced therein, and the publication may not proceed until Licensor's opposition based on the above has been resolved as set forth herein. Any disagreement regarding proposed publications contemplated by this Section shall be escalated for resolution to representatives of the Licensor, the Sublicensor and the Sublicensee.
- (iv) Sublicensee shall have the right to use Clinical Data developed or generated by them only for regulatory filings, Commercialization, or otherwise to enable or facilitate access to Licensed Product, in the country(ies) in the Territory for which it has a license.
- (v) Licensor shall have the sublicensable right to use all Development Results, including any and all Clinical Data, not owned by it for development, regulatory filings, manufacturing, commercialization or otherwise to enable or facilitate access to any product containing cefiderocol worldwide.

### **General Conditions Applicable to all Sublicense Results**

- (a) Sublicensee grants Licensor a free, perpetual, nonexclusive, sublicensable license to use Sublicense Results owned by Sublicensee (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization of the Licensed Product worldwide.
- (b) Sublicensee grants Sublicensor a free, nonexclusive, sublicensable license to use Sublicense Results owned by Sublicensee (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization of the Licensed Product in the Territory pursuant to the License Agreement.
- (c) All Sublicense Results owned by Licensor (including any intellectual property rights thereon) shall be included in the License Rights licensed to Sublicensor pursuant to the License Agreement and sublicensed to Sublicensee pursuant to this Sublicense Agreement.

7. Recalls, Market Withdrawals or Corrective Action. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Licensed Product in the countries in the Territory covered by the Sublicense, or in the event Sublicensor, Licensor and/or Sublicensee reasonably determine that an adverse event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the countries in the Territory covered by the Sublicense, the party notified of such recall or similar action, or the party(ies) that desire(s) such recall or similar action, must within twenty-four (24) hours, advise the other party(ies) by telephone (with written confirmation notice to follow) or by email to the address specified in Section [INSERT REFERENCE TO NOTICE SECTION]. The Parties will consult to decide whether to conduct any recall of Licensed Product in the Territory (except in the case of a Regulatory Authority mandated recall, in which case either Sublicensee or Sublicensor may act without such advance notice but, will notify the other Party and Licensor as soon as possible) and the manner in which any such recall will be conducted, it being understood that any one of Licensor, Sublicensor or Sublicensee may in any case require such a recall to be conducted. Sublicensee shall bear the sole expense of any recall of Licensed Product in the Territory.

8. Records. Sublicensee shall keep at its principal place of business true and accurate records of Net Sales, quantities of Licensed Product, and raw materials used to make Licensed Product, manufactured and/or sold pursuant to this Agreement (itemized by number of units of Licensed Product sold by strength and by country, together with current inventory reports), proper and comprehensive books of account including all information required to calculate the Cost Recoupment Fees and other moneys from time to time payable pursuant to this Sublicense Agreement this Agreement. Records must be maintained for at least ten (10) years.

9. Licensor's Right of Audit and Inspect. Sublicensee agrees at all reasonable times to permit Licensor's or Sublicensor's auditor to access, inspect and review the accounts, books and records referred to in Section 8. Such examination shall be conducted at Licensor's or Sublicensor's, as applicable, expense by an independent accountant, subject to execution of a customary confidentiality agreement with Sublicensee. The accountant may take copies of or extracts from the accounts, books and records, subject to the confidentiality agreement entered into by the accountant. Such audits may not be conducted more than once each calendar year and shall be conducted with reasonable prior notice and during normal office hours. Sublicensee agrees to give Licensor's representatives reasonable assistance, access and facilities to enable them to verify such accounts, books and records and supply such other information as may be necessary or proper to enable Sublicensee's compliance with this Agreement to be verified. The auditor shall only report to Licensor and/or Sublicensor whether Sublicensee is in compliance with its obligations and/or such information as is reasonably necessary to demonstrate any deviation. If an audit conducted in accordance with this Section [9] identifies a deviation of more than ten percent (10%) from the amounts identified as payable in statements provided by Sublicensee pursuant to Section [INSERT REFERENCE TO RECOUPMENT OF COSTS SECTION] in any consecutive period of four quarters, the costs of the audit are to be reimbursed to Licensor by Sublicensee on demand. Licensor's and Sublicensor's rights under this Section [9] above apply during the Term and for four (4) years thereafter.

Sublicensee also agrees to permit appropriate representatives of Licensor and/or Sublicensor to inspect, at their cost, Sublicensee's manufacturing facilities and those of any permitted sub-contract manufacturers in order to verify Sublicensee's compliance with this Agreement. At least ten Business Days' advance notice of any such inspection will be given and such inspection shall be conducted with reasonable prior notice, during normal office hours and in a manner to minimize disruption of manufacturing operations. Sublicensee may require such representatives to sign a customary confidentiality agreement and may limit their access to facilities and documents that are reasonably necessary to verify that the manufacture of Licensed Compound and Licensed Product are compliant with the Sublicense Agreement.

10. Indemnification by Sublicensee of Licensor. Sublicensee hereby agrees to defend, hold harmless and indemnify Licensor and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns, and representatives (**Licensor Indemnitees**), from and against any and all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments, whether for money or equitable relief, of any kind from a Third Party (**Losses and Claims**) arising out of or in connection with:

- (a) any activities conducted by Sublicensee or its Affiliates pursuant to this Sublicense Agreement;
- (b) any material breach by Sublicensee of any of the provisions of this Sublicense Agreement ;
- (c) any negligence or willful misconduct by or on behalf of Sublicensee;
- (d) Sublicensee's use and practice of the Licensed Rights and Licensed Manufacturing Know-How, including claims and threatened claims based on:
  - (i) any product liability, bodily injury, risk of bodily injury, death, or property damage;
  - (ii) infringement or misappropriation of Third-Party patents, copyrights, trademarks, or other intellectual property rights; or
  - (iii) the failure to comply with applicable laws related to the matters referred to in the foregoing with respect to the Licensed Compound and/or any Licensed Product.

11. Indemnification Procedures. Each Party will promptly notify the other Party when it becomes aware of a Third Party claim for which indemnification may be sought hereunder (a **Claim**). To be eligible to be indemnified for a Claim, a Person seeking indemnification (the "Indemnified Party") shall (i) provide the Party required to indemnify such Person (the "Indemnifying Party") with prompt written notice of the Claim giving rise to the indemnification obligation under this Section [X], provided that, the failure to provide such prompt notice shall not relieve the Indemnifying Party of any of its obligations under this Section [X] except to the extent the Indemnifying Party is actually prejudiced thereby; (ii) provide the Indemnifying Party with the exclusive ability to defend (with the reasonable cooperation of the Indemnified Party) against the Claim; and (iii) not settle, admit or materially prejudice the Claim, without the Indemnifying Party's prior written consent. The Indemnified Party shall reasonably cooperate with the Indemnifying Party, at the Indemnifying Party's expense, in the defense of any Claim. Notwithstanding the foregoing, the Indemnified Party shall have the right to participate in and have its own counsel participate in any action or proceeding for which the Indemnified Party seeks to be indemnified by the Indemnifying Party. Such participation shall be at the Indemnified Party's expense, unless (i) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. The Indemnifying Party's obligations under Section [X], as the case may be, shall not apply to the extent of the Indemnified Party's failure to take reasonable action to mitigate any Losses. The Indemnifying Party shall not settle or compromise, or consent to the entry of any judgment with respect to, any Claim, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld or delayed.

12. Compliance with Laws. Sublicensee shall comply with all applicable laws and regulations in the Territory in exercising its rights and performing its obligations under this Agreement. Without limiting the foregoing, Sublicensee shall: (a) mark, and shall cause its sub-sublicensees to mark, all Licensed Product manufactured or sold under this Agreement with all notices relating to the Sublicensed Rights to the extent required by the marking laws of the countries in which Sublicensee (or its sub-sublicensees) commercialize Licensed Product under the Sublicense Agreement; (b) record this Agreement (or the relevant portions or summary hereof) with the applicable regulatory authority if required under applicable law; (c) comply with all applicable laws and regulations concerning the export of any Licensed Product, including any requirements for obtaining an export license or other required governmental approval; and (d) comply with any Sanctions legislation administered or enforced by the Sanctions Authorities or the national governments of the relevant country(ies) covered by the Sublicense Agreement.

13. Enforcement. Each Party shall promptly notify the other Party of any actual or suspected infringement of the Sublicensed Rights in the Territory to the extent relating to the Licensed Product. Sublicensee acknowledges that, in accordance with the License Agreement, Licensor has the right, in its discretion and at their expense, to bring any action or proceeding with respect to such infringement and to control its conduct (including any settlement).

14. Insurance.

14.1 Sublicensee and its Affiliates and sub-sublicensees, must take out and maintain the following insurances with a reputable insurer during the Term and, if the policy is on a claims-made basis, for five years thereafter:

- (a) a comprehensive commercial general liability and product liability policy to cover all sums which it may become legally liable to pay as compensation consequent upon:
  - (i) death of, or bodily injury (including disease or illness) to, any person in connection with the use or administration of Licensed Product; and
  - (ii) loss of, or damage to, property, happening in any country where Sublicensee is conducting any activities pursuant to the Sublicense Agreement and arising out of or in connection with this Sublicense Agreement.

The limit of liability provided by this policy must be not less than [\$10 million].

- (b) if they conduct any clinical trials of Licensed Product, clinical trial liability insurance in respect thereof; and
- (c) any other insurance required by law.



14.2 To the extent practicable, Sublicensor and Licensor shall be noted as an interested party on all policies required under Section [14.1(a) and 14.1(b)], and within ten (10) Business Days of a request from Sublicensor or Licensor, Sublicensee must produce evidence that the insurances required by this Section [14] are being maintained, including providing copies of policy documents. Sublicensee must notify Sublicensor and Licensor immediately of any cancellation or material change to a relevant insurance policy which would cause its coverage to no longer be compliant with the obligations of this Section 10.

14.3 If any event occurs which may give rise to a claim involving Sublicensor or Licensor under any policy of insurance to be taken out by Sublicensee under this Section [14], then Sublicensee must:

- (a) notify Sublicensor and/or Licensor as soon as reasonably practicable but in any event within ten (10) Business Days of the occurrence of that event; and
- (b) ensure that Sublicensor and/or Licensor is kept fully informed of any subsequent actions and developments concerning the relevant claim.

#### 15. Non-Diversion.

15.1 Sublicensee acknowledges that the sublicense to Licensed Rights granted under Section [X] is granted solely under and with respect to the Licensed Rights and Licensed Manufacturing Know-How for the purposes of Manufacturing Licensed Product for and supplying Licensed Product in the Field in the Territory.

15.2 Sublicensee acknowledges and agrees nothing in this Agreement will be construed as granting Sublicensee any rights under any patents, know-how, or otherwise to use, make, have made, sell, or have sold the Licensed Compound or any Licensed Product for ultimate use outside of the Field and/or outside of the Territory.

15.3 Subject to any applicable competition law, Sublicensee acknowledges and agrees the Licensed Product intended for distribution in the Territory is strictly prohibited from being diverted outside the Territory.

16. Licensed Product Trademarks. Subject to any limitations set forth herein, Sublicensee shall own all right, title, and interest to the Licensed Product Trademarks in the Territory, and shall be responsible for the registration, prosecution, and maintenance thereof. All costs and expenses of registering, prosecuting, and maintaining the Licensed Product Trademarks shall be borne solely by Sublicensee. Notwithstanding the foregoing, (i) each Licensed Product Trademark must have color, markings and other presentation to be distinctive from the Licensor's Licensed Product; and (ii) Sublicensee must obtain Licensor's prior written approval (such approval not to be unreasonably withheld) for Sublicensee's proposed Licensed Product Trademarks, trade dress or product markings. Licensor shall provide its feedback for any proposed trademark or trade dress promptly following its receipt of all information requested in order to fully evaluate such request. If Licensor reasonably objects to such request within the foregoing time-period, the Parties shall discuss in good faith Licensor's concerns, and Sublicensee will agree to make such modifications to Sublicensee's proposed trademark, trade dress or product markings as are necessary to address

Licensors' concerns. For the purposes of this Agreement, "**Licensed Product Trademarks**" means the trademark(s) to be used by Sublicensee or its Affiliates for the Commercialization of the Licensed Product in the countries covered by the Sublicense and any registrations thereof or any pending applications relating thereto in such countries (excluding, in any event, any trademarks that include any corporate name or logo of the Parties or their Affiliates, including Licensor's corporate names).

## 17. Confidentiality and Non-Disclosure.

**17.1 Confidentiality Obligations.** At all times during the Term and for a period of ten (10) years following termination or expiration of this Sublicense Agreement, or indefinitely with respect to all Confidential Information that constitutes trade secrets (including, without limitation, any Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of the Licensor's European Union and United States cefiderocol regulatory filings received or accessed by Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), for so long as the relevant trade secrets do not become publicly available other than as a result of a fault attributable to the receiving Party or its agents or sublicensees, each Party shall, and shall cause its Affiliates and their respective officers, directors, employees and agents to, keep completely confidential and not publish or otherwise disclose to a Third Party and not to use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or such use is reasonably necessary for the performance of its obligations or the exercise of its rights under this Agreement. "**Confidential Information**" means any information provided by one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") under or in connection with this Agreement, including the terms of this Agreement or any information relating to the Licensed Product (including the regulatory documentation and market approvals and any information or data contained therein), any information relating to any exploitation of the Licensed Product in the Territory or the scientific, regulatory or business affairs or other activities of either Party. For the purposes hereof, the Licensed Rights [(including the Licensed Manufacturing Know-How) – IF APPLICABLE], shall be deemed to be Confidential Information of GARDP, and the terms of this Sublicense Agreement shall be deemed Confidential Information of both Parties. The obligations under Section 17.1 will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by written evidence:

- (a) is or was publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party; or
- (b) was known to the Receiving Party or any of its Affiliates, without any obligations to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party; or

- (c) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in the possession thereof and without any obligation to keep it confidential or any restriction on its use; or
- (d) is published by a Third Party or otherwise becomes publicly available, either before or after it is disclosed to the Receiving Party; or
- (e) has been independently developed by employees or contractors of the Receiving Party without the aid, application, or use of Confidential Information of the Disclosing Party.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

**17.2 Authorized Disclosures.** Each Receiving Party may disclose Confidential Information disclosed to it by the Disclosing Party to the extent (and only to the extent) that such disclosure by the Receiving Party is reasonably necessary in the following instances:

- (i) regulatory filings;
- (ii) prosecuting or defending litigation;
- (iii) complying with applicable governmental laws and regulations (including the rules and regulations of the Securities and Exchange Commission or any national securities exchange or laws and regulations) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; and
- (iv) disclosure, in connection the receiving Party's performance of its obligations or exercise of its rights under this Agreement and solely on a "need-to-know basis", to Affiliates, potential sub-sublicensees and sub-sublicensees, potential donors and donors, research collaborators, employees, consultants, contractors or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use substantially equivalent in scope to those set forth in this Section 17 (the duration of such obligations being at least for the duration of the agreement with such other Person and a period of ten (10) years thereafter, or indefinitely with respect to all Confidential Information that constitutes trade secrets (including, without limitation, any Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Licensor's European Union and United States cefiderocol regulatory filings received or accessed by

Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available), for so long as the relevant trade secrets do not become publicly available other than as a result of a fault attributable to the receiving Party or to such other Person; provided, however, that the Receiving Party will remain responsible for any failure by any such Person who receives Confidential Information to treat such Confidential Information as required under this Section 17.

- (f) If and whenever any Confidential Information is disclosed in accordance with this Section 17.2, such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible, the receiving Party will notify the disclosing Party of the receiving Party's intent to make such disclosure pursuant to this Section 17.2 sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

**17.3 Destruction of Confidential Information.** Within sixty (60) Business Days after termination or expiration of this Agreement, each Party shall at the other Party's request: (A) return to the other Party or destroy all documents and tangible materials (and any copies) containing Confidential Information of the other Party; and (B) certify to the other Party in writing that it has complied with the requirements of this Section 17.3; provided that: (i) the Receiving Party may retain one archival copy of the Confidential Information of the other Party, but not any Confidential Information that constitutes trade secrets of the other Party (including, without limitation, the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Licensor's European Union and United States cefiderocol regulatory filings received or accessed by Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available, except for any of such that has become publicly available other than as a result of a fault attributable to GARDP and/or a Sublicensee) in a limited access file (meaning only accessible by such Party's Information Technology (IT) department or by such Party's legal personnel) to the extent that the receiving Party requires such Confidential Information for the purpose of performing any obligations or exercising any rights under this Agreement that may survive such expiration or termination, subject in any case to continued compliance by such Party of its confidentiality obligations as set out in Section 17 above; (ii) the receiving Party may retain Confidential Information of the other Party to the extent that the receiving Party is required to retain such information for compliance purposes under applicable laws and regulations; and (iii) the above obligations shall not require either Party to delete any automatic electronic backup files maintained in accordance with its standard policies and to which access is limited and only accessible by such Party's IT department. Notwithstanding any of the foregoing, Sublicensees are prohibited from retaining any Confidential Information received by the Sublicensee that constitutes trade secrets, including, without limitation, the Licensed Manufacturing Know-How, including the content of the Technical Transfer Package, and

the content of Licensor's European Union and United States confidential regulatory filings received or accessed by Sublicensee, and any other trade secrets of the Licensor, including all Confidential Information that is of a technical nature, is identifiable and substantial, and has commercial value because it is not publicly available, except for any of such that has become publicly available other than as a result of a fault attributable to Sublicensee or its agents or sublicensees and except as may be required for compliance purposes under applicable laws and regulations, and subject in any case to continued compliance by such Party of its confidentiality obligations as set out in Section 17 above.

18. Assignment. Sublicensee may not assign or transfer any of its rights or delegate any of its obligations hereunder, in each case whether voluntarily, involuntarily, by operation of law or otherwise, without the prior written consent of Sublicensor. No delegation or other transfer will relieve Sublicensee of any of its obligations or performance under this Agreement. Any purported assignment, delegation, or transfer in violation of this Section is void ab initio. This Agreement is binding upon and inures to the benefit of the Parties and their respective permitted successors and assigns. For clarity, Sublicensee's use of contractors for which it remains entirely responsible to perform its obligations under this Sublicense Agreement shall not be considered an assignment or delegation of its obligations under the Sublicense Agreement.

19. Choice of Law. This Agreement will be governed, and will be construed in accordance with the laws of \_\_\_\_\_, without regard to its conflicts of law provisions.

20. Additional Waiver (Disclaimer of Warranty). SUBLICENSEE AGREES THAT: (A) THE LICENSED RIGHTS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND SUBLICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST LICENSOR OR SUBLICENSOR FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE LICENSED RIGHTS; (B) SUBLICENSEE AGREES THAT LICENSOR AND SUBLICENSOR WILL HAVE NO LIABILITY TO SUBLICENSEE FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENSE OR OTHER HANDLING OF THE LICENSED RIGHTS; AND (C) SUBLICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED RIGHTS HAVE APPLICABILITY OR UTILITY IN SUBLICENSEE'S CONTEMPLATED EXPLOITATION OF THE LICENSED PRODUCT, AND SUBLICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.