MANUFACTURING SUBLICENSE AND TECHNOLOGY TRANSFER AGREEMENT

This manufacturing sublicense and technology transfer agreement (the "**Sublicense Agreement"**) is made and entered into as of September 07, 2023 (the "**Effective Date**") by and between:

(1) **GARDP Foundation**, a Swiss foundation having its principal place of business at Chemin Camille-Vidart 15, 1202 Geneva, Switzerland,

Hereinafter referred to as "**GARDP**",

And,

(2) **Orchid Pharma Ltd**, a Public Limited Company registered under the laws of India, and having its principal place of business at 151, SIDCO Industrial Area, Alathur, Dist. Chengalpattu, Tamil Nadu, India 603110.

Hereinafter referred to as the "**Sublicensee**",

Hereinafter referred to individually as the "**Party**" or collectively as the "**Parties**".

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. GARDP shall be understood as the sub-licensor in accordance with the Agreement.

(B) The Sublicensee is a leading manufacturer specialized in Cephalosporin Antibiotics, with its facilities approved worldwide.

(C) Shionogi & Co., Ltd., a Japanese pharmaceutical company with a global outreach ("**Shionogi**"), owns and/or Controls certain rights with respect to the Licensed Compound and the Licensed Product with respect to the Territory (each capitalized term as defined below).

(D) On June 15, 2022 (the "**Shionogi License Agreement Effective Date**"), GARDP and Shionogi entered into a License and Technology Transfer Agreement (the "**Shionogi License Agreement**") under which Shionogi granted GARDP a license to certain of its rights in respect of the Licensed Compound and the Licensed Product with respect to the Territory, and pursuant to which GARDP is entitled among other things to grant sublicenses to manufacture and to commercialize Licensed Compound and Licensed Product for use and for the benefit of patients in the Territory.

(E) The common objectives of Shionogi and GARDP under the Shionogi License Agreement are to enable sublicensees to provide, with a sense of urgency, affordable and sustainable access to quality Licensed Product for patients in need in countries in the Territory while preserving the efficacy and appropriate use of the Licensed Product and encouraging good antimicrobial stewardship (the "**Access and Stewardship Objectives**").

(F) The Sublicensee desires to obtain, and GARDP is willing to grant Sublicensee, a manufacturing sublicense under GARDP's rights in and to the Sublicensed Rights (as defined below), for the purpose of manufacturing Licensed Compound and Licensed Product at the Facility for the

Territory, on the terms and conditions of this Sublicense Agreement and subject to all applicable restrictions and limitations on the rights granted to GARDP under the Shionogi License Agreement, in order to promote access to the Licensed Product in the Territory in accordance with the Access and Stewardship Objectives.

(G) The Parties also wish to provide for certain technology transfer arrangements pursuant to which Shionogi will transfer Sublicensed Manufacturing Know-How (as defined below) to the Sublicensee to be used for the manufacture of Licensed Compound and Licensed Product in accordance with the terms of this Sublicense 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. DEFINITIONS AND INTERPRETATION

1.1 Definitions

Access and Stewardship Objectives has the meaning given to it in the preamble hereto.

Access Action Plan has the meaning given to it in Section 2.2.

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. In the case of GARDP, Affiliate shall mean also each Person listed in Schedule E of this Sublicense Agreement.

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., Geneva, Switzerland, Tokyo, Japan or India are authorized or obligated by law to remain close.

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).

Commercial Sublicensee means any Person that has been approved by Shionogi and GARDP to Commercialize Licensed Product in one or more countries in the Territory and with which GARDP has entered into a commercial sublicense agreement (each a **Commercial Sublicense Agreement**). For clarity, the Sublicensee may also be a Commercial Sublicensee if and when it enters into a Commercial Sublicense Agreement with GARDP. **Commercial Sublicense** means the commercial sublicense granted to a Commercial Sublicensee under a Commercial

Sublicense Agreement.

Confidential Information has the meaning given to it in Section 10.1.

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 Sublicense 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.

Customer means each customer, whether a Commercial Sublicensee or GARDP, with which the Sublicensee has entered into a Supply Agreement for the manufacture and/or supply of Licensed Product.

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).

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

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

Facility means, the facility(ies) at which the Sublicensee shall perform the Manufacturing undertaken under this Sublicense Agreement and defined in Schedule G. For the avoidance of doubt, the Sublicensee shall not perform Licensed Compound or Licensed Product production activities hereunder at any location other than the Facility, it being understood that certain ancillary Manufacturing activities that do not involve the production of Licensed Compound or Licensed Product (such as conducting tests on samples or storage) may be conducted at other facility(ies) located within India.

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 14.5.

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.

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

Licensed Product means any human pharmaceutical product or products produced under the Sublicense from GARDP 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 rights granted hereunder are limited 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 Shionogi License Agreement Effective Date, as described in Schedule A, and do not include rights to any other form, presentation, dose or formulation of cefiderocol.

Manufacture and **Manufacturing** mean any and all activities related to the production, primary 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.

Manufacturing Action Plan has the meaning given to it in Section 5.3(e).

Manufacturing Approvals means any manufacturing approvals or quality assurance assessments that may be required for the Sublicensee to Manufacture Licensed Compound and Licensed Product at the Facility in accordance with this Sublicense Agreement and to sell Licensed Product to Customers for subsequent Commercialization in the Territory, including without limitation the WHO Prequalification for the Manufacture of Licensed Compound and Licensed Product by the Sublicensee at the Facility(ies).

Minor Changes means changes to the chemistry, manufacturing and controls information described in the marketing authorisation for a given medicinal product that have minimal or no impact on the quality, safety or efficacy of the medicinal product and that do not require prior approval from the competent Regulatory Authority before implementation by the marketing authorisation holder (and that would not, if such change were made to a marketing authorisation approved by the European Medicines Agency, require the prior approval of the competent European Regulatory Authority under applicable European regulations and guidelines).

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 8.1(a).

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 Regulatory Approvals has the meaning given to it in Section 4.1.

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 means the plan of Manufacturing and Manufacturing Approval objectives and specific target dates to be achieved by the Sublicensee. The initial Sublicense Access Plan is attached as Schedule F. Any modifications thereto shall require the agreement of GARDP and the Sublicensee.

Sublicense Agreement means this Manufacturing Sublicense and Technology Transfer Agreement, together with all attached schedules, as the same may be amended or supplemented from time to time.

Sublicensee Contractor(s) has the meaning given to it in Section 3.9.

Sublicensee Licensed Product Contractor has the meaning given to it in Section 3.9.

Sublicensee Sole Inventions has the meaning given in Section 8.1(b).

Sublicensed Manufacturing Know-How means all technical information and know-how owned and/or Controlled by Shionogi or its Affiliates as of the Shionogi License Agreement Effective Date and licensed from Shionogi to GARDP under the Shionogi License Agreement (including all manufacturing data, the percentages and specifications of ingredients, the manufacturing process, specifications, assays, quality control, and testing procedures) that has been 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 or Licensed Product have been manufactured by or for Shionogi as of the Shionogi License Agreement Effective Date, including without limitation all of such disclosed or made available pursuant to Sections 4.1 or 4.2 below.

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

Sublicensed Rights means:

(a) the patents and patent applications owned or Controlled by Shionogi within India related to the Licensed Compound or Licensed Product or their Manufacturing or use that are listed on Schedule B;

(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 related to the Licensed Compound and/or the Licensed Product, and in particular the Manufacture thereof, that are necessary for the Manufacture of the Licensed Compound and/or the Licensed Product and disclosed or made available to the Sublicensee in connection with this Sublicense Agreement, all as set forth in Schedule C, which schedule may be updated from time to time by mutual agreement of the Parties. For clarity, the Sublicensed Rights include the Sublicensed Manufacturing Know-How.

Supply Agreement means each agreement for the supply of Licensed Product for use in the Territory entered into by the Sublicensee with a Commercial Sublicensee or with GARDP, as applicable, for the supply of Licensed Product to such Customer.

Technical Transfer and Technical Transfer Package have the meanings given to them in Section 4.2.

Term has the meaning given to in Section 12.1.

Territory means the countries listed in Schedule D.

Third Party means any Person other than GARDP, the Sublicensee and their respective Affiliates.

WHO means the World Health Organization.

WHO Prequalification means the prequalification by the WHO of a given active pharmaceutical ingredient ("**API"**) or finished pharmaceutical product ("**FPP"**), as applicable, and corresponding manufacturer and manufacturing site, as evidenced by the inclusion thereof in the WHO's List of Prequalified APIs or List of Prequalified FPPs, as applicable.

1.2 Interpretation

In this Sublicense Agreement:

(a) section headings are for convenience only and are not intended to affect the interpretation of this Sublicense 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 Sublicense 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.

2. SHIONOGI LICENSE AGREEMENT

2.1 Compliance with Shionogi License Agreement

The Sublicensee confirms that it has reviewed the terms and conditions of the Shionogi License Agreement, as published on GARDP's website. The Sublicensee acknowledges and agrees that this Sublicense Agreement and Sublicensee's rights and obligations under it are subject and subordinate to, and the Sublicensee shall comply with, all terms and conditions of the Shionogi License Agreement applicable to GARDP's sublicensees thereunder. To the extent that the Shionogi License Agreement explicitly requires that any terms or conditions be included in any agreement granting a sublicense under the Shionogi License Agreement, such terms and conditions are deemed to be incorporated by reference in this Sublicense Agreement. More generally, the Sublicensee shall not perform any acts or make any omissions that would place GARDP in breach of its obligations under the Shionogi License Agreement. For the avoidance of doubt, any right of GARDP under the Shionogi License Agreement not expressly sublicensed to the Sublicensee under this Sublicense Agreement remains the right of GARDP and is not implicitly sublicensed to the Sublicensee.

2.2 Access and Stewardship Objectives

As a manufacturing sublicensee of GARDP under the Shionogi License Agreement, the Sublicensee will, in furtherance of the Access and Stewardship Objectives of the Shionogi License Agreement: (a) use its best efforts to achieve the objectives set out in the Sublicense Access Plan to diligently implement the Manufacturing of, and to obtain all required Manufacturing Approvals for, the Manufacture of quality Licensed Compound and Licensed Product at the Facility(ies), and (b) use its reasonable best efforts to Manufacture sufficient and affordable quantities of quality Licensed Compound and Licensed Product to supply in a timely manner the requirements of Customers for patients in need in the Territory.

3. LICENSE GRANT

3.1 License to Sublicensed Rights and Sublicensed Manufacturing Know-How

(a) Upon the terms and subject to the conditions set out in this Sublicense Agreement, GARDP hereby grants to the Sublicensee, and the Sublicensee hereby accepts, a non-exclusive, non-sublicensable, royalty-free, non-transferable license under the Sublicensed Rights and the Sublicensed Manufacturing Know-How to Manufacture

the Licensed Compound and Licensed Product at the Facility(ies) exclusively for sale to Customers for use and distribution in the Field in the Territory and to obtain Manufacturing Approvals, strictly in accordance with this Sublicense Agreement and the Sublicense Access Plan.

(b) Notwithstanding the non-exclusive nature of the license granted by GARDP to the Sublicensee, GARDP undertakes, so long as Orchid is complying with its diligence obligations in accordance with the Sublicense Access Plan and is otherwise in compliance with this Agreement, not to grant any other sublicense under the Sublicensed Rights and the Sublicensed Manufacturing Know-How to Manufacture the Licensed Compound and Licensed Product during a period of 5 years following the Effective Date. Further, GARDP undertakes that it will not grant any such other manufacturing sublicense for an additional 2 years (*i.e.* until the 7 year anniversary of the Effective Date) so long as the demand for cefiderocol in the Territory is at most 1.5 million doses per year, Orchid is complying with its diligence obligations in accordance with the Sublicense Access Plan and is otherwise in compliance with this Agreement and Orchid is able to supply that demand during such 2-year period.

(c) These sublicense rights shall also include the right for the Sublicensee to conduct Development activities relating to chemistry, manufacturing and controls (CMC) and Manufacturing process Development activities conducted as part of the Technical Transfer, including without limitation testing activities required to demonstrate the pharmaceutical equivalence of Licensed Compound and Licensed Product Manufactured by the Sublicensee with those Manufactured by Shionogi (such activities collectively, "CMC Development Activities"), but excluding any and all other Development activities; provided, however, that Sublicensee may not perform or have performed any CMC Development Activities without the prior written consent of GARDP and Shionogi. Notwithstanding the above, Development activities that only relate to potential Minor Changes to the CMC and/or Manufacturing process shall not require the prior written consent of GARDP and Shionogi, but the Sublicensee shall provide prior written notification describing in detail any of such proposed Minor Changes to GARDP and Shionogi at least fourteen (14) days before the date on which Orchid seeks to implement such Minor Changes (the "Proposed Implementation Date").. Orchid shall not implement any such changes before GARDP and Shionogi confirm in writing their agreement that such proposed changes constitute Minor Changes; provided, however, that Orchid shall be free to move forward with implementation if neither GARDP nor Shionogi object to the proposed Minor Changes prior to the Proposed Implementation Date.

Without limiting the foregoing, any and all preclinical Development activities relating to the therapeutic indications of Licensed Compound or Licensed Product and all clinical Development activities are excluded from the license granted under this Sublicense Agreement, and the Sublicensee shall have no right to conduct any such activities under this Sublicense Agreement

(d) The Sublicensee will not have any right to practice the Sublicense granted under this Section 3.1 or otherwise exploit the Sublicensed Rights and Sublicensed Manufacturing Know-How for any other purpose. In particular, the Sublicensee may not Manufacture or sell the Licensed Compound and/or Licensed Product in combination with other active pharmaceutical ingredients.

(e) For sake of clarity, no Commercialization rights of Licensed Compound or Licensed Product are granted to the Sublicensee pursuant to this Sublicense Agreement. The

Sublicensee may not sell, transfer or supply Licensed Compound to any other person (including any Customer) and shall only sell, transfer or supply Licensed Product to Customers.

3.2 Term of Sublicense grant

The Sublicense granted to the Sublicensee in Section 3.1 with respect to Sublicensed Rights will expire upon the expiry of the Term, subject to an earlier termination in accordance with Section 12.

3.3 Sublicensee Sublicense Access Plan Commitment

The Sublicensee shall use its best efforts to achieve the Manufacturing and Manufacturing Approval objectives and specific target dates set out in the Sublicense Access Plan in furtherance of the Access and Stewardship Objectives.

Should the Sublicensee not achieve any of the objectives set out in the Sublicense Access Plan by the corresponding target dates, the Parties shall consult in good faith to discuss the situation, the causes of any such delays, and possible actions to minimize the delay and/or prevent future delays. If requested by GARDP, the Parties shall discuss and agree an access action plan to remedy the situation (each an "**Access Action Plan**"), and the Sublicensee shall diligently and in good faith implement the Access Action Plan.

3.4 No Trademark License; No Trademark Registration

No right or license, express or implied, is granted to the Sublicensee under this Sublicense Agreement to use any trademark, trade name, logo, trade dress, or service mark owned or Controlled by GARDP or by Shionogi or any of its Affiliates.

The Sublicensee shall have no right pursuant to this Sublicense Agreement to develop, register or use any trademarks or distinctive trade dress or product markings in connection with Licensed Compound and/or Licensed Product Manufactured under this Sublicense Agreement, in respect of which the Sublicensee may only use the international nonproprietary name cefiderocol and/or cefiderocol sulfate tosylate.

3.5 No Implied License

No license or other right is or will be created or granted under this Sublicense Agreement by implication, estoppels or otherwise. All licenses and rights are or will be granted only as expressly provided in this Sublicense Agreement.

3.6 Retained Rights

(a) All rights not expressly granted under this Sublicense Agreement are reserved by Shionogi and GARDP, as applicable, and Shionogi's and GARDP's use thereof for any purpose is not restricted by this Sublicense Agreement.

(b) Without limiting the foregoing, Shionogi retains any and all rights under the Sublicensed Rights and Sublicensed Manufacturing Know-How to make, have made, use, offer for sale, sell, have sold, export, import, license or exploit:

(a) the Licensed Compound and products containing the Licensed Compound for any use whether within or outside the Territory and whether within or outside the

Field; and

(b) compounds other than the Licensed Compound covered by one or more claims in the patents included in the Sublicensed Rights, for any use.

(c) Shionogi and GARDP also expressly reserve and retain the right to make or have made, and use, the Licensed Compound and the Licensed Product for any internal research purpose.

3.7 Non-diversion

(a) The Sublicensee acknowledges that the sublicense to Sublicensed Rights granted under Section 3.1 is granted solely under and with respect to the Sublicensed Rights and Sublicensed Manufacturing Know-How for the purposes of Manufacturing Licensed Product for and supplying Licensed Product in the Field in the Territory.

(b) The Sublicensee acknowledges and agrees nothing in this Sublicense Agreement will be construed as granting the 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.

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

(d) The Sublicensee shall implement a system of batch control and tracing following the GSI Global Traceability or comparable standards which will enable the identification and batch tracing of any such Licensed Product, notably so as to facilitate the determination as to whether any of such are subsequently re-exported outside the Territory. In addition, the Sublicensee shall include provisions in its Supply Agreements with each Customer to ensure that such Customer and any subsequent purchasers of the Licensed Product in all countries within the Territory shall not sell, distribute, export or donate the Licensed Product or offer the Licensed Product for sale or donation in any country outside of the countries in the Territory where the Customer has a right under its Commercial Sublicense to sell Licensed Product.

3.8 OFAC Licenses

(a) The Sublicensee represents that, to its knowledge, neither the Sublicensee nor any of its Affiliates, directors, officers, or employees, is a Sanctions Target.

(b) The Sublicensee agrees that it will not, with respect to the licensed intellectual property (including the Sublicensed Rights and Sublicensed 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. The Sublicensee shall convey such license or other authorization to GARDP and Shionogi, if required and obtained, prior to any such transactions or dealings.

The Sublicensee also agrees that prior to, directly or indirectly,

(a) making any Licensed Compound or any Licensed Product available to, or contracting for Licensed Product Manufacture with, any Sanctions Target; or

(b) 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 GARDP and Shionogi to obtain such a license or other authorization in each case to permit the Sublicensee, GARDP 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 and GARDP are in agreement with the decision to try to obtain such license or other authorization (such decision to be made in their sole discretion), GARDP shall, and shall in accordance with the Shionogi License Agreement request that Shionogi provide, reasonable assistance as requested by the Sublicensee and as may be reasonably necessary to obtain the license or other authorization; and

in the event that performance of this Sublicense Agreement by the Sublicensee would (or might), in the reasonable opinion of GARDP or Shionogi, breach, or expose GARDP or 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 Sublicense Agreement, and whether or not there have been any other changes in circumstance from those that existed at the Effective Date of this Sublicense Agreement), GARDP or Shionogi shall be entitled to immediately request that the Sublicensee (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 the Sublicensee 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 Sublicense Agreement (including any supply provisions) which require or permit performance by either Party or Shionogi which, in the reasonable opinion of Shionogi or GARDP, would result in a breach of, or expose Shionogi or GARDP to potential liability under, any such Sanctions, controls, or laws, until, in the reasonable discretion of Shionogi or GARDP, as applicable, until such time as all necessary approvals or licenses have been obtained to enable the Sublicense Agreement to continue in a lawful and compliant manner and without exposure to liability for Shionogi or GARDP. Notwithstanding any provision of the Sublicense Agreement, neither Shionogi nor GARDP shall be obliged to pay any compensation to the 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.

3.9 Sublicensee Contractors

The Sublicensee may perform its obligations under this Sublicense Agreement through one or more collaborators, consultants, agents or other contractors (**Sublicensee Contractors**) acting on behalf of the Sublicensee; provided that: (a) the activities of such Sublicensee Contractors would not require a sub-sublicense to the Sublicensed Rights (it being understood that the fact that a Sublicensee Contractor has had access to use Confidential Information in and of itself shall not require a sub-sublicense for the purposes hereof); (b) the Sublicensee remains

entirely responsible for such performance in accordance with the terms and conditions of this Sublicense Agreement as if such obligations had been performed directly by the Sublicensee, and (c) the Sublicensee shall have entered into a written agreement with such Sublicensee Contractors ensuring that the Sublicensee shall be able to comply with its obligations under this Sublicense Agreement applicable to the activities conducted by the Sublicensee Contractor, including confidentiality obligations in accordance with Section 10.2(d) and, if applicable, obligations requiring the Sublicensee Contractor to assign to the Sublicensee all intellectual property rights in and to any results generated by them in a manner that enables the Sublicensee to comply with its obligations in relation thereto as set out in Section 8. The Sublicensee shall in particular ensure that all Sublicensee Contractors comply with all quality and Manufacturing standards applicable to the activities conducted by them, including without limitation those contemplated in Sections 6.2 through 6.4 hereto.

Schedule H attached hereto contains a table of all Sublicensee Contractors that the Sublicensee currently intends to engage to conduct any activities under this Sublicense Agreement, indicating for each the activities to be conducted by the Sublicensee Contractor and the location where such activities will be conducted. The Sublicensee shall from time to time, and in any case prior to engaging a Sublicensee Contractor that is not included in the table or modifying the activities to be conducted by a Sublicensee Contractor, provide GARDP with an updated version of the table.

The Sublicensee may not engage any Sublicensee Contractors to conduct activities involving the production or making of Licensed Compound or Licensed Product without GARDP's prior written consent.

For clarity, the Sublicensee may not grant to Sublicensee Contractors any sublicense rights to Develop, Manufacture or Commercialize Licensed Compound or Licensed Product for their own account or benefit, or any right to produce, make or sell Licensed Compound or Licensed Product, it being understood that ancillary Manufacturing activities (such as conducting certain tests on samples or storage) that do not involve the production of Licensed Compound or Licensed Product may be subcontracted by the Sublicensee to Sublicensee Contractors solely to assist Sublicensee in the performance of its obligations hereunder.

4. TECHNICAL ASSISTANCE

4.1 Documentation and Assistance; Regulatory Filings in the Territory

(a) Upon the Sublicensee's request, GARDP will provide, or will in accordance with the Shionogi License Agreement request that Shionogi provide, the Sublicensee with access to the content of the regulatory filings included within the Sublicensed Rights and described on Schedule C (collectively, the "**Shionogi Regulatory Approvals"**) to the extent reasonably required for the Manufacture of Licensed Product(s) by the Sublicensee and for obtaining Manufacturing Approvals, all for use in accordance with the license granted pursuant to this Sublicense Agreement.

(b) The documentation provided by GARDP and/or Shionogi (including the Shionogi Regulatory Approvals) will not be used by the Sublicensee for any purpose other than the Development (solely to the extent permitted by Section 3.1(c)) and Manufacture of the Licensed Compound and Licensed Product in accordance with this Sublicense Agreement, and constitutes Confidential Information and trade secrets of GARDP and Shionogi.

(c) The Sublicensee shall be responsible for seeking all Manufacturing Approvals required for the Manufacture of the Licensed Product as contemplated in this Sublicense Agreement, which Manufacturing Approvals shall be in the Sublicensee's name and in respect of which the Sublicensee shall have all rights and responsibilities. The Sublicensee shall be responsible to maintain its own regulatory documentation, provided that, if Shionogi regulatory documentation has been provided to the Sublicensee, the Sublicensee shall use and maintain such documentation as it maintains its own regulatory documentation. The Sublicensee assumes full responsibility and liability to GARDP and Shionogi for any unauthorized use or disclosure of any Confidential Information received by the Sublicensee from GARDP and/or Shionogi. Any and all such documents and materials delivered to the Sublicensee pursuant to this Section 4 are and will remain the sole property of Shionogi and/or GARDP, as applicable.

(d) Shionogi will be responsible for providing one set of electronic copies only. GARDP will, or will in accordance with the Shionogi License Agreement request that Shionogi, respond to reasonable requests from the Sublicensee for clarification on the information provided under this Section 4.1, where responses to such requests are, in Shionogi's good faith judgment reasonably necessary to clarify the Manufacture (in the manner Manufactured by or for Shionogi and registered by Shionogi on the effective date of the Shionogi License Agreement) of the Licensed Compound or the Licensed Product.

(e) Notwithstanding the foregoing, the Sublicensee acknowledges that neither GARDP nor Shionogi represents that, merely because the Sublicensee is Manufacturing the Licensed Product using the Manufacturing process transferred by Shionogi, such Licensed Product Manufactured by the Sublicensee 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. Orchid shall have the right and responsibility to demonstrate the equivalence of the Licensed Product Manufactured by the Sublicensee with the product Manufactured by Shionogi for all regulatory purposes in accordance with the applicable regulatory guidelines.

(f) The Sublicensee acknowledges and agrees that neither Shionogi nor GARDP shall be responsible for the performance of additional studies or submission of additional data for the grant of Manufacturing Approvals for Licensed Compound and Licensed Product Manufactured pursuant to this Sublicense Agreement. The Sublicensee agrees not to seek any further regulatory exclusivity (*i.e.* other than Shionogi's, if applicable) in any country.

4.2 Technical Transfer Package and Technical Transfer

(a) GARDP shall transfer, or in accordance with the Shionogi License Agreement request that Shionogi transfer, to the Sublicensee one set of electronic copies of a package of documentation prepared by Shionogi of the technical information owned or controlled by Shionogi that Shionogi reasonably believes is necessary for the effective transfer to the Sublicensee of the Manufacturing process used to Manufacture the Licensed Compound and Licensed Product in the same manner that such were Manufactured on the effective date of the Shionogi License Agreement (the "**Technical Transfer Package**"). The Technical Transfer Package and all information and materials provided by or on behalf of Shionogi in connection with the technical transfer process contemplated by this Section 4.2 are trade secrets of Shionogi,

subject to the confidentiality and restricted use obligations of this Sublicense Agreement applicable to Confidential Information received by the Sublicensee.

(b) If requested by the Sublicensee, GARDP shall in accordance with the Shionogi License Agreement request that Shionogi, its Affiliates and/or its contractors conduct a technical transfer process (the "**Technical Transfer**") to provide reasonable assistance to enable the Sublicensee (and if applicable a Sublicensee Contractor) to understand and implement the Sublicensed Manufacturing Know-How. Each party involved in the Technical Transfer shall be responsible for all its own costs (including the costs of its personnel, travel and lodging) incurred in connection therewith, including those of its respective Affiliates and contractors. For clarity, the Sublicensee shall thereafter be responsible for all its Manufacturing Development costs and the costs incurred to obtain Manufacturing Approvals. If requested by Shionogi, the Sublicensee (and if applicable any Sublicensee Contractor involved in any such technical transfer process) shall enter into a separate agreement with Shionogi to govern the terms and conditions of such technical transfer process, which agreement shall be consistent with all the relevant terms and conditions of this Sublicense Agreement. If requested by GARDP, the Sublicensee shall permit representatives of GARDP to participate in the technical transfer process and shall share with GARDP one electronic copy of all information received from Shionogi or its contractors in connection with such technical transfer.

4.3 Regulatory Assistance to Commercial Sublicensees

The Sublicensee shall provide assistance to any Commercial Sublicensees as may be reasonably requested by them to make submissions to obtain regulatory approval to Commercialize Licensed Product in the countries for which they have a Commercial Sublicense. This assistance shall include providing access to any information included in the Sublicensee's WHO Prequalification filings as may be required for the regulatory submissions of Commercial Sublicensees or to respond to any enquiries by the competent regulatory authorities.

4.4 Technical Transfer to Other Manufacturer

(a) GARDP may at any time request that the Sublicensee perform a technical transfer of the Manufacturing processes used by Sublicensee to Manufacture Licensed Compound and/or Licensed Product to a Third Party manufacturer. This technical transfer shall include a transfer to the Third Party manufacturer of a copy of all relevant documentation in the Sublicensee's [or its contractor's] possession or control describing the relevant Manufacturing processes, and if applicable the right for the Third Party manufacturer to access and/or refer to the Sublicensee's Manufacturing Approvals. The Sublicensee shall assign qualified personnel of the Sublicensee [and/or its contractors] to diligently and in good faith perform the technical transfer to the Third Party manufacturer, including if applicable by training Third Party manufacturer personnel at its or its contractor's facility(ies) or at the Third Party's manufacturing facility, and generally providing reasonable assistance to enable the Third Party to understand and implement at their facility(ies) the Manufacturing processes used by or for the Sublicensee to Manufacture Licensed Compound and Licensed Product. The technical transfer to the Third Party shall include a non-exclusive, fully paid-up license to use and practice the transferred processes and any intellectual property (including know-how and trade secret and if applicable patent rights) the Sublicensee may have in or to the transferred processes, solely for the purposes of the Licensed Compound and Licensed Product licenses

granted to the Third Party by GARDP and/or Shionogi. If requested by the Sublicensee, the Third-Party manufacturer shall enter into a written agreement with the Sublicensee undertaking to protect the confidentiality of the transferred processes and to use them solely for the purposes for which it has obtained a license from GARDP and/or Shionogi.

(b) GARDP shall compensate the Sublicensee for the time spent performing the technical transfer services contemplated in paragraph (a) above based on a reasonable fee agreed by the Parties and shall reimburse the Sublicensee for any reasonable out of pocket expenses engaged to give effect to the technical transfer. Notwithstanding the preceding sentence, the Sublicensee's conduct of any such technical transfer shall be at its entire cost if the technical transfer is requested by GARDP following a breach by the Sublicensee of its obligations under this Sublicense Agreement and/or if the technical transfer is required because the Sublicensee has not successfully implemented an Access Action Plan agreed by the Parties pursuant to Section 3.3 above or a Manufacturing Action Plan agreed by the Parties pursuant to Section 5.3 below.

5. MANUFACTURE AND SUPPLY

5.1 Manufacture and Supply Obligations

(a) The Sublicensee shall enter into a written Supply Agreement with each Customer for the supply of Licensed Product manufactured under this Sublicense Agreement. Each such Supply Agreement shall be consistent with all the terms and conditions of this Sublicense Agreement. The Sublicensee shall provide to GARDP a copy of each proposed Supply Agreement and of any amendments thereto for GARDP's review, and shall not enter into any such agreement without GARDP's prior written consent. The Sublicensee shall provide GARDP with a copy of each signed Supply Agreement and amendment thereto within thirty (30) days following their execution. In the event of any inconsistency between the obligations of this Sublicense Agreement and those set out any Supply Agreement, the terms of this Sublicense Agreement shall prevail for the purposes of this Sublicense Agreement. The Sublicensee shall also enter into a Quality Agreement with each Customer setting out the Parties' respective responsibilities for all quality and regulatory matters, and shall share a copy thereof with GARDP. For the avoidance of doubt, the Sublicensee shall not transfer, supply or sell Licensed Compound to any Customer or other Third Party (other than Sublicensee Contractors that require such for the Manufacturing activities conducted by them for the account of the Sublicensee).

(b) The Sublicensee shall perform all its obligations under this Sublicense Agreement in compliance with all applicable laws and regulations and with all the obligations and specifications set out in this Sublicense Agreement and its Schedules, together with all applicable obligations set out in the relevant Supply Agreement.

(c) The Sublicensee will be solely responsible at its expense for making or having made Licensed Compound and Licensed Product, including all costs for procuring and qualifying equipment and materials, at the designated Facility(ies) in conformity with all applicable specifications and will hold all relevant authorizations and permits required in this respect. The Sublicensee shall in particular be responsible for obtaining and maintaining throughout the Term all Manufacturing Approvals for the Manufacture of Licensed Compound and Licensed Product at the Facility(ies) and all

required certifications, approvals or licenses from national or local authorities for the Facility(ies) involved in the production thereof.

(d) The Sublicensee will use its reasonable best efforts to Manufacture sufficient quantities of the Licensed Compound and the Licensed Product to supply in a timely manner the requirements of all Commercial Sublicensees and GARDP for Licensed Product in the Territory. In furtherance of this objective, the Sublicensee shall in particular devote adequate facilities and equipment, shall order and maintain a sufficient buffer stock of materials, and shall Manufacture and maintain a sufficient buffer stock of Licensed Compound, as required to Manufacture and supply in a timely manner the quantities of Licensed Product forecast and ordered by Customers. The Sublicensee shall use its reasonable best efforts to supply all Customer orders for Licensed Product within one hundred and twenty (120) days from the order at the latest, unless otherwise agreed in the relevant Supply Agreement.

5.2 Price

In furtherance of the access objective of making Licensed Product for the Territory available at an affordable and sustainable price, the Sublicensee shall sell Licensed Product to Customers at a price equal to the cost of goods to Manufacture Licensed Product plus a maximum agreed profit margin, calculated in accordance with the principles set out in Schedule I hereto. The actual price at which the Sublicensee shall sell Licensed Product to any given Customer shall be negotiated by the Sublicensee in each Supply Agreement, but shall in any case be subject to the maximum price calculated in accordance with the principles set out above.

The Sublicensee shall make all its accounts used to calculate its cost of goods available to GARDP or its agent on an open book basis and shall report these costs to GARDP on a regular basis in accordance with Section 9.1 and make its accounts available for audit in accordance with Section 9.3(a).

5.3 Forecasts and Management of Supply

(a) GARDP and the Sublicensee shall consult with each other from time to time and in any case at least quarterly concerning estimated dates at which Commercial Sublicensees will file applications for and obtain regulatory approvals to Commercialize Licensed Product in various countries in the Territory and estimated requirements for Licensed Product in countries in which an application for a regulatory approval has been filed. The estimates exchanged in such consultations shall be indicative only, and neither Party shall have any liability in respect thereof.

(b) The forecasting and ordering conditions for each Customer of Licensed Product shall be defined in the Supply Agreement entered into by the Sublicensee with such Customer, which shall include for example as applicable: a forecasting mechanism, minimum order quantities linked to the batch size for Manufacturing, timelines between orders and delivery and remaining shelf life at delivery.

(c) The Sublicensee shall allocate supply of Licensed Product among its Customers and if applicable itself as a Commercial Sublicense on an equitable first ordered first served basis.

(d) The Sublicensee and GARDP shall discuss and agree on specific key performance indicators to assess and track the Sublicensee's Manufacturing and delivery

performance under this Sublicense Agreement. The Sublicensee shall report all such key performance indicators agreed by the Parties to GARDP on a quarterly basis in accordance with Section 9.1, which shall include at least the following: (a) the latest forecasts received from each Customer (and shall in such report provide a corresponding forecast for Licensed Product to be Manufactured for Commercialization by the Sublicensee in countries for which the Sublicensee has a Commercial Sublicense); (b) all indicative and firm orders received from each Customer and if applicable by the Sublicensee and corresponding contractual delivery dates; (c) all deliveries of Licensed Product made (whether to a Customer or to the Sublicensee for Commercialization in countries for which it has a Commercial Sublicense); (d) any delays in Licensed Product deliveries as compared with the contractual delivery dates; and (e) any rejections by Customers or by the Sublicensee of Licensed Product deliveries or other concerns raised by Customers or identified by the Sublicensee as to the conformity of Licensed Product deliveries with specifications or other Manufacturing obligations, and updates to any such rejections or concerns; in each case (a) through (e) occurring during the corresponding reporting period.

(e) Should the Sublicensee not have sufficient capacity to Manufacture and supply the Licensed Product requirements of all Customers and of the Sublicensee or should there be any recurrent delays in the deliveries of Licensed Product to one or more Customers or should there be any recurrent rejections of Licensed Product deliveries or other concerns raised as to the quality or conformity of Licensed Product deliveries, the Parties shall consult in good faith to discuss the situation, the causes of any such delays, incidents or concerns and possible actions to address the insufficient capacity or prevent future delays, incidents or concerns. If requested by GARDP, the Parties shall discuss and agree a manufacturing action plan to implement actions to remedy the situation (each a "**Manufacturing Action Plan**"), and the Sublicensee shall diligently and in good faith implement the Manufacturing Action Plan.

6. PHARMACOVIGILANCE AND QUALITY MATTERS

6.1 Pharmacovigilance and Adverse Event Reporting

(a) The Parties agree that the primary regulatory responsibility for pharmacovigilance and adverse event reporting for Licensed Product in any given country in the Territory shall lie with the Commercial Sublicensee commercializing Licensed Product in such country. However, the Sublicensee will, in accordance with its standard protocols, maintain effective and reliable systems for receiving and tabulating any reports of adverse reactions to the Licensed Product and any quality concerns reported to the Sublicensee by any Customers or other Third Parties. The Sublicensee will promptly report to any Customers concerned any safety concerns relating to Licensed Product identified by the Sublicensee. The responsibilities of the Sublicensee for safety related or Licensed Product related inquiries will be performed in accordance with applicable local laws and regulations and with the relevant Supply Agreement(s) and if applicable any Safety Data Exchange Agreement entered into pursuant to paragraph (b) below.

(b) The Sublicensee acknowledges that Shionogi will be responsible for maintaining the global pharmacovigilance database for the Licensed Product. The Sublicensee undertakes to enter into a Safety Data Exchange Agreement ("**SDEA**") with Shionogi, GARDP and Commercial Sublicensees on terms reasonably acceptable to Shionogi and

based on a first draft proposed by Shionogi, governing the exchange of Licensed Product safety information among the Sublicensee, Shionogi, GARDP and Commercial Sublicensees that is consistent with applicable regulations and global pharmacovigilance standards. Such SDEA shall be entered into by the parties no later than the first sale of Licensed Product by the Sublicensee to a Customer.

6.2 Quality – Manufacturing Standards

(a) The Sublicensee will Manufacture the Licensed Compound and the Licensed Product in a manner consistent with:

(i) Good Manufacturing Practices; and

(ii) the WHO Prequalification standards and specifications set out in the Sublicensee's WHO Prequalification submission and approval.

If applicable and if requested by GARDP in the event the Facility(ies) is/are audited and approved by a Stringent Regulatory Authority ("**SRA**"), and as an alternative to WHO Prequalification contemplated in (ii) above, the Sublicensee will Manufacture the Licensed Compound and the Licensed Product in a manner consistent with the standards of the SRA.

(b) Until the Facilities are audited and approved by WHO Prequalification or an SRA, the Sublicensee shall if requested by GARDP allow a Third Party regulatory expert appointed by GARDP to conduct a GMP audit of the Sublicense's Facility and Manufacturing processes (and if applicable those of any Sublicensee Contractors involved in the production of Licensed Compound of Licensed Product) and to assess and confirm the Sublicensee's compliance with WHO Prequalification standards or a SRA's standards, and in such case the Sublicensee will Manufacture the Licensed Compound and the Licensed Product in a manner consistent with the relevant standards.

(c) The Sublicensee shall provide GARDP and Shionogi the ability to review and comment on the content of any preclinical and clinical data portions of all filings for any Manufacturing Approvals made by or for the Sublicensee for the Licensed Product as well as, if applicable, all proposed product labels, package inserts and Company Core Data Sheets (CCDS) (including a list prepared by GARDP and/or the Sublicensee of deviations between the proposed CCDS and the then-existing CCDS of Shionogi) proposed to be submitted to Regulatory Authorities or other competent authorities (including the WHO), if any, for Manufacturing Approvals to be obtained by the Sublicensee for the Licensed Product. Copies of all such documents shall be provided to GARDP and Shionogi in English. GARDP and Shionogi shall have the right to oppose any proposed 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 GARDP's or Shionogi's opposition, as applicable, has been resolved.

6.3 Environmental, Health, Safety, Labor, Ethics and Antibiotic Manufacture Standards

The Sublicensee shall Manufacture all Licensed Compound and Licensed Product in accordance with the standards and requirements set out in Schedule K attached hereto. The Sublicensee shall allow GARDP or its agents to conduct periodic reviews (including on-site audits and/or inspections) of the Sublicensee and its Facility(ies) and practices to confirm compliance with

these standards and requirements. The Sublicensee shall implement at its cost any required actions to remediate any noncompliance identified in any such audits.

The Sublicensee shall in particular Manufacture Licensed Compound and Licensed Product in accordance with any applicable industry standards for the responsible Manufacture of antibiotics.

6.4 Stability Testing and Storage

The Sublicensee shall perform stability testing for and storage of Licensed Compound and Licensed Product in accordance with applicable WHO Prequalification guidelines.

7. REPRESENTATIONS AND WARRANTIES

7.1 General

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

(a) it is duly organized and validly existing under the applicable law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Sublicense Agreement and to carry out the provisions hereof;

(b) it is qualified to do business and is in good standing in each jurisdiction in which it conducts business;

(c) it is duly authorized to execute and deliver this Sublicense Agreement and to perform its obligations hereunder, and the Person executing this Sublicense Agreement on its behalf has been duly authorized to do so by all requisite corporate or institutional action;

(d) this Sublicense Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Sublicense 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;

(e) the performance of this Sublicense Agreement by either Party does not create a breach or default under any other agreement to which it is a party; and

(f) 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).

7.2 Representations, warranties and covenants of the Sublicensee

The Sublicensee warrants and covenants to GARDP and Shionogi that:

(a) it has the capability and intent to manufacture the Licensed Compound and Licensed Product to ensure affordable and sustainable access to quality Licensed Products through this Sublicense Agreement, and will use reasonable best efforts to seek, obtain and thereafter maintain continuously in good standing all Manufacturing Approvals required for such manufacture and related activities;

(b) 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; and the Sublicensee will certify to GARDP, at the frequency requested by GARDP (and at least once annually), its compliance with its obligations under this Sublicense Agreement (including compliance with the U.S. Foreign Corrupt Practices Act and the UK Bribery Act 2010);

(c) all of its activities related to the use of the Sublicensed Rights and Sublicensed Manufacturing Know-How and the Development and Manufacture of the Licensed Compound and of the Licensed Product pursuant to this Sublicense Agreement will comply with all applicable legal and regulatory requirements;

(d) it will, during the Term, perform regular internal due diligence to ensure ongoing compliance with all applicable laws and the terms of this Sublicense Agreement; and

(e) it will not engage in any activities that use the Sublicensed Rights and/or Sublicensed Manufactured Know-How in a manner that is outside the scope of the license rights granted to it under this Sublicense Agreement and that any modifications to the manufacturing process or compound technology will be undertaken at the Sublicensee's sole risk and in no event will Shionogi or GARDP indemnify, hold harmless or defend Sublicensee for any such modifications.

7.3 "AS IS" license

(a) Notwithstanding any other provision of this Sublicense Agreement, the Sublicensee acknowledges and agrees that the Sublicensed Rights and Sublicensed Manufacturing Know-How are licensed to the Sublicensee "as is".

(b) The Sublicensee acknowledges and agrees that neither Shionogi nor any of its Affiliates nor GARDP will have any 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 Compound and/or Licensed Product by the Sublicensee.

(c) Notwithstanding any other provision of this Sublicense Agreement, neither GARDP nor Shionogi nor any of its Affiliates makes any representation or warranty of non-infringement or any representation or warranty that the Sublicensed Rights or Sublicensed Manufacturing Know-How is suitable for any purpose for which it may be used by the Sublicensee.

(d) The Sublicensee acknowledges that Shionogi, its Affiliates and GARDP have made no representations or warranties to the Sublicensee regarding the Sublicensed Rights or the Licensed Product, and that the Sublicensee has independently evaluated any information supplied by or on behalf of Shionogi, its Affiliates and GARDP before making its decision to enter into the Sublicense Agreement and undertake the commitments and obligations set forth herein.

7.4 Disclaimer

(a) Shionogi and its Affiliates makes no, and except for Section 7.1 GARDP 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 Sublicensed Rights or Sublicensed Manufacturing Know-How or any license granted by GARDP under this Sublicense Agreement, or with respect to any compounds or products.

(B) FURTHERMORE, NOTHING IN THIS SUBLICENSE AGREEMENT WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE SUBLICENSED RIGHTS ARE VALID OR ENFORCEABLE OR THAT THE SUBLICENSEE'S USE OF THE SUBLICENSED RIGHTS AND SUBLICENSED MANUFACTURING KNOW-HOW CONTEMPLATED UNDER THIS SUBLICENSE AGREEMENT DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

7.5 Additional Waiver

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

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 THE SUBLICENSEE BY GARDP WITH RESPECT TO THE ACTIVITIES CONTEMPLATED BY THIS SUBLICENSE AGREEMENT, WHETHER BY MEANS OF INDEMNIFICATION OR OTHERWISE, SHALL BE LIMITED TO THE INSURANCE PROCEEDS ACTUALLY RECOVERED BY GARDP FROM ITS INSURERS FOR THE CORRESPONDING CLAIM(S). For the avoidance of doubt, the fact that no amount will be due to the Sublicensee unless insurance proceeds are received by GARDP may not be used as a justification not to pay the corresponding insurance proceeds to GARDP that would otherwise be due by the insurer.

8. INTELLECTUAL PROPERTY, PATENT MAINTENANCE, INFRINGEMENT

8.1 Intellectual property

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 or after the Effective Date relating to the Licensed Compound or any Licensed Product, including the Sublicensed 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 granted to GARDP.

(a) **Manufacturing Process Results**

(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 non-public proprietary information or confidential information or intellectual property of Shionogi and the Sublicensee will provide reasonable assistance to Shionogi, as may be required, for such patenting and related prosecution; and

The 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 Shionogi.

(ii) The Process Results shall be considered confidential information of the party who owns the results, provided that each of Shionogi, GARDP and the 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 Shionogi License Agreement.

(iii) Shionogi shall have the sub-licensable 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.

(b) **General Conditions Applicable to all Sublicense Results**

(i) The Sublicensee grants Shionogi a free, perpetual, nonexclusive, sub-licensable license to use Sublicense Results owned by the Sublicensee (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization, of the Licensed Product worldwide.

(ii) The Sublicensee grants GARDP a free, nonexclusive, sublicensable license to use Sublicense Results owned by the Sublicensee (including any intellectual property rights thereon) for the Development, Manufacture, and Commercialization of the Licensed Product in the Territory pursuant to the Agreement.

(iii) All Sublicense Results owned by Shionogi (including any intellectual property rights

thereon) shall be included in the License Rights licensed to Shionogi pursuant to the Agreement and Sublicensed to Sublicensee pursuant to this Sublicense Agreement.

8.2 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 Sublicensed Rights in the Territory. The 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.

8.3 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. The Sublicensee acknowledges that, in accordance with the Shionogi License Agreement, Shionogi has the right, in its discretion and at its expense, to bring any action or proceeding with respect to such infringement and to control its conduct (including any settlement). 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.

9. AUDITS AND REPORTS

9.1 Reports

The Sublicensee will send to GARDP, following the end of each calendar quarter, a report setting out all information required to be reported to GARDP pursuant to this Sublicense Agreement, including in particular the information set out in Schedule J hereto. The specific timeframes for reporting each category of information is specified in Schedule J. The Sublicensee and GARDP agree to confer on a quarterly basis regarding such reports the activities and information contained therein. GARDP agrees that information contained in quarterly and other such reports shall be treated as Confidential Information. The Sublicensee agrees that GARDP may share such information and reports with Shionogi and that GARDP and Shionogi may share all such information and reports with their Affiliates or with Third Parties for the purposes of pursuing the Access and Stewardship Objectives (subject to confidentiality and non-use obligations substantially similar to those set out in Section 10 hereof).

9.2 Records

The Sublicensee shall keep at its principal place of business true and accurate records of all the information underlying the reports made to GARDP pursuant to Section 9.1, including without limitation proper and comprehensive books of account of all costs used to calculate the cost of goods to Manufacture Licensed Product. Records must be maintained for at least ten (10) years, or such longer period as may be required by applicable laws or regulations.

9.3 Audits and Inspections

(a) The Sublicensee agrees at all reasonable times to permit Shionogi's and/or GARDP's

auditor to access, inspect and review the accounts, books and records referred to in Section 9.2. Such examination shall be conducted at Shionogi's or GARDP's, as applicable, expense by an independent accountant, subject to execution of a customary confidentiality agreement with the 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. The Sublicensee agrees to give Shionogi's and/or GARDP'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 the Sublicensee's compliance with this Sublicense Agreement to be verified. If an audit conducted in accordance with this Section 9.3(a) identifies an overstatement by the Sublicensee of more than ten percent (10%) as compared with the actual cost of goods incurred in any consecutive period of four quarters, the costs of the audit are to be reimbursed to Shionogi and/or GARDP by the Sublicensee on demand. In any such case, the Sublicensee shall if applicable credit or reimburse to the relevant Commercial Sublicensees any excess price that may have been invoiced by the Sublicensee as compared with the maximum sales price defined in Section 5.2. Shionogi's and GARDP's rights under this Section 9.3(a) above apply during the Term and for four (4) years thereafter.

(b) The Sublicensee also agrees to permit appropriate representatives of Shionogi and/or GARDP to inspect, at their cost, the Sublicensee's facilities and those of any Sublicensee Contractors involved in any Licensed Compound or Licensed Product Manufacturing activities (including any storage facilities) in order to verify the Sublicensee's compliance with this Sublicense Agreement, including without limitation compliance with GMP and with the standards and requirements set out in Schedule K. At least ten (10) 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. The 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. The Sublicensee shall implement at its cost any required actions to remediate any noncompliance identified in any such inspections. The Sublicensee shall discuss in good faith and agree with GARDP (including with respect to timing) an action plan to remediate any such noncompliance, and the Sublicensee shall diligently and in good faith implement the action plan and provide GARDP a periodic progress report.

(c) The Sublicensee shall promptly inform GARDP of any SRA or WHO audits or findings, including any of such that relate to the Facility generally, that could have an adverse effect on the Sublicensee's Manufacture of Licensed Compound and/or Licensed Product or on their availability.

(d) The Sublicensee shall share and discuss with GARDP its plans for the design, installation and operation of the Facility for the Manufacture of Licensed Product, and shall keep GARDP regularly informed of the implementation thereof.

10. CONFIDENTIALITY AND NON-DISCLOSURE

10.1 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 Sublicensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Shionogi's European Union and United States cefiderocol regulatory filings received or accessed by the Sublicensee, and any other trade secrets of Shionogi, 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 Sublicense Agreement or such use is reasonably necessary for the performance of its obligations or the exercise of its rights under this Sublicense 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 Sublicense Agreement, including the terms of this Sublicense 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 Sublicensed Rights (including the Sublicensed Manufacturing Know-How), 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 10.1 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.

10.2 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:

(a) regulatory filings;

(b) prosecuting or defending litigation;

(c) 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

(d) disclosure, in connection the receiving Party's performance of its obligations or exercise of its rights under this Sublicense 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 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, without limitation, any Sublicensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Shionogi's European Union and United States cefiderocol regulatory filings received or accessed by the Sublicensee, and any other trade secrets of Shionogi, 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.

(e) 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 Sublicense 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.

10.3 Destruction of Confidential Information.

Within sixty (60) Business Days after termination or expiration of this Sublicense 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 10.3; 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 Sublicensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Shionogi's European Union and United States cefiderocol regulatory filings received or accessed by the Sublicensee, and any other trade secrets of the Shionogi, 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 the 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 Sublicense 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 10 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, the Sublicensee is prohibited from retaining any Confidential Information received by the Sublicensee that constitutes trade secrets, including, without limitation, the Sublicensed Manufacturing Know-How, including the content of the Technical Transfer Package, and the content of Shionogi's European Union and United States cefiderocol regulatory filings received or accessed by the Sublicensee, and any other trade secrets of Shionogi, 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 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 10 above.

11. INDEMNITY

11.1 Indemnification by Sublicensee of GARDP and Shionogi

The Sublicensee hereby agrees to defend, hold harmless and indemnify GARDP and Shionogi and their respective Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns, and representatives, 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 the Sublicensee or its Affiliates pursuant to this Sublicense Agreement;

(b) any material breach by the Sublicensee of any of the provisions of this Sublicense Agreement;

(c) any negligence or willful misconduct by or on behalf of Sublicensee;

(d) the Sublicensee's use and practice of the Sublicensed Rights and Sublicensed 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.

11.2 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 11.2, provided that, the failure to provide such prompt notice shall not relieve the Indemnifying Party of any of its obligations under this Section 11.2 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 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.

11.3 Insurance

(a) The Sublicensee and its Affiliates 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 (5) years thereafter:

(i) 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:

- death of, or bodily injury (including disease or illness) to, any person in connection with the use or administration of Licensed Product; and

- loss of, or damage to, property, happening in any country where the 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 USD $10 million.

and

(ii) Any other insurance required by law.

(b) To the extent practicable, GARDP and Shionogi shall be noted as an interested party on all policies required under Section 11.3, and within ten (10) Business Days of a request from GARDP or Shionogi, the Sublicensee must produce evidence that the insurances required by this Section 11 are being maintained, including providing copies of policy documents. The Sublicensee must notify GARDP and Shionogi 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 11.

(c) If any event occurs which may give rise to a claim involving GARDP or Shionogi under any policy of insurance to be taken out by the Sublicensee under this Section 11, then Sublicensee must:

(i) Notify GARDP and/or Shionogi as soon as reasonably practicable but in any event within ten (10) Business Days of the occurrence of that event; and

(ii) Ensure that GARDP and/or Shionogi is kept fully informed of any subsequent actions and developments concerning the relevant claim.

12. TERM AND TERMINATION

12.1 Term

(a) This Sublicense Agreement will commence as of the Effective Date and, unless sooner terminated in accordance with the terms of this Sublicense Agreement or by mutual written consent, will expire upon the date of expiry 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, if at such date any Commercial Sublicensee is pursuing the Commercialization of Licensed Product Manufactured by the Sublicensee, the Sublicense Agreement will survive for so long as the Commercialization of Licensed Product Manufactured by the Sublicensee is being pursued (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).

(b) The Sublicense Agreement shall also terminate automatically upon the termination of the Shionogi License Agreement; provided that, in such a case, GARDP will if requested by the Sublicensee and if the Sublicensee is in material compliance with its obligations under this Sublicense Agreement, request that Shionogi negotiate in good faith with the intent to enter into a new and separate license agreement directly between Shionogi and the Sublicensee on terms reasonably acceptable to Shionogi and the Sublicensee, it being understood and agreed that Shionogi reserves the right to require additional terms to be included in such license as may be needed to protect its interests.

12.2 Termination by either Party

Either Party will have the right to terminate this Sublicense 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, insolvent or cannot pay its debts when due; or

(b) a material breach of this Sublicense 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) GARDP will have the right to terminate this Sublicense Agreement upon delivery of written notice to the Sublicensee upon the occurrence of any of the following:

(i) the failure of the Sublicensee to use its reasonable best efforts to diligently implement the Manufacturing of, and to obtain and maintain all required Manufacturing Approvals for, the Manufacture of quality Licensed Compound and Licensed Product at the Facility(ies) and to Manufacture sufficient and affordable quantities of quality Licensed Compound and of Licensed Product to supply in a timely manner the requirements of Commercial Sublicensees and of GARDP for patients in need in the Territory.

(ii) the failure of the Sublicensee to diligently implement a Manufacturing Action Plan agreed in accordance with Section 5.3(e);

(iii) the failure of the Sublicensee to comply with GARDP's or Shionogi's reasonable requests under Sections 2.3(n) through (q) of the Shionogi License Agreement;

(iv) any failure by the Sublicensee to ensure compliance with relevant OFAC regulations under Section 3.8 of this Sublicense Agreement;

(v) the occurrence of any material safety issue that Shionogi or GARDP reasonably believes makes it inadvisable to proceed or continue with the Commercialization of the Licensed Product in the Territory;

(vi) without prejudice to Section 3.7, a cross border diversion of the Licensed Product whereby the Sublicensee uses, offers for sale, sells, or has sold Licensed Products for use in any country outside of the Territory, whether directly or indirectly or through a Third Party, located in or out of the Territory, except in

cases where such diversion outside of the Territory results from the action of a Commercial Sublicensee without knowledge of the Sublicensee, and where the Sublicensee, upon becoming aware of such diversion, takes all appropriate action and uses diligent efforts to cause such diversion to cease;

(vii) any failure by the Sublicensee to comply with the quality requirements under Section 6.2 of this Sublicense Agreement for any Licensed Product Manufactured by Sublicensee;

(viii) the failure of the Sublicensee to diligently implement an Access Action Plan agreed in accordance with Section 3.3;

(ix) the occurrence of a direct or indirect Change of Control of the Sublicensee (with control having the meaning set out in the definition of Affiliate), unless Shionogi and GARDP have previously confirmed in writing that they would not terminate the Sublicense Agreement based on such change of control;

(x) in the event of any serious or intentional violation of any laws and regulations or misappropriation of a Third Party's intellectual property rights by the Sublicensee anywhere in the world, which in GARDP's or Shionogi's judgment, may reflect unfavorably on GARDP or Shionogi, their reputation or the Licensed Product.

(b) GARDP may terminate this Sublicense Agreement without cause at any time upon a fifteen (15) month advance written notice given to the Sublicensee. If the effective date of termination were to occur during the first 5 years of commercialization of the Licensed Product in the Territory, Orchid will, in accordance with the principles relating thereto agreed by the Parties in writing, be entitled to a reimbursement by GARDP of the remaining balance (if any) of its capital expenditure investments specifically made to Manufacture Licensed Product, after deducting any grants or subsidies received and all recoupment fees received and/or depreciation amounts accrued for such investments by the Sublicensee.

12.4 Scope of termination

Except as otherwise expressly provided in this Sublicense Agreement, any termination of this Sublicense 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 Sublicense Agreement, all rights and licenses granted to the Sublicensee under Section 3 will terminate, and all rights, licenses and cross-references will revert to GARDP, and the Sublicensee will cease all use of the Sublicensed Rights and the Sublicensed Manufacturing Know-How ; provided, however, that Sublicensee may make use of the Sublicensed Rights and Sublicensed Manufacturing Know-How solely to perform its obligations under section 12.5 (c).

(b) Upon termination of this Sublicense Agreement, Sublicensee will immediately cease all Manufacturing of the Licensed Compound and/or Licensed Product, and upon GARDP's request and with Shionogi's prior written consent, Sublicensee will (x) sell to designated Customer(s), or (y) destroy at Sublicensee's cost and expense, remaining Licensed Product and/or Licensed Compound.

(c) Upon termination of the Sublicense Agreement for any reason, GARDP retains the right to compel the Sublicensee to conduct a technical transfer to a Third Party manufacturer in accordance with Section 4.4.

(d) It is understood and agreed that GARDP 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.

(e) Neither Party will be relieved of any obligation that accrued prior to the effective date of termination.

The Parties acknowledge that the right of either Party to terminate this Sublicense 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 to either of the Parties or to Shionogi.

12.6 Survival

The following provisions will survive termination or expiration of this Sublicense Agreement, as well as any other provisions which by their nature are intended to survive termination or expiration: Section 1 (as applicable), Sections 7.4, 7.5, 7.6, 8, 9, 10, 11, 12, 13 and 14.

12.7 Termination cooperation

Upon the termination or expiration of this Sublicense Agreement, the Parties will cooperate with one another to provide for an orderly wind-down of the transactions contemplated in this Sublicense Agreement, including as applicable an orderly management of any remaining inventory of the Licensed Compound and the Licensed Product in accordance with Section 12.5(b).

12.8 Bankruptcy

The Parties agree that in the event a Party becomes a debtor under Title 11 of the U.S. Code, this Sublicense 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 Sublicense Agreement will be deemed to be "agreements supplementary to" this Sublicense Agreement for the purposes of Section 365(n) of such Title 11.

12.9 Business Continuity Plan

The Sublicensee shall diligently develop and implement a manufacturing and business continuity plan to ensure the continued supply of Licensed Product to its Customers. This plan shall be shared and discussed with GARDP.

13. DISPUTE RESOLUTION

13.1 Resolution by senior executives

(a) All disputes, controversies or claims between the Parties in connection with this

Sublicense Agreement, its construction, or the rights, duties or liabilities of either Party under this Sublicense Agreement (a "**Dispute**") must be resolved pursuant to the following resolution process in this Section 13.1 and the arbitration process in Section 13.2. The Parties to any such Dispute 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 Executive Director of GARDP and to Whole-time Director of the Sublicensee (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 demand resolution of the Dispute by binding arbitration pursuant to Section 13.2.

13.2 Arbitration and Injunctive Relief

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 in accordance with the WIPO arbitration rules. The arbitration proceedings shall be conducted in the English language and the place of arbitration shall be Geneva, Switzerland, or another WIPO arbitration location as may be mutually agreed by the Parties.

Notwithstanding the above, if any Dispute that is not resolved in accordance with Section 13.1 also involves a dispute under the Shionogi License Agreement or involves a matter in respect of which Shionogi may be a party in interest, then the preceding paragraph shall not apply and 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 in such case 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.

The Parties acknowledge and agree that the breach by either Party of the provisions of this Sublicense 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 also 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.

14. MISCELLANEOUS

14.1 Sublicense Agreement Management

(a) At the Effective Date, GARDP and the Sublicensee will each appoint an individual as **Sublicense Agreement Manager**. GARDP and the Sublicensee may update the identity of its Sublicense Agreement Manager during the Term by notice in writing to the other Party.

(b) The Sublicense Agreement Managers of each Party will meet in person or discuss via teleconference at least once a quarter during the Term to discuss performance of each Party's obligations under this Sublicense Agreement and any other matters as notified by either Party in advance of such meeting.

14.2 Severability

If any one or more of the provisions of this Sublicense Agreement is held to be invalid or unenforceable, the provision will be considered severed from this Sublicense Agreement and will not serve to invalidate any remaining provisions of this Sublicense 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 Sublicense Agreement may be realized.

14.3 Compliance with Laws

The Sublicensee shall comply with all applicable laws and regulations in the Territory in exercising its rights and performing its obligations under this Sublicense Agreement. Without limiting the foregoing, the Sublicensee shall: (a) mark, and shall cause its sub-sublicensees to mark, all Licensed Product Manufactured or sold under this Sublicense Agreement with all notices relating to the Sublicensed Rights to the extent required by the marking laws of the countries in which the Licensed Product will be Commercialized; (b) record this Sublicense 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.

14.4 Notices

(a) Any notice required or permitted to be given under this Sublicense 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 GARDP:

GARDP Foundation
15 Chemin Camille-Vidart
1202 Geneva, Switzerland
Attention: General Counsel
Email: legal@gardp.org

(ii) If to the Sublicensee:

Orchid Pharma Ltd,
151, SIDCO Industrial Area, Alathur, Dist. Chengalpattu, Tamil Nadu, India 603110

(b) Any such notice will be deemed delivered on the date received. A Party and/or Shionogi 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 and/or Shionogi's notices in accordance with this Section 14.4.

14.5 Force Majeure

(a) No Party will be liable for any failure to perform its obligations under this Sublicense 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.

(b) As used in this Sublicense 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 Party of such declaration.

(c) 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.

(d) If an event of Force Majeure occurs, the obligations of the Parties under this Sublicense 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.

14.6 Assignment

(a) GARDP may, without the Sublicensee's consent, assign or transfer all of its rights and obligations under this Sublicense Agreement to any Affiliate of GARDP or to any Person that acquires all or substantially all of its assets to which this Sublicense Agreement relates (including the Shionogi License Agreement), provided that such Affiliate or Person shall undertake directly in writing to the Sublicensee to assume and

comply with all of GARDP's obligations under this Sublicense Agreement, including, without limitation, the grant of the license to the Sublicensee pursuant to Section 3.1.

(b) The 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 GARDP. No delegation or other transfer will relieve the Sublicensee of any of its obligations or performance under this Sublicense Agreement. Any purported assignment, delegation, or transfer in violation of this Section is void *ab initio*. This Sublicense Agreement is binding upon and inures to the benefit of the Parties and their respective permitted successors and assigns. For clarity, the Sublicensee's use of contractors for which it remains entirely responsible to perform its obligations under this Sublicense Agreement as permitted by Section 3.9 above shall not be considered an assignment or delegation of its obligations under the Sublicense Agreement.

14.7 Waiver and modifications

The failure of any Party to insist on the performance of any obligation under this Sublicense Agreement will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision of this Sublicense 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 Sublicense Agreement will be valid or effective unless in writing and signed by all Parties.

14.8 Choice of law

This Sublicense Agreement will be governed and will be construed in accordance with the laws of the State of New York, U.S.A., without regard to its conflicts of law provisions thereof that would require the application of the laws of any other jurisdiction.

14.9 Publicity

The Parties agree that no Party will issue a press release or public announcement concerning the transactions contemplated by this Sublicense Agreement without the advance written consent of the other Party. If a Party intends to issue a press release, it will submit a draft of such proposed press release to the other Party at least five (5) Business Days prior to the date such Party intends to issue the release and will agree to consider the comments of the other Party 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 Sublicense Agreement, the identity of the Parties, and terms, conditions and subject matter previously disclosed about the Sublicense Agreement, provided such disclosures or statements are accurate and complete with respect to the subject matter thereof and the information disclosed therein.

14.10 Relationship of the Parties

Each Party is an independent contractor under this Sublicense Agreement. Nothing contained in this Sublicense Agreement is intended or is to be construed so as to constitute Shionogi, GARDP and the Sublicensee as partners, agents or joint venturers. 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 Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

14.11 Headings

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

14.12 Entire Agreement

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

14.13 Counterparts

This Sublicense 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.

14.14 Ambiguities

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

14.15 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 the Sublicensee conducts business with GARDP and/or Manufactures or sells Licensed Product.

14.16 Business conduct and ethics

GARDP and Shionogi take seriously their compliance and ethics responsibilities and seek to collaborate only with Third Parties who share their high standards of ethical behavior. To that end, Shionogi has adopted Standards of Business Conduct and Ethics for Third Parties (**3P Standards**). GARDP and Shionogi encourage the Sublicensee to comply with the elements of the 3P Standards. For 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

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

For and on behalf of
GARDP Foundation

[redacted]

[redacted]

[redacted]

For and on behalf of
Orchid Pharma Ltd.

[redacted]

[redacted]

[redacted]

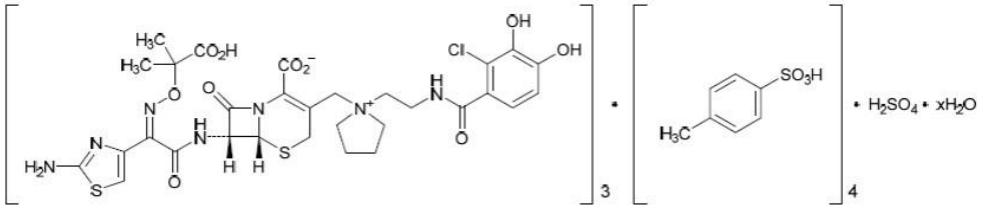
Schedule A Licensed Compound and Licensed Product

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 $3C_{30}H_{34}ClN_7O_{10}S_2 \bullet 4C_7H_8O_3S \bullet H_2SO_4 \bullet xH_2O$.

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 Sublicensed Patent Rights

Publication/ Application No.	Name	Filing date	Status in India
WO2010/050468	CEPHALOSPORIN HAVING CATECHOL GROUP	2009-10-27	Granted
WO2016/035847	INTERMEDIATE OF CEPHALOSPORIN DERIVATIVES AND METHOD FOR PRODUCING SAME	2015-09-03	Granted

Schedule C Sublicensed Know-How Rights

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

Schedule D Territory

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

Schedule E GARDP Deemed Affiliates

- DNDI GARDP Southern Africa NPC
- GARDP North America Inc.

SCHEDULE F - Sublicense Access Plan

The Sublicensee:

1. Will initiate the Manufacturing development for the Licensed Compound and Licensed Product (i.e., commence the manufacturing development process for API) **at the latest six (6) months** from the technology transfer[a] kick-off meeting with Shionogi and GARDP

2. Will commence the construction of the Fixed dose formulation facility **within 15 months** from the technology transfer kick-off meeting with Shionogi and GARDP

3. Will commence the manufacturing of stability batches "to support the WHO PQ dossier" for drug substance (API) **within 20 months** from the technology transfer kick-off meeting with Shionogi and GARDP

4. Will commence the manufacturing of R&D batches (non-sterile lab scale lyophilised product meant for lab feasibility and validation) for drug product (FDF) **within 25 months** from the technology transfer kick-off meeting with Shionogi and GARDP

5. Will complete the submission of active pharmaceutical ingredient (API) and finished pharmaceutical product (FPP) applications for WHO Prequalification **at the latest 44 months** from the Shionogi Technical Transfer kick-off meeting.[c]

6. Will ensure that it has the capacity to produce 3 validation batches[b] of licensed product and if it receives an order or financial support or guarantees to do so, use such validation batches if they are still within shelf-life parameters of Licensed Product **to supply at the latest 46 months** from the Shionogi Technical Transfer kick-off meeting. Supply of Licensed Product assumes the appropriate regulatory approvals or other permissions from relevant authorities are in place to allow importation and use of Licensed Product.[c]

a. Note: Technology transfer is anticipated to be an on-going process where GARDP (and its partner CHAI) shall be extending support to the sub-licensee beyond the face-to-face kick-off meeting with relevant experts from Shionogi.

b. Note: If validation batches have expired before receiving the order, the sub-licensee may need to produce a batch of licensed product. This is also assuming appropriate regulatory approvals or other permissions from relevant authorities are in place.

c. Note (on milestones 5 & 6): These timelines are subject to the receipt of manufacturing license for Cefiderocol, from the central and state regulatory authorities in India, by the sub-licensee.

SCHEDULE G Sublicensee Manufacturing Facility(ies)

A. Manufacturing Facility for Licensed Compound

Orchid Pharma Limited
151, SIDCO Industrial Area, Alathur, Dist. Chengalpattu, Tamil Nadu, India 603110

B. Manufacturing Facility for Licensed Product

Orchid Pharma Limited
151, SIDCO Industrial Area, Alathur, Dist. Chengalpattu, Tamil Nadu, India 603110

SCHEDULE H Sublicensee Contractors

None.

SCHEDULE I Licensed Product Maximum Price

A. Principles applicable to the calculation of cost of goods to Manufacture Licensed Product

For the purposes of the Sublicense Agreement, the Sublicensee's cost of goods to Manufacture Licensed Product shall consist of the following elements:

- Raw Material Costs
- Packaging Material Costs (glass vial, insert, pallet....)
- Direct Labor Costs
- Quality Control Costs
- Attributable Administrative Overhead Costs
- Investment costs (Depreciation cost for dedicated FDF facility), but only during the agreed depreciation period
- Loan interest for FDF facility investment, but only until the end of the agreed depreciation period

Following the finalization of the Manufacturing process for Licensed Product and Licensed Compound, the Sublicensee shall present to GARDP a calculation of the cost of goods for the Manufacture of Licensed Product based on the above principles, and GARDP shall conduct an audit of the Sublicensee's accounts relating to such costs. Based on such presentation and audit, the Parties shall discuss the initial cost of goods to be used for the calculation of the price of Licensed Product.

B. Maximum profit margin

Initial maximum profit margin: [Twenty five Percent (25%)]

The Sublicensee shall regularly consider implementing actions that would enable it to reduce its cost of goods for Licensed Product without negatively impacting quality. The benefit of any such reduction in costs achieved by the Sublicensee shall be shared equitably between a reduction in the price charged by the Sublicensee to its customers and an increase in the Sublicensee's margin.

SCHEDULE J

Information to be Included in Quarterly Sublicensee Reports to GARDP

I. Manufacturing Development and Regulatory Activities – 30 Days after End of Quarter

- Manufacturing development and Manufacturing Approval filing, obtaining, or maintaining activities conducted during the preceding quarter
- status / expected timing of the milestones set out in the Sublicense Access Plan

II. Commercial Sublicensee Contracting – 30 Days after End of Quarter

- Commercial Sublicensee contracting activities conducted during the preceding quarter
- status / expected timing of Supply Agreements

III. Manufacturing Activities – 30 Days after End of Quarter

- number of units of Licensed Compound and Licensed Product Manufactured
- quantities of Licensed Product sold per Customer and intended country of final sale, if known

in each case itemized by batch number, strength, presentation and formulation and applicable stock keeping unit

IV. Inventory Control – 75 Days after End of Quarter

- remaining inventory of Licensed Compound and Licensed Product at the end of the calendar quarter
- raw materials used and inventory at the end of the calendar quarter

in each case itemized by batch number, strength, presentation and formulation and applicable stock keeping unit

V. Forecasting and Order / Delivery Management– 30 Days after End of Quarter

- Key Performance Indicators agreed by the Parties pursuant to Section 5.3(d)
- Updated forecasts received from each Customer during the calendar quarter and updated forecast of Licensed Product to be Manufactured for Commercialization by the Sublicensee in countries for which the Sublicensee has a Commercial Sublicense
- all indicative and firm orders received from each Customer and if applicable by the Sublicensee and corresponding contractual delivery dates

- all deliveries of Licensed Product made (whether to a Customer or to the Sublicensee for Commercialization in countries for which it has a Commercial Sublicense), and for each delivery the actual lead time between firm order and delivery

- any delays in Licensed Product deliveries as compared with the contractual delivery dates

- any rejections by Customers or by the Sublicensee of Licensed Product deliveries or other concerns raised by Customers or identified by the Sublicensee as to the conformity of Licensed Product deliveries with specifications or other Manufacturing obligations, and updates to any such rejections or concerns

VI. Cost of Goods– 75 Days after End of Quarter

- Itemized list and calculation of Cost of Goods incurred during the preceding quarter

- quantities of Licensed Product delivered and corresponding amounts invoiced during the preceding quarter, itemized by Customer and intended country of final sale

VI. Business Continuity– 30 Days after End of Quarter

- update on status of business continuity plan contemplated by Section 12.9 and actions taken in implementation of the business continuity plan

SCHEDULE K

Environment, Health and Safety, and Labor Standards and Requirements

I. General Obligations. The Sublicensee shall:

1) provide to GARDP all information related to the Environment, Health and Safety (**EHS**) and Labor laws applicable to the Manufacture of Licensed Compound and Licensed Product at the Facility(ies), and any updates thereto;

2) have a documented, comprehensive EHS policy (with a clear focus on environmental protection, pollution prevention, waste reduction and management – including hazardous waste);

3) have documented labor standard policies/codes of conduct including: discrimination and harassment, fair compensation, child labor, labor contracts and policy for foreign workers, and preventive actions or policies regarding forced labor;

4) ensure that its own suppliers and contractors follow all applicable environmental, health and safety, and labor laws and regulations; and

5) develop the appropriate measures to be at the standards defined by AMR Industry Alliance.

II. Specific Obligations. In particular, the Sublicensee shall comply with the following standards and requirements:

- The Sublicensee shall ensure that the Facility(ies) is/are operated in an environmentally responsible and efficient manner to minimize adverse impacts on the environment.

- The Sublicensee must comply with all applicable environmental regulations, namely: all required environmental permits and licenses must be valid (expired permits or licenses are not allowed), information registrations and restrictions shall be obtained, and their operational and reporting requirements must be followed.

- The Sublicensee shall share with GARDP the Environmental Management System (EMS) audit reports.

- The Sublicensee shall share with GARDP the Occupational Health and Safety Management System (OHSMS) audit reports.

- The Sublicensee shall have in place procedures and systems that ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges.

- The Sublicensee shall ensure that any waste, wastewater, or emissions with the potential to adversely impact human or environmental health, namely containing Active Pharmaceutical Ingredients (API), will be appropriately treated, controlled, and managed prior to its release into the environment.

- The Sublicensee shall align with the AMR Industry Alliance standards, including Predicted No-Effect Concentrations (PNECs) for both environment (PNEC-ENV) and minimum inhibitory concentrations (PNEC-MIC).

- The Sublicensee shall ensure that any wastewater containing API must achieve, at the very least, the PNEC limits proposed by the AMR Industry Alliance before it is discharged into receiving waters / released into the environment. If data is not yet available for a specific API, a default PNEC of 0.05 µg/L or the limit of detection (L_D) will be used as the maximum threshold.

- The Sublicensee must guarantee the proper functioning of industrial cooling systems, taking into account the best available techniques available in the country where the manufacturing site is located, as well as ensuring compliance with established good practices for the prevention and control of *legionella* in water systems.

- Industrial cooling systems: the Sublicensee must keep on file and make available, whenever requested by the competent authorities and/or GARDP, the results of all analytes and of the maintenance interventions carried out in accordance with the procedures in place in the country of operation.

- The Sublicensee must operate in a transparent way and disclose any data requested by GARDP regarding any environmental aspect.

- The Sublicensee shall have procedures and systems in place to prevent and mitigate accidental spills and releases of fuels, raw materials, chemicals, intermediates, products, and other hazardous materials to the environment.

- The Sublicensee shall conserve energy and natural resources, to avoid the use of hazardous materials (including chlorofluorocarbons) where possible, and to promote activities that reuse and recycle materials.

III. Notice of Incidents, Accidents and Breaches. The Manufacturer shall inform GARDP in case of any environmental accident or incident, or non-compliance with the environmental permits and/or licenses that it holds.

In case of an accident, incident, or non-compliance with the environmental permits/licenses or in case of breach of any of the environmental clauses in this Sublicense Agreement, namely the situations specified below, the Sublicensee must:

a. Inform the competent authorities and GARDP within a maximum period of forty-eight (48) hours, by any available means that proves to be efficient (i.e., by email).

b. Immediately carry out the necessary measures to re-establish the optimal operating conditions in the shortest possible time.

c. The notification to be sent to GARDP must in particular include the information listed below:

1. Date and time of the occurrence / incident / accident / non-compliance.
2. Analysis of the facts that led to the occurrence / incident / accident / non-compliance.

3. Characterization - qualitative and quantitative - of the risk associated with the situation.
4. Complaints received associated with the situation.
5. Action plan for the correction and mitigation of the situation in the shortest amount of time.
6. Mitigation actions implemented immediately, and other adaptation actions planned to implement in the near future.

If it is not possible to send all the referred information within forty-eight (48) hours, a report completing the notification must be sent later and within fifteen (15) days of the date of the occurrence.

The following situations in particular require notification:

- Technical failure detected in production equipment or emission treatment/reduction systems.

- Malfunction or breakdown of monitoring or control equipment, likely to lead to loss of control of the emission treatment/reduction systems.

- Technical failure detected in the waterproofing, drainage or retention systems.

- Technical failure in the manufacturing's site existing emission reduction/treatment systems.

- Unscheduled release of pollutants and/or API into the atmosphere, receiving waters, soil or third-party collectors, due to other causes, namely human error and/or causes external to the manufacturing site (of natural or human origin).

- Emissions that do not comply with the emission limit values imposed by the competent authorities in the existing environmental permits and the specificities of the Sublicense.