

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

This Collaboration Agreement relating to the development, manufacture and commercialisation of zoliflodacin is entered into on the 4th day of July 2017 (the “**Effective Date**”) by and between:

- (1) Drugs for Neglected Diseases initiative (“**DNDi**”), a Swiss foundation with its registered office located at 15 Chemin Louis-Dunant, CH-1202 Geneva, Switzerland acting through the Global Antibiotic Research and Development Partnership (“**GARDP**”) which is currently hosted within DNDi;

and

- (2) Entasis Therapeutics Limited, a company registered in England and Wales under company number 09475809 and having its registered office at One Ashely Road, 3rd Floor, Altrincham, Cheshire WA14 2DT, United Kingdom (“**Entasis**”)

Each a “**Party**” and collectively as the “**Parties**”.

BACKGROUND:

WHEREAS, GARDP’s mission is to develop new antibiotic treatments addressing antimicrobial resistance and to promote their responsible use for optimal conservation, while ensuring equitable access for all in need;

WHEREAS, the API (as defined below) is a first-in-class drug that inhibits bacterial topoisomerase II and shows *in vitro* antibacterial activity against several sexually transmitted infection pathogens, including *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Mycoplasma genitalium*;

WHEREAS, Entasis either owns or has been granted exclusive intellectual property rights in the API and related technology;

WHEREAS, Entasis filed an IND for the API with the United States Food and Drug Administration (“**FDA**”) in September 2013 and has completed in the field of urogenital gonorrhoea in the United States of America a phase I single-ascending dose study and a phase I absorption, distribution, metabolism and excretion trial (the “**Phase I Clinical Trials**”);

WHEREAS, Entasis, in collaboration with the United States National Institution of Allergies and Infectious Diseases (“**NIAID**”) under a separate IND, has conducted a phase II study involving people with confirmed uro-genital gonococcal infection (the “**Phase II Clinical Trial**”);

WHEREAS, the Parties wish to enter into a collaboration to further develop a drug product containing the API (“**Drug Product**”) for the treatment of gonorrhoea caused by *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and/or *Mycoplasma genitalium* (the “**Field**”) including further chemistry, manufacturing and controls activities (“**CMC**”) to be performed by DNDi, non-clinical studies to be conducted by DNDi and Entasis respectively, clinical development through a QT (TQT) study in the United States of America to be performed by Entasis in collaboration by NIAID, an international phase III multi-centre clinical trial to be sponsored by DNDi, registration of the drug product by the Parties in their respective territories, and its manufacture in order to supply and distribute the drug product in those territories on a sustainable, equitable and affordable basis; and

1 | Page

WHEREAS, Entasis wishes to grant to DNDi an exclusive licence to use the Entasis Background Technology (as defined below) to enable DNDi to develop the Drug Product and to register and commercialise it in certain territories, and each Party wishes to grant to the other Party certain exclusive licensing rights to use its respective Collaboration Technology (as defined below) to enable the other Party to register and commercialise the Drug Product in its territory.

NOW THEREFORE, in consideration of the mutual agreements and undertakings herein contained, the Parties agree as follows:

1. DEFINITIONS

For purposes of this Agreement (including the recitals and the Schedules), the following capitalized terms shall have the following meanings (whether used in singular or plural form):

- 1.1 “**Affiliate**” shall mean, with respect to either Party, any corporation or entity controlled by, controlling or under common control with such Party. The terms “controlling”, “controlled by” or “control” shall mean: (i) the direct or indirect ownership of more than fifty percent (50%) of the voting securities of any corporation or entity, or (ii) the power to direct or cause the direction of the management or policies of such corporation or entity through the ownership of securities or interests, by contract or otherwise;
- 1.2 “**Agreement**” shall mean this Collaboration Agreement, including the recitals and the attached Schedules, as may be amended from time to time by the Parties in accordance with its terms;
- 1.3 “**Anti-Bribery Law**” shall mean any applicable law, rule, regulation, or other legally binding measure of any jurisdiction that relates to bribery or corruption;
- 1.4 “**API**” has the meaning set forth on Schedule 6;
- 1.5 “**Background Technology**” means the IP and other rights in the DNDi Background Technology or the Entasis Background Technology respectively that were either: (i) Controlled by the relevant Party as of the Effective Date; or (ii) conceived and reduced to practice, made or developed and Controlled by a Party during the Term outside the scope of the Collaboration Programme;
- 1.6 “**Change of Control**” means the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalisation, reverse split, sale or transfer of assets or other transaction, as a result of which any natural or legal person gains control of an entity or a group;
- 1.7 “**Clinical Trial**” shall mean any clinical study on the Drug Product where the Drug Product is administered to humans;
- 1.8 “**CMC**” shall mean have the meaning set out in the recitals;
- 1.9 “**Collaboration Programme**” shall mean the collaboration programme to: (i) develop a Drug Product in the Field and to register such Drug Product in the Field in the DNDi Territory and the Entasis Territory in accordance with the Development Plan and the Regulatory Plan; and (ii) organise the Manufacture of such Drug Product for Commercialisation in the Field in the DNDi Territory and the Entasis Territory in accordance with the Manufacturing and Supply Plan;
- 1.10 “**Collaboration Technology**” shall mean any IP and other rights in the API, the Drug Product and the Regulatory Dossier developed or conceived and reduced to practice in the performance of the Collaboration Programme;

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- 1.11 “**Commercialise**” or “**Commercialisation**” shall mean any relevant activities directed to marketing, promoting, importing, distributing, offering for sale, having sold and/or selling a pharmaceutical product;
- 1.12 “**Confidential Information**” means any non-public information that is: (i) disclosed to the other Party (whether directly or indirectly) pursuant to or in the course of this Agreement howsoever disclosed that contains or relates to its Background Technology or its plans to Commercialise the Drug Product; or (ii) is generated pursuant to this Agreement by a Party including, without limitation, the respective Collaboration Technology of each Party;
- 1.13 “**Contract Service Provider**” or “**CSP**” shall mean any Third Party service provider contracted by either Party to perform certain aspects of the Collaboration Programme;
- 1.14 “**Control**” or “**Controlled**” shall mean with respect to relevant Background Technology and Collaboration Technology possession of the right, whether directly or indirectly, and whether by ownership, licence or otherwise, to assign or grant a licence, sublicense or other rights under this Agreement without violating the terms of any agreement or other arrangement with any Third Party;
- 1.15 “**Data Room**” shall have the meaning set out in Clause 7.11;
- 1.16 “**Development Plan**” shall mean a development plan outlining the non-clinical and clinical development plans and CMC plans for the Drug Product to meet the criteria of the TPP, which Development Plan is attached as Schedule 1 hereto, as

amended from time to time in accordance with the terms of this Agreement;

- 1.17 **“DNDi Background Technology”** shall mean any Background Technology of DNDi that is necessary or useful for the performance of the Collaboration Programme;
- 1.18 **“DNDi Collaboration Technology”** shall mean: (i) [*]; and; (ii) [*]; and (iii) all other Collaboration Technology that is developed or conceived by DNDi (or its employees, Sublicensees or agents, including CSPs) in the performance of the Collaboration Programme;
- 1.19 **“DNDi Indemnified Parties”** shall have the meaning set out in Clause 11.1;
- 1.20 **“DNDi Territory”** means all those countries and regions listed as being in DNDi’s Territory as described in Schedule 2;
- 1.21 **“Drug Product”** shall have the meaning set out in the recitals;
- 1.22 **“Drug Regulatory Authority”** shall mean any competent authority in any country of the Territory with authority over the Drug Product and/or a Clinical Trial including, without limitation, the FDA and the EMA;
- 1.23 **“Effective Date”** shall mean the date set forth at the head of this Agreement;
- 1.24 **“EMA”** shall mean the European Medicines Agency;
- 1.25 **“Enforcing Party”** shall have the meaning set out in Clause 7.19;
- 1.26 **“Entasis Background Technology”** shall mean any Background Technology of Entasis relating to the API that is necessary or useful for the performance of the Collaboration Programme; provided, however, that if any Third Party becomes an Affiliate of Entasis after the Effective Date, Entasis Background Technology shall exclude any IP controlled by such Third Party before such Third Party became Entasis’s Affiliate;

3 | Page

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- 1.27 **“Entasis Collaboration Technology”** shall mean any Collaboration Technology that is developed or conceived by Entasis (or its employees, Sublicensees or agents, including CSPs) in the performance of the Collaboration Programme;
 - 1.28 **“Entasis Indemnified Parties”** shall have the meaning set out in Clause 11.2;
 - 1.29 **“Entasis Patents”** shall mean Patent Rights included in the Entasis Background Technology as of the Effective Date as described in Schedule 3;
 - 1.30 **“Entasis Territory”** means all those all those countries listed as being in Entasis’ Territory as described in Schedule 2;
 - 1.31 **“FDA”** shall mean the meaning set out in the recitals;
 - 1.32 **“Field”** shall have the meaning set out in the recitals;
 - 1.33 **“Filing Party”** shall have the meaning set out in Clause 5.8;
 - 1.34 **“Force Majeure”** shall mean an event which is (i) unpredictable, (ii) unavoidable and (iii) outside of the reasonable control of a Party or its CSP that prevents or substantially interferes with the performance by such Party of any of its obligations under this Agreement;
 - 1.35 **“Future Indications”** shall mean any community-acquired indications outside of the Field;
 - 1.36 **“Future Indications Technology”** shall have the meaning set out in Clause 7.10;
 - 1.37 **“Good Clinical Practice”** shall mean the guideline of the ICH Harmonized Tripartite Guidelines: Guidelines for Good Clinical Practice E6 (R1) of 10 June 1996 (as amended from time to time), being an international ethical and scientific quality standard for designing, conducting, recording, and reporting Clinical Trials that involve the participation of human subjects;

- 1.38 “**Good Manufacturing Practices**” or “**GMP**” shall mean regulations and published guidelines related to current good manufacturing practices that relate to the testing, manufacturing, processing, packaging, holding or distribution of drug or biologic drug substances and finished drugs or biologics as set forth in the EU GMP Guide on good manufacturing practices for medicinal products for human use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively, as amended during the Term of this Agreement;
- 1.39 “**Granule Formulation**” means a formulation of the API that has been developed by Entasis using granules containing amorphous drug substance in a water-dispensable sachet;
- 1.40 “**Holding Point**” shall have the meaning set out in Clause 4.4;
- 1.41 “**ICH**” shall mean the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use;
- 1.42 “**IND**” shall mean an investigational new drug application, clinical trial authorization or equivalent application filed with the applicable Drug Regulatory Authority, which application is required to commence human clinical trials in the applicable country;
- 1.43 “**Indemnification Claim Notice**”, “**Indemnified Party**”, and “**Indemnifying Party**” shall each have the meaning set out in Clause 11.3;

4 | Page

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- 1.44 “**Know How**” means technical and other information which is not in the public domain including information relating to: (i) non-clinical data including pharmacological, toxicological and metabolic data and results of any non-clinical studies relevant to the API and the Drug Product; (ii) clinical safety and efficacy data including data analyses, study reports and information contained in protocols, filings or other submissions to or responses from ethical committees and Drug Regulatory Authorities; (iii) pharmacovigilance data; (iv) production processes including any drug master file, specifications, techniques, manufacturing line procedures, CMC data, SOPs, quality analysis and quality control processes and techniques and other documentation retained to comply with GMP; and (v) any relevant information relating to product supply chain of the Drug Product including the API, fill, finish and primary and secondary items. Know How includes: (a) documents containing Know How; and (ii) any legal rights including trade secrets, copyright, database or design rights protecting such Know How;
- 1.45 “**Infringement Notice**” shall have the meaning set out in Clause 7.19;
- 1.46 “**Intellectual Property**” or “**IP**” shall mean Patent Rights, Know How, copyrights, any improvements, enhancements or modifications to any of the foregoing and any rights or property similar to any of the foregoing in any part of the world, whether registered or not;
- 1.47 “**Joint Steering Committee**” or “**JSC**” shall mean the joint steering committee having the role specified in Clause 8.
- 1.48 “**Losses**” shall mean any and all losses, damages, liabilities, costs and expenses (including without limitation reasonable legal fees and expenses) taking account of the duty on the Party suffering such Losses to mitigate such Losses;
- 1.49 “**Manufacturing**” shall mean all activities relating to making/or having made the API and/or the Drug Product and all associated activities including labelling/or having labelled, and packaging or having packaged the Drug Product in accordance with GMP;
- 1.50 “**Manufacturing and Supply Plan**” shall mean the plan for manufacture of the API and the Drug Product and its supply to the DNDi Territory and to the Entasis Territory to be developed and by the Parties in accordance with Clause 6;
- 1.51 “**Marketing Authorisation**” shall mean all approval(s), registration(s) and authorisation(s) necessary to be obtained from an applicable Drug Regulatory Authority to lawfully import, promote, distribute and sell the Product in the Field in a country of the DNDi Territory or the Entasis Territory, as applicable;
- 1.52 “**NIAID**” shall have the meaning set out in the recitals;

- 1.53 “**Non-Filing Party**” shall have the meaning set out in Clause 5.8;
- 1.54 “**Patent Rights**” shall mean any: (i) patents and patent applications (provisional and non-provisional); (ii) continuations, divisionals, continuations-in-part, continued prosecutions, re-examinations, reissues, utility models, petty and other patent applications claiming subject matter therein or claiming priority from any of the foregoing, and all patents that issue there from; (iii) counterparts, substitutions, restorations, extensions (including, without limitation, patent term extensions), supplementary protection certificates, registrations, confirmations, validations and renewals of any of the foregoing; and (iv) invention certificates and other government grants for the protection of inventions or industrial designs;
- 1.55 “**Pharmacovigilance Agreement**” shall have the meaning set out in Clause 9.2;

5 | Page

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- 1.56 “**Phase I Clinical Trials**” shall have the meaning set out in the recitals;
- 1.57 “**Phase II Clinical Trial**” shall have the meaning set out in the recitals;
- 1.58 “**Phase III MC Trial**” shall mean an international phase III multi-centre Clinical Trial to be conducted consistent with the Development Plan with the objective of demonstrating the safety and efficacy of the Drug Product in people infected with *Neisseria gonorrhoeae*.
- 1.59 “**Phase IV Clinical Trial**” shall mean any Clinical Trial conducted after the first Marketing Authorisation for the Drug Product has been obtained;
- 1.60 “**Project Leader**” shall have the meaning set out in Clause 8.2;
- 1.61 “**Promotional Materials**” shall mean promotional, advertising, communication and educational materials relating to the Drug Product for use in connection with the marketing, promotion and sale of the Drug Product and includes promotional literature, product support materials and promotional giveaways;
- 1.62 “**QT (TQT) Study**” shall mean a study aimed at investigating the API liability to prolong the QT interval (incorporating a bioavailability study) to be performed on the Granule Formulation by Entasis in collaboration with NIAID prior to commencement of the Phase III MC Trial;
- 1.63 “**Regulatory Dossier**” means all regulatory documents and filings registered with a Drug Regulatory Authority for a Marketing Authorisation containing the administrative, safety, efficacy, quality, non-clinical and clinical data and CMC data for the Drug Product as it may change from time to time;
- 1.64 “**Regulatory Plan**” shall mean a regulatory plan outlining the regulatory strategy for obtaining Marketing Authorisations for the Drug Product and split of regulatory responsibilities of the Parties with the aim of ensuring equitable and affordable access to the Product for people in the DNDi Territory and the Entasis Territory at the earliest possible date, as further described in Schedule 4 hereto and in Clause 5, as may be amended from time to time;
- 1.65 “**Standard Operating Procedure**” or “**SOP**” shall mean detailed, written instructions to achieve uniformity of the performance of a specific function, adopted within the organisation of each of the Parties;
- 1.66 “**Sublicensee**” shall mean a Third Party appointed by either Entasis or DNDi or an Affiliate of Entasis or DNDi (other than a CSP) to carry out Manufacturing and/or Commercialisation of the Drug Product in its Territory or a part thereof;
- 1.67 “**Target Product Profile**” or “**TPP**” shall mean the set of potential characteristics and attributes for the Drug Product, described in Schedule 5 hereto, and revised from time to time by mutual consent through the JSC;
- 1.68 “**Term**” shall mean the period commencing after the Effective Date and unless terminated earlier in accordance with the terms of this Agreement, expiring country by country of the DNDi Territory and the Entasis Territory until the longer of: (i) the expiry of any Patent Rights in such country; or (ii) ten years from the first Marketing Authorisation for such Drug Product for the Field in such country.
- 1.69 “**Territory**” shall mean the DNDi Territory and/or the Entasis Territory as the context requires;

1.70 “**Third Party**” shall mean any person, organization or entity other than the Parties and their Affiliates;

1.71 “**Third Party Claim**” shall have the meaning set out in Clause 11.3.

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2. OBJECTIVE OF THIS AGREEMENT

2.1 The objective of this Agreement is to set forth:

- 2.1.1 the principles of the collaboration between DNDi and Entasis in the performance of the Collaboration Programme;
- 2.1.2 the obligations and roles and responsibilities of the Parties with respect to performance of the Collaboration Programme;
- 2.1.3 the conditions pursuant to which DNDi shall provide to Entasis the right to use the DNDi Background Technology and Entasis shall provide to DNDi the right to use the Entasis Background Technology; and
- 2.1.4 licensing and rights to use the Collaboration Technology.

3. COLLABORATION PROGRAMME

- 3.1 Except to the extent otherwise specified in any specific clause of this Agreement, each Party shall use commercially reasonable endeavours to perform its roles and activities within the Collaboration Programme and in a timely manner.
- 3.2 Each Party may enlist the services of any CSP to perform its duties under the Collaboration Programme. The Party engaging a CSP shall ensure that the CSP allocates sufficient time, effort, equipment and facilities to the Collaboration Programme and utilizes personnel with sufficient skills and experience as are required to satisfy the requirements of the Collaboration Programme.
- 3.3 In the performance of its obligations in relation to the Collaboration Programme each Party shall comply with its own SOPs, all applicable laws and regulations (including but not limited to Good Clinical Practice, Good Manufacturing Practices and ICH guidelines and national regulatory requirements and codes of practice and ethics committee or similar approvals) and shall obtain all applicable approvals and licences that may be required in order for it to perform its activities.
- 3.4 Except as otherwise expressly set out in this Agreement, each Party shall bear any and all costs that are incurred by it in connection with any activity for which such Party is responsible pursuant to this Agreement. Each Party shall have the right, in consultation with the other Party, to seek financing from funding agencies for any part of the Collaboration Programme, provided always that the Party obtaining such funding continues to comply with its obligations hereunder and that obtaining such funding does not lead to any conflict or restriction with respect thereto.

4. DEVELOPMENT OF THE DRUG PRODUCT

- 4.1 The Parties shall use commercially reasonable endeavours to develop the Drug Product in the Field in accordance with this Clause 4, the Development Plan and the Regulatory Plan.
- 4.2 Each Party in the performance of its activities in relation to the Development Plan will reasonably consider the views of the other Party.
- 4.3 The Party conducting a study (e.g., Entasis for the QT (TQT) Study and DNDi for the Phase III MC Trial as per below) or pharmaceutical development shall make appropriate updates to the investigator’s brochure as required by Drug Regulatory Authorities and/or ethics committees, and the other Party shall reasonably co-operate with the first Party.

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- 4.4 At each decision point specified set out in the Development Plan (a “**Holding Point**”), the Parties shall determine through the JSC whether development of the Drug Product should continue beyond the Holding Point and if so, whether changes to the Development Plan are required prior to commencement with the remainder of the activities set out in the Development Plan.

QT (TQT) Study

- 4.5 The Development Plan envisages that clinical development activities will commence with a QT (TQT) Study on the Granule Formulation in the United States of America. Entasis shall use commercially reasonable endeavors perform and fund the QT (TQT) Study in collaboration with NIAID (including procuring samples of the Granule Formulation for the QT (TQT) Study).
- 4.6 Entasis shall:
- 4.6.1 regularly update DNDi of status of the QT (TQT) Study and in particular shall notify DNDi promptly of any serious adverse events and any communications with or inspections by the Drug Regulatory Authority; and
 - 4.6.2 promptly provide to DNDi once finalized and validated by Entasis with NIAD the results of the TQ (TQT) Study including without limitation clinical study reports.

Phase III MC Trial

- 4.7 The Parties will collaborate in the design of the Phase III MC Trial to be approved by the JSC in accordance with Clause 8.11.
- 4.8 DNDi shall use commercially reasonable endeavours to perform and fund the Phase III MC Trial including:
- 4.8.1 select the centres at which the Phase III MC Trial will be conducted;
 - 4.8.2 submit an IND and the regulatory clinical trial application(s) for the Phase III MC Trial to the FDA, EMA, and other applicable Drug Regulatory Authorities;
 - 4.8.3 arrange with a CSP for the Drug Product manufacturing that is required for the Phase III MC Clinical Trial;
 - 4.8.4 regularly update Entasis through the JSC about the regulatory status of clinical trial applications and the status of the Phase III MC Trial; and
 - 4.8.5 promptly provide to Entasis once finalized and validated by DNDi the results of the Phase III MC Trial including without limitation clinical study reports.
- 4.9 Entasis shall co-operate with DNDi in DNDi’s performance of the Phase III MC Trial including, without limitation, by:
- 4.9.1 providing DNDi with all Know How relating to the API and the Drug Product that is necessary for DNDi to perform its obligations; and
 - 4.9.2 assisting DNDi to develop a robust protocol for the Phase III MC Trial and committing reasonably sufficient time and resources to do so.

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Pharmaceutical Development

- 4.10 Pharmaceutical development of the Drug Product will commence as set out in the Development Plan in order to explore alternative formulations of the Drug Product used in the Phase III MC Trial.

- 4.11 DNDi shall use reasonable endeavours to perform and finance the CMC activities (as detailed in the Development Plan) in accordance with the Development Plan. Entasis shall provide all Know How relating to the API that DNDi requires including the Granule Formulation.
- 4.12 DNDi shall be responsible for organising the manufacture and supply of the Drug Product for the Phase III MC Trial and selecting its CSP for this purpose.
- 4.13 DNDi shall have title to all batches of the Drug Product produced in the course of the Development Plan and may use such Drug Product for the purpose of any Clinical Trial that it performs or for Commercialisation in the DNDi Territory. Should it be impracticable for DNDi to use such batches prior to expiration, the Parties will collaborate to identify different ways to use such batches, which options may include, if agreed by the Parties at such time, the purchase by Entasis of batches of the Drug Product for use in the Entasis Territory at fair market value.

Future Indications

- 4.14 In order to preserve efficacy and responsible use of the Drug Product, each Party agrees that neither the API nor the Drug Product shall be developed by or on behalf of either Party for the Future Indications without the prior consent of the other Party, not to be unreasonably withheld.

Further Development Responsibilities

- 4.15 If a Party desires to conduct a Clinical Trial in the Territory of the other Party, then such Party shall (i) provide the other Party with a copy of the proposed protocol of such Clinical Trial for review and comment by the other Party, which such comments shall be considered by the first Party in good faith, and (ii) obtain the consent of the other Party, such consent not to be unreasonably withheld.
- 4.16 Each Party shall keep or cause to be kept written laboratory notebooks and other records and reports of the progress of the Development Plan and its activities in sufficient detail and in good scientific manner. Such notebooks and other records must properly reflect all work done in relation to the Development Plan and the results achieved.
- 4.17 Should any animals be involved in any aspect of the Development Plan each Party will treat such animals with humane care and shall adhere to the following core animal welfare principles: (a) animals must be provided a physical environment that is consistent with their physiological and behavioral needs; (b) animals must be provided potable water and a diet that meets their nutritional requirements; (c) animals must be provided a basic standard of medical care for all health issues, including those related to research, which is consistent with current veterinary medical standards; (d) efforts should be made to avoid, or when this is not possible, to minimize each animal's pain, discomfort and distress. Anesthetics and analgesics should be used wherever necessary and feasible; (e) attending veterinarians must be provided the necessary resources and have the authority to manage animal welfare issues and to minimize pain and distress; (f) individuals responsible for the care and use of laboratory animals must be adequately trained in current standards of care and ethical treatment of laboratory animals and competency in planned animal procedures should be assessed prior to working with the animals; (g) whenever possible, the 3Rs of refinement, reduction and replacement will be adopted if compatible with the objectives of the study design; (h) when necessary, animals must be provided a humane death using techniques that are consistent with current veterinary medical standards when predetermined endpoints have been achieved or when pain or distress cannot otherwise be alleviated.

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5. REGULATORY STRATEGY AND ACTIVITIES FOR OBTAINING MARKETING AUTHORIZATION

- 5.1 The regulatory strategy (including timelines and milestones) and the regulatory responsibilities of the Parties are set out in detail in the Regulatory Plan. As of the Effective Date the regulatory strategy is based on the principles that:
- 5.1.1 clinical development is intended to facilitate the process for registration of the Drug Product in the first instance with the FDA and the EMA;
- 5.1.2 Entasis shall use its best efforts to file the application for the first Marketing Authorisation for the Drug Product in the Field with the FDA, provided that, in Entasis' reasonable determination, the data generated by completion

of the Phase III MC Trial will be acceptable by the FDA, and would not otherwise cause Entasis to violate applicable law; and

- 5.1.3 Entasis is responsible for obtaining Marketing Authorisations for the Drug Product in the Entasis Territory if and as it elects, and DNDi is responsible for obtaining Marketing Authorisations for the Drug Product in such countries of the DNDi Territory as it elects.

First Marketing Authorisation with the FDA and the EMA

5.2 Entasis shall:

- 5.2.1 use its best efforts to file the application for the first Marketing Authorisation for the Drug Product in the Field with the FDA by no later than six (6) months from the completion of the Phase III MC Trial (which shall mean database lock for clean file for the Phase III MC Trial) provided that, in Entasis's reasonable determination, the data generated by completion of the Phase III MC Trial will be acceptable by the FDA, and would not otherwise cause Entasis to violate applicable law;
- 5.2.2 use commercially reasonable endeavors to maintain the Marketing Authorisation with the FDA when granted;
- 5.2.3 use commercially reasonable endeavors to file the application for the first Marketing Authorisation for the Drug Product in the Field with the EMA;
- 5.2.4 use commercially reasonable endeavors to reasonably support DNDi in its conduct of any additional activities conducted by DNDi pursuant to Clause 5.3.2;
- 5.2.5 permit DNDi to review and make suggestions in relation to the Regulatory Dossier prior to submission to the FDA and EMA and reasonably consider such suggestions;
- 5.2.6 inform DNDi regularly through the JSC of the progress of the regulatory activities for obtaining Marketing Authorization with the FDA and the EMA; and
- 5.2.7 promptly provide to DNDi a copy of the Regulatory Dossier file submitted to the FDA and the EMA and any correspondence in relation thereto.

5.3 DNDi shall:

- 5.3.1 provide to Entasis relevant clinical and CMC data in its possession that is required for the purpose of registering the Drug Product with the FDA and the EMA, and, upon reasonable request by Entasis, DNDi shall reasonably assist Entasis in the preparation of regulatory

10 | Page

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materials for the FDA and the EMA registration, including the applicable portion of the CMC section;

- 5.3.2 use commercially reasonable endeavors to conduct any additional activities that may be required by the FDA or be agreed between the Parties in addition to those set forth in the Development Plan to obtain the FDA Marketing Authorization;
- 5.3.3 be responsible for the full costs of the additional activities mentioned under clause 5.3.2 to obtain the FDA Marketing Authorization;
- 5.3.4 review and make suggestions in relation to the Regulatory Dossier prior to submission by Entasis to the FDA and the EMA; and
- 5.3.5 reimburse Entasis for [*] of costs incurred by Entasis in filing the Marketing Authorisation for the Drug Product in the Field with the EMA if DNDi uses or references such Marketing Authorisation in any filing for Marketing Authorisation in the DNDi Territory in accordance with Clause 5.7 within [*] of DNDi submitting any such Marketing Authorisation in the DNDi Territory.

Phase IV Clinical Trials

- 5.4 Each Party shall be responsible for financing such additional Clinical Trials in its respective Territory as it elects to conduct in accordance with this Agreement.

Market Authorizations in countries other than the USA

- 5.5 Each Party will, except as otherwise specified in this Agreement, be responsible at its own cost, for using commercially reasonable endeavours to take all other necessary steps for obtaining and, during the Term of this Agreement, maintaining Marketing Authorisations in its Territory on behalf of itself or its Sublicensee if appropriate.
- 5.6 Each Party shall use commercially reasonable endeavours to assist the other Party (and where appropriate its Sublicensee), at the other Party's cost, to register the Drug Product for use in the Field in its Territory accordance with the Regulatory Plan, and to answer questions from any Drug Regulatory Authority with respect to the API and the Drug Product.

Use of Regulatory Dossier and References

- 5.7 Each Party (and where appropriate its Sublicensees) shall be entitled, without the approval or consent of the other Party, to have full access to the Regulatory Dossier submitted to the FDA and the EMA by Entasis, to use it with any Drug Regulatory Authority in its Territory and to exercise its licensing rights (including sublicensing rights in accordance with this Agreement).
- 5.8 The Party submitting a filing to a Drug Regulatory Authority (the "**Filing Party**") shall have discretion to decide the documents (or extracts thereof) which will be included in the particular Regulatory Dossier that it submits and to modify and translate such documents as required. Promptly after such submission, the Filing Party shall notify the other Party (the "**Non-Filing Party**") that such regulatory filing has been made, and upon the request of the Non-Filing Party, provide it with a copy of each such submission. Each Party shall update the other Party as to the status of each Regulatory Dossier within the different countries where it is submitted in its Territory, and will provide the other Party through the JSC with a report on its exchanges with the applicable Drug Regulatory Authority.
- 5.9 The Filing Party shall provide to the Non-Filing Party (and use commercially reasonable endeavours to procure that its Sublicensees provide) in writing letters of reference, granting the Non-Filing Party

11 | Page

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(and its Affiliates and/or Sublicensees) the right of reference for all purposes relating to the development, Manufacturing or Commercialization of the API and the Drug Product in the Non-Filing Party's Territory, with respect to all filings with any Drug Regulatory Authority made by the Filing Party or on its (or its Affiliates or Sublicensees behalf) to the extent available to Filing Party, and to all applicable Marketing Authorisations for such products in the Filing Party's Territory. Such rights of reference shall expressly be binding on any assignee or transferee of the Filing Party's rights to such filings and such Marketing Authorisations.

- 5.10 If any Drug Regulatory Authority in a Territory requires access to certain portions of any filing or Marketing Authorisation related to the API or the Drug Product for legal or regulatory purposes in connection with the Non-Filing Party (or its Affiliates' or Sublicensees') development, Manufacturing and/or Commercialization efforts, then the Filing Party shall reasonably cooperate with such Drug Regulatory Authority and seek to make such portions available to the Drug Regulatory Authority and, if legally required for the Non-Filing Party (or its Affiliates or Sublicensees) to submit or pursue an application for Marketing Authorisation, to the Non-Filing Party, solely for such purpose, and the Filing Party shall use reasonable efforts to obtain similar cooperation from its Sublicensees.

Parallel Imports

- 5.11 To the extent not otherwise prohibited by applicable laws, each Party shall not, and shall cause its Affiliates and sublicensees not to, directly sell any Drug Product to persons in the Territory of the other Party or to sell any Drug Product to distributors or Third Parties in the Territory of the other Party or to any Third Party that a Party has reasonable grounds to believe are likely to import any Drug Product into the Territory of the other Party. If a Party becomes aware that a Third Party is exporting Drug Products acquired from such Party or its Affiliates or sublicensees to a country in the Territory of the other Party, then such first Party shall, within its legal rights and the remedies afforded by applicable laws, stop or

deter such Third Party from continuing such exportation, including by ceasing or limiting the supply of Drug Products to such Third Party. All inquiries or orders received by a Party or its Affiliates or sublicensees for Drug Products to be delivered or distributed in the Territory of the other Party shall be referred to the other Party or its designee.

- 5.12 The restrictions set out in Clause 5.11 shall not apply with respect to any individual that makes an unsolicited request for the Drug Product for treatment in the Field solely for individual therapeutic use. The Party receiving such unsolicited request will be entitled to respond provided that responding to such request is not in violation of applicable laws and the aggregate quantity of such sales are *de minimus* relative to such Party's Territory. Upon the reasonable request of a Party, the other Party shall report a summary of such sales of which it is aware. This Section 5.12 does not permit a Party to establish any marketing or sales channel (such as remote ordering by the Internet or other means) directed to persons in the other Party's Territory and requires a Party to take all reasonable actions to prevent sales originating from the other Party's Territory.

6. PRODUCT MANUFACTURE AND SUPPLY

- 6.1 Within six (6) months of the Effective Date or such longer period as may otherwise be agreed in writing (including by email), the Parties shall agree a detailed Manufacturing and Supply Plan for the supply of the Drug Product through the JSC. The Manufacturing and Supply Plan shall be based on the following principles:
- 6.1.1 the Parties shall develop a detailed forecasting, supply, access and implementation plan for the supply of the Drug Product and define related operational supply chain management processes to ensure availability and access of the Drug Product in the Field with the consultation, as appropriate, of one or more funding agencies or partners, e.g., the World Health Organisation;
- 6.1.2 the Parties will use commercially reasonable endeavours to optimize production costs and will seek opportunities to jointly appoint Manufacturing Sublicensee(s) where possible;
- 6.1.3 the Parties will give due consideration to the need to ensure continued efficacy and responsible use of the Drug Product and will therefore seek to minimize the number of Sublicensees for Manufacturing;
- 6.1.4 if the appointment of joint Manufacturing Sublicensee(s) is not possible, each Party will have the right to Manufacture the Drug Product anywhere in the world (and subject to Clauses 7.6 and 7.8 appoint a Sublicensee to do so) and to Commercialise the Drug Product in the countries in its respective Territory for which a Marketing Authorization has been obtained;
- 6.1.5 each Party shall make reasonably available to nominated representatives of the other Party appropriate personnel to educate and train such representatives in relation to Know How that may be required to Manufacture the Drug Product;
- 6.1.6 each Party will ensure that any Drug Product is supplied with appropriate instructions for use and neither Party will promote the Drug Product for any use or indication other than those specified in the Marketing Authorisation in the Territory or part thereof from time to time or make any medical or promotional claims regarding the Drug Product other than permitted by law;
- 6.1.7 each Party will use commercially reasonable endeavours to ensure that the Drug Product is made available at price which is affordable and sustainable in its respective Territory and any part thereof;
- 6.1.8 the Drug Product manufactured for Commercialisation in the Entasis Territory shall be reasonably distinguished from the Drug Product for Commercialisation in the DNDi Territory, as agreed by Parties;
- 6.1.9 unless otherwise agreed each Party will be responsible for packaging and labelling of Drug Products in its Territory;
- 6.1.10 each Party shall be responsible for its own Promotional Materials for use in its Territory and for filing such Promotional Materials with the relevant Drug Regulatory Authority as required;

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- 6.1.11 each Party (or its Sublicensee) shall use its own name and/or logo for Commercialisation in its Territory unless otherwise agreed.
- 6.2 DNDi will promptly notify Entasis in accordance with the Development Plan if DNDi, either itself or through an Affiliate or a Third Party on its behalf, improves, modifies, or enhances the formulation of the Drug Product;
- 6.3 It is acknowledged that Entasis has certain obligations to make milestone payments to Astra Zeneca AB (and/or its affiliates) in relation to the API ("**Astra Zeneca**"). The Parties agree that any such payments to Astra Zeneca will be paid in full by Entasis and that such costs shall not be transferred to DNDi (and/or any of its Sublicensee(s)) whether directly or indirectly or applied to the costs of any supply of Drug Product for Commercialisation in the DNDi Territory.

13 | Page

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7. INTELLECTUAL PROPERTY

Ownership

- 7.1 All rights in, title to and interest in the DNDi Background Technology and the DNDi Collaboration Technology shall be owned by DNDi. DNDi shall promptly notify Entasis upon the creation of DNDi Background Technology and DNDi Collaboration Technology. Notwithstanding the foregoing or Clause 7.17, DNDi shall solely own all rights, title, and interest in and to all IP developed or conceived and reduced to practice in DNDi's performance of [*] as DNDi Collaboration Technology; provided, that if DNDi does not file for Patent Rights on DNDi Collaboration Technology that would be reasonably patentable in the DNDi Territory or Entasis Territory within six (6) months of making such invention, or thereafter does not use commercially reasonable endeavors to prosecute and maintain such Patent Rights, then DNDi shall and hereby does assign to Entasis all of DNDi's right, title, and interest in and to such IP. DNDi shall take, and shall cause its employees, agents, sublicensees, and contractors to take, all further acts reasonable required to effectuate the transfer of such IP. Any IP transferred to Entasis pursuant to this Clause 7.1 shall thereafter be considered as Entasis Collaboration Technology.
- 7.2 All rights in, title to and interest in the Entasis Background Technology and the Entasis Collaboration Technology shall be owned by Entasis. Entasis shall promptly notify DNDi upon the creation of Entasis Background Technology and Entasis Collaboration Technology.
- 7.3 The Parties agree that each Party shall retain ownership of all rights, title and interest in any part of the Regulatory Dossier which it (or any Party acting on its behalf) has authored provided that each Party shall be entitled to use the Regulatory Dossier for the purposes set out in Clauses 5.7 to 5.9 inclusive without the approval of the other Party.
- 7.4 Each Party shall procure that under the terms of any appointment of a CSP or Sublicensee that the CSP or Sublicensee does all such acts and things necessary to vest all right, title and interest in its Collaboration Technology in such Party.

Licensing

- 7.5 Entasis hereby grants to DNDi, a worldwide, fully paid up, exclusive and royalty-free license with the right to sublicense to any Sublicensee (subject to Clause 7.6) through multiple tiers to use the Entasis Background Technology and the Entasis Collaboration Technology:
- 7.5.1 in connection with all activities associated with the development of the Drug Product in the Field in accordance with the Development Plan and the Regulatory Plan;
- 7.5.2 to Manufacture the API and the Drug Product for Commercialisation in the Field in the DNDi Territory; and
- 7.5.3 to register and obtain and maintain Marketing Authorisation in the DNDi Territory and to Commercialise the Drug Product in the Field in the DNDi Territory.

For the avoidance of doubt, subject always to Clause 4.14, Entasis retains the right to use and grant licenses to the Entasis Background Technology and the Entasis Collaboration Technology (i) to perform its obligations under this Agreement and (ii) for any purposes not set out above.

- 7.6 The appointment of distributors and other commercial Sublicensees (for clarity, excluding all CSPs) by DNDi will be subject to Entasis' prior written consent, not to be unreasonably withheld or delayed, provided that the Sublicensee is required to comply with the restrictions set out in sub-clauses Clause 7.5.1 to 7.5.3 inclusive.

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- 7.7 DNDi hereby grants to Entasis, a worldwide, fully paid up, exclusive and royalty-free license with the right to sublicense to any Sublicensee through multiple tiers to use the DNDi Background Technology and the DNDi Collaboration Technology:

- 7.7.1 in connection with the development of the Drug Product in the Field in accordance with the Development Plan and the Regulatory Plan;
- 7.7.2 to Manufacture the API and the Drug Product for Commercialisation in the Field in the Entasis Territory; and
- 7.7.3 to register and obtain and maintain Marketing Authorisation in the Entasis Territory and to Commercialise the Drug Product in the Field in the Entasis Territory.

For the avoidance of doubt, subject always to Clause 4.14, DNDi retains the right to use and grant licenses to the DNDi Background Technology and the DNDi Collaboration Technology (i) to perform its obligations under this Agreement and (ii) to enable registration of the Drug Product in the DNDi Territory and for any purposes not set out above (including, without limitation, for academic and research purposes).

- 7.8 The appointment of a Sublicensee (other than a CSP) by Entasis will not be subject to DNDi's prior written consent.

Future Indications

- 7.9 If the Parties agree to develop a Drug Product for Future Indications, each Party shall and hereby does grant to the other a worldwide, fully paid up, non-exclusive and royalty-free license to use its respective Background Technology and Collaboration Technology for development for Future Indications.
- 7.10 If a Drug Product is developed by a Party for Future Indications in accordance with Clause 4.14, the Party that develops technology for such purpose ("**Future Indications Technology**") shall: (a) provide to the other on a confidential basis, details of any Future Indications Technology arising from such development activities that is necessary for the performance of the other Party's obligations under the Collaboration Programme; and (b) grant to the other Party a right to use such Future Indications Technology in the Field (including for Future Indications in accordance with Clause 4.14) on the same terms set out in Clauses respectively in Clauses 7.5 and 7.7 respectively, provided that such licence shall be non-exclusive.

Information exchange

- 7.11 Within thirty (30) days of the Effective Date, the Parties shall establish an electronic data room in which of all documents that relate to the Collaboration Programme must be filed (the "**Data Room**").
- 7.12 Within thirty (30) days of the Effective Date, Entasis shall provide to DNDi all of the Entasis Background Technology in its possession on the Effective Date. Each Party shall deposit any relevant documents relating to its Background Technology that is not in its possession on the Effective Date in the Data Room within thirty (30) days of such Background Technology being included in the Development Plan.
- 7.13 During the Term of this Agreement, each Party shall promptly communicate and make available to the other Party in a prompt manner and as it becomes available all of its Collaboration Technology and Regulatory Dossiers shall deposit all relevant documents in the Data Room as soon as reasonably practicable and in any event within thirty (30) days of creation of any relevant document.

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- 7.14 Entasis shall be responsible for maintaining the Data Room for a period of one (1) year following expiry or termination of this Agreement and shall permit nominated representatives of DNDi or any DNDi CSP or Sublicensee to have access to the data room during that period.

Filing, prosecution and maintenance and infringement

- 7.15 Entasis shall use its best efforts to file, prosecute, and maintain the Patent Rights claiming the Entasis Background Technology or the Entasis Collaboration Technology in all countries in the DNDi Territory listed on Schedule 3 as of the Effective Date and in any country in Schedule 3 in the DNDi Territory or the Entasis Territory in which Manufacturing is agreed to take place in accordance with the Manufacturing and Supply Plan.
- 7.16 Entasis shall notify DNDi (i) within ten (10) business days for any material updates, and (ii) every six (6) months for non-material changes with regard to all filings made for Patent Rights in the DNDi Territory including sending DNDi a copy of any such filing and otherwise shall keep DNDi informed of all material developments in relation to such Patent Rights and shall promptly provide DNDi with copies of relevant documents related to the filing, prosecution and maintenance of such Patent Rights. Entasis shall consider in good faith any reasonable comments made by DNDi in relation to the prosecution of Patent Rights in the DNDi Territory when making any submission to a Patent Rights office and in the conduct of any proceedings in relation to such Patent Rights. DNDi shall reimburse Entasis for costs and expenses for the maintenance of such Patent Rights in the DNDi Territory.
- 7.17 DNDi shall have the right but not the obligation to file, prosecute, and maintain the Patent Rights claiming the DNDi Background Technology and the DNDi Collaboration Technology on a world-wide basis (including for the avoidance of doubt in the Entasis Territory and the DNDi Territory).
- 7.18 DNDi shall keep Entasis promptly informed of all filings made for Patent Rights in the Entasis Territory including sending Entasis a copy of any such filing and otherwise shall keep Entasis informed of all material developments in relation to such Patent Rights and shall promptly provide Entasis with copies of relevant documents related to the filing, prosecution and maintenance of such Patent Rights. DNDi shall consider in good faith any reasonable comments made by Entasis in relation to the prosecution of Patent Rights in the Entasis Territory when making any submission to a Patent Rights office and in the conduct of any proceedings in relation to such Patent Rights. In the event that DNDi declines to file prosecute, maintain or defend any pending Patent Rights in any country of the Entasis Territory or the DNDi Territory it shall notify Entasis in writing of such decision and within thirty (30) days and Entasis and/or its Sublicensee shall have the right (but not the obligation) to file, prosecute and maintain such Patent Rights in the Entasis Territory or the DNDi Territory at Entasis' costs and expense. DNDi shall execute any documents to transfer control of such filing and maintenance to Entasis.
- 7.19 If a Party becomes aware of any actual, threatened or suspected infringement or misuse by a Third Party of any Patent Rights belonging to the other, it shall promptly notify the other Party in writing of all available evidence and details available to it (the **"Infringement Notice"**). The Party in whose Territory the infringement is occurring (i.e., DNDi in the DNDi Territory and Entasis in the Entasis Territory) (the **"Enforcing Party"**) will discuss the matter with the other Party to solicit its views as to any action that may or not be taken in relation thereto. The Enforcing Party shall have the sole right, but not the obligation to bring, defend, or maintain and control any suit or action against any actual, threatened or suspected infringement. The Enforcing Party will bear the relevant expenses, but the other Party shall reasonably assist and cooperate with the Enforcing Party in any enforcement or defence at the Enforcing Party's cost. If the other Party or its Sublicensee is required to join the Enforcing Party in such suit or action in order to enforce such Patent Rights, the other Party shall use commercially reasonable endeavors to execute all papers and perform all other acts as may be reasonably required at the cost of the Enforcing Party. If the Enforcing Party (or its

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Affiliate) lacks standing to bring any such action due to lack of ownership, it may ask the owning Party or its Sublicensee to do so at the Enforcing Party's cost and in which case the owning Party or its Sublicensee will conduct such action in accordance with the Enforcing Party's instructions. In any infringement proceedings, the Enforcing Party shall retain all costs and damages recovered, whether ordered or as part of a settlement.

- 7.20 If DNDi is the Enforcing Party and fails to take proceedings for more than six (6) months after having been alerted to the infringement, Entasis may give notice to DNDi demanding that DNDi take such proceedings within thirty (30) days of the date of the notice and, if DNDi does not do so, Entasis shall be entitled to take over such proceedings at its own cost and expense in which case DNDi shall transfer to Entasis the conduct of any claim or proceedings, including any counterclaim for invalidity or unenforceability or any declaratory judgment action. DNDi shall provide all necessary assistance to Entasis in relation to such proceedings at Entasis's cost. Entasis shall have the sole right to settle such proceedings including any counterclaim for invalidity or unenforceability. If Entasis succeeds in such proceedings, for any amounts attributable to lost sales of Drug Product in the DNDi Territory, such amounts will be distributed to DNDi and any other amounts will be retained by Entasis.
- 7.21 In the event of any Third Party challenge to the validity of any Patent Rights, the Enforcing Party shall have the sole right to decide upon and to implement the course of action with respect to such challenge (including but not limited to, the decision to defend, not to defend or settle such challenge) at its own cost or expense and the other Party shall reasonably assist in any defence at the cost of the Enforcing Party (including, without limitation the provision of information and expertise relating to the relevant Patent Rights). Notwithstanding the foregoing, if DNDi is the Enforcing Party and fails to take action within six (6) months after having been alerted to the Third Party challenge to the validity of DNDi's Patent Rights, Entasis may give notice to DNDi demanding that DNDi take such action within thirty (30) days of the date of the notice and, if DNDi does not do so, Entasis shall be entitled to take such actions at its own cost and expense in which case DNDi shall transfer to Entasis the conduct of any actions. DNDi shall provide all necessary assistance to Entasis in relation to such actions at Entasis's cost. Entasis shall have the sole right to settle such actions. If Entasis succeeds in such proceedings, for any amounts attributable to lost sales of Drug Product in the DNDi Territory, such amounts will be distributed to DNDi and any other amounts will be retained by Entasis.
- 7.22 If either Party receives a formal notice from a Third Party that the development, Manufacture or Commercialisation of the Drug Product in its Territory under this Agreement infringes or otherwise violates the intellectual property rights of such Third Party in its Territory or a part thereof, then such Party must promptly notify the other Party in writing of such allegation. As soon as reasonably practicable after the receipt of such notice, the Parties will meet and consider the course of appropriate action with respect to such allegation of infringement. In such instance, each Party will, have the right to defend any action naming it; however, at all times the Parties will cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use good faith efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defence and/or settlement of any such claim. The rights and obligations set out in this paragraph will apply even if only one Party defends any such claimed infringement action commenced by a Third Party. A non-owning Party will not enter into any settlement of such proceedings without the owning Party's prior consent, not to be unreasonably withheld or delayed.
- 7.23 The Parties agree to use commercially reasonable endeavors to cooperate in an effort to avoid loss of Patent Rights related to the Drug Product including by executing any documents as may be reasonably required.

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8. **GOVERNANCE AND PROJECT MANAGEMENT**

- 8.1 Within thirty (30) days from the Effective Date, the Parties shall establish and run a JSC to oversee the Collaboration Programme and which will be responsible for ensuring strategic coordination and exchange of information between the Parties.
- 8.2 Each Party shall further appoint a project leader for the Collaboration Programme (each, a "**Project Leader**"). Each Party may replace its Project Leader from time to time by giving a written notice to the other Party (including by email) as soon as reasonably practicable following such change. Each Project Leader shall be the primary point of contact for the Collaboration Programme for that Party.
- 8.3 The JSC shall be composed of six (6) representatives. Each Party shall be entitled to appoint three (3) representatives to the JSC (one of whom must be the Project Leader). JSC representatives must be appropriate for the primary function of the JSC in terms of their seniority, availability and function in their respective organisations, training and experience. The chairperson of the JSC will alternate between the Project Leader of DNDi and the Project Leader of Entasis at each JSC meeting.

- 8.4 Each Party shall be entitled to change its JSC representatives and will notify the other of any change. Each Party shall use reasonable efforts to keep an appropriate level of continuity in representation. JSC representatives may be represented by another person designated in writing (which shall include email) by the absent JSC representative.
- 8.5 The JSC shall hold meetings in person or by teleconference or videoconference as frequently as members of the JSC may agree shall be necessary, but no less frequently than (4) times per year. The chairperson shall be responsible for organising the JSC meeting, the first of which shall be held within thirty (30) days after the Effective Date at the premises of DNDi. Special meetings of the JSC may be called by any JSC member on written request to the then current chairperson of the JSC. Each Party shall provide the agenda items and written copies of associated materials that it wishes to be considered no later than seven (7) days prior to the relevant JSC meeting.
- 8.6 The venue for meetings of the JSC will alternate between the premises of the Parties, unless held by teleconference or videoconference. Each Party will be responsible for its own expenses for attendance of JSC meetings including travel and subsistence expenses.
- 8.7 The JSC shall have the power to invite guests to attend and address JSC meetings. Guests will not be representatives of the JSC and will not have voting rights. The Project Leaders will agree in advance on which Party will bear the costs of engaging a particular guest.
- 8.8 The current JSC chairperson shall be responsible for promptly preparing the minutes of any JSC meeting, seeking unanimous approval of those minutes from the JSC representatives by signing and dating the approved minutes and promptly distributing a copy of the signed minutes to each Party. It is only such signed and dated minutes that shall constitute a decision of the JSC.
- 8.9 The JSC shall have the purposes set out below but has no authority to amend, or to waive compliance with, any term or condition of this Agreement. The JSC shall:
- 8.9.1 guide the overall strategy for the Collaboration Programme including without limitation, discussing the TPP of the Drug Product, development, Manufacturing and Commercialisation activities;
 - 8.9.2 consider and discuss various aspects of the Collaboration Programme, submitted to the JSC by the Project Leaders;
 - 8.9.3 review study protocols and any amendments thereto as part of the Collaboration Programme and any study that may form part of the Regulatory Dossier;

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- 8.9.4 make the decision whether to proceed beyond a Holding Point specified in the Development Plan;
 - 8.9.5 make the decision whether to amend the Development Plan and the Regulatory Plan;
 - 8.9.6 review all on-going activities and progress relating to the Collaboration Programme; and
 - 8.9.7 agree a detailed Manufacturing and Supply Plan for the supply of the Drug Product.
- 8.10 Each Party shall have one vote at the JSC. Conclusions and decisions of the JSC shall be made by agreement whenever possible and recorded in the minutes that are signed and dated by the JSC members. Both Parties will use reasonable endeavours to reach agreement. Any decision made by the JSC through this process shall be binding on the Parties.
- 8.11 Any differences of opinion between the Parties with regard to the Collaboration Programme shall be discussed in good faith within the JSC. If the JSC is unable to reconcile the opinions within thirty (30) days or to make a decision within the scope of its responsibility, then the Parties shall submit the difference of opinion to each Party's senior executive officer, which, in the case Entasis, shall be the chief executive officer and, in the case of DNDi, shall be the GARDP Executive Director, to enable a compromise between different views with respect to such issue. If such senior executives of the Parties cannot successfully reconcile the difference of opinion within a fifteen (15) day period after the moment of formal submission to them, then the Party that has responsibility for the performance of the activity in question in its Territory shall have the final decision making authority on such matter, provided, that:

- 8.11.1 Following the grant of the first Marketing Authorisation, DNDi may conduct Clinical Trials: (a) in DNDi's Territory without any requirement of consent of Entasis provided that the design of any Clinical Trial with an intent to change the label shall require Entasis's prior written consent, not to be withheld, conditioned, or delayed unless there are reasonable objections on scientific grounds to the conduct of such Clinical Trial, and (b) in Entasis's Territory, solely with Entasis's prior written consent, not to be unreasonably withheld, conditioned, or delayed. Notwithstanding the foregoing, following a Change of Control of Entasis, DNDi will not require the prior consent of any Third Party acquiror to the performance of any Clinical Trial; and
- 8.11.2 Neither party shall have final decision-making authority with respect to any decision that would restrict or limit the Manufacture or supply of the API or Drug Product in or for the other Party's respective Territory.

9. SAFETY REPORTING, RECALLS AND INFORMATION EXCHANGE

- 9.1 Each Party will be responsible for ensuring that it complies with its regulatory obligations as either sponsor or as Marketing Authorisation holder, and for the management of clinical safety and pharmacovigilance with regard to the Drug Product in its respective Territory.
- 9.2 Within ninety (90) days from the Effective Date or such other period as the Parties may agree before enrolment of the first trial subject in the QT (TQT) Study, the Parties will conclude a pharmacovigilance agreement to govern the investigation of and action to be taken with regard to Drug Product related adverse experience reports, to enable each Party to comply with its legal obligations ("**Pharmacovigilance Agreement**").
- 9.3 Each Party shall exchange with the other Party all relevant information that relates to the safety and efficacy of the Drug Product as set out in the Pharmacovigilance Agreement. Each Party will

19 | Page

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reasonably co-operate with the other Party to ensure that regulatory requirements concerning drug safety surveillance are complied with in all countries in which the Drug Product is developed, Manufactured or Commercialised both in the Field and for any Future Indications.

- 9.4 Entasis will be responsible for setting up a worldwide Drug Product safety database, the details of which will be set out in the Pharmacovigilance Agreement.

10. REPRESENTATIONS AND WARRANTIES

- 10.1 DNDi represents and warrants the following:
- 10.1.1 It is duly authorized and validly existing under the laws of Switzerland and has full power and authority to enter into this Agreement and to carry out its provisions;
- 10.1.2 it is duly authorized to execute and deliver this Agreement and perform its obligations hereunder;
- 10.1.3 the person(s) executing this Agreement on DNDi's behalf has/have been duly authorized to do so by all requisite corporate action;
- 10.1.4 this Agreement is a legal and valid obligation binding upon DNDi and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by DNDi will not: (i) be prevented or impaired by any agreement, instrument or understanding, oral or written to which DNDi is a party or by which it is bound; or (ii) violate any legal requirement to which it is subject;
- 10.1.5 it shall perform its obligations under this Agreement in accordance with applicable laws and regulations;
- 10.1.6 as of the Effective Date: (a) it is the sole and exclusive owner or licensee of the entire right title and interest in the DNDi Background Technology; (b) it has not previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, licensed, transferred, conveyed or otherwise created an encumbrance on its right title and interest in the DNDi Background Technology that would prevent DNDi from granting Entasis rights hereunder, (c) to DNDi's knowledge, the conception, development and reduction to practice of Patent Rights and Know How relating to the DNDi Background Technology existing as of the Effective Date have not

constituted or involved the misappropriation of trade secrets or other rights of property of any person; and
(d) DNDi has the right, power and authority to grant all of the rights granted to Entasis hereunder;

10.1.7 DNDi has not received any notice or threat from any Third Party asserting or alleging, nor does DNDi have any knowledge of any basis for any assertion or allegation, that use of the DNDi Background Technology would infringe the intellectual property rights of a Third Party;

10.1.8 during the Term of this Agreement, it will not grant any right to any Third Party any right relating to any portion of the Collaboration Programme any right that would conflict with, limit or adversely affect the rights granted to Entasis hereunder;

10.2 Entasis represents and warrants the following:

10.2.1 It is duly authorized and validly existing under the laws of England and Wales and has full power and authority to enter into this Agreement and to carry out its provisions;

20 | Page

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10.2.2 it is duly authorized to execute and deliver this Agreement and perform its obligations hereunder;

10.2.3 the person(s) executing this Agreement on Entasis's behalf has/have been duly authorized to do so by all requisite corporate action;

10.2.4 this Agreement is a legal and valid obligation binding upon Entasis and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by Entasis will not: (a) be prevented or impaired by any agreement, instrument or understanding, oral or written to which Entasis or its Affiliates is a party or by which it or they are bound; or (b) violate any legal requirement to which it is or they are subject;

10.2.5 it shall perform its obligations under this Agreement in accordance with applicable laws and regulations;

10.2.6 as of the Effective Date, (a) it is the sole and exclusive owner or licensee of the entire right title and interest in the Entasis Background Technology, (b) it has not previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, licensed, transferred, conveyed or otherwise created an encumbrance on its right title and interest in the Entasis Background Technology that would prevent Entasis from granting DNDi rights hereunder, (c) to Entasis's knowledge, the conception, development and reduction to practice of Patent Rights and Know How relating to the Entasis Background Technology existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights of property of any person; and (d) Entasis has the right, power and authority to grant all of the rights granted to DNDi hereunder;

10.2.7 the Entasis Patent Rights listed in Schedule 3 represent all Patent Rights within Entasis's Control relating to the Drug Product which as of the Effective Date are necessary for DNDi to perform its obligations hereunder and enjoy the benefit of the licences and rights granted to it hereunder;

10.2.8 Entasis has not received any notice from any Third Party asserting or alleging, nor does Entasis have any knowledge of any basis for any assertion or allegation, that use of the Entasis Background Technology would infringe the intellectual property rights of a Third Party;

10.2.9 the Patent Rights set out in Schedule 3 that have been granted have been properly and correctly maintained in accordance with all applicable laws and all applicable fees have been paid on or before the due date for payment; and

10.2.10 during the Term of this Agreement, it will not grant any right to any Third Party any right relating to any portion of the Collaboration Programme any right that would conflict with, limit or adversely affect the rights granted to DNDi hereunder.

10.3 Each Party represents and warrants to the other Party that:

10.3.1 it will not utilise in connection with the Commercialization of the Drug Product any person or entities that are debarred by any applicable Drug Regulatory Authority;

- 10.3.2 neither that Party nor its Affiliates nor any director, officer, employee, agent or shareholder of any such person has taken any action that would violate any applicable Anti-Bribery Law nor in the last five (5) years has received any allegation of such violation or has been subjected to any investigation or inquiry by a competent authority relating to any Anti-

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Bribery Law and to the best of its knowledge, no such investigation or inquiry is pending or threatened;

- 10.3.3 that it has instituted and maintains policies designed to ensure compliance with applicable Anti-Bribery Laws;

- 10.3.4 the representations and warranties set out in this Clause 10.3 shall remain true and correct at all times;

- 10.3.5 it will provide written notice to the other Party as soon as practicable and in any event within seven (7) days should such warranty fail to be true or correct.

- 10.4 A breach of the representations and warranties set out in Clause 10.3 shall be considered a material breach that gives rise to an immediate termination right for the other Party on written notice.

- 10.5 Each Party shall inform the other Party as soon as reasonably practicable, but in any event within fourteen (14) days, after the occurrence of any of the following events:

- 10.5.1 cessation of conducting its business or trading;

- 10.5.2 a Change of Control of it or any of its Affiliates;

- 10.5.3 sale of all or any material portion of its assets or business to which this Agreement relates;

- 10.5.4 entry of any declaratory, injunctive or other remedy or court order that would materially impair its ability to conduct its business or perform its obligations under this Agreement;

- 10.5.5 any attachment or seizure (including prejudgment attachment or seizure) of material assets;

- 10.5.6 any entry into any restructuring agreement or workout agreement, or similar agreement, relating to any material indebtedness; and

- 10.5.7 loss of any permits, licences or governmental authorisations that are necessary for it to engage in its current business.

- 10.6 EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS AND EXCLUDES ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PURPOSE OR ANY WARRANTY THAT THE PHASE III MC TRIAL OR THE PERFORMANCE OF THE COLLABORATION PROGRAMME WILL PRODUCE ANY PARTICULAR RESULT.

11. INDEMNIFICATION AND LIABILITY

Entasis Indemnities

- 11.1 Entasis shall defend, indemnify and hold harmless DNDi, its Affiliates and their respective directors, officers, employees and agents (the “**DNDi Indemnified Parties**”) from and against all Losses arising from or occurring as a result of a Third Party’s claim, action, suit, judgment or settlement to the extent such Losses arise out of:

- 11.1.1 the negligent conduct of the QT (TQT) Study;

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- 11.1.2 the negligent conduct any Clinical Trial conducted by or on behalf of Entasis or its Affiliates in the context of the Collaboration Programme;
 - 11.1.3 any research and development activities performed by Entasis or its Affiliates outside of the Field;
 - 11.1.4 the Manufacture or Commercialization of the Drug Product by or on behalf of Entasis;
 - 11.1.5 any defects in any Drug Product either supplied by Entasis for the purpose of a Clinical Trial or supplied to DNDi or its Sublicensee by Entasis or its Sublicensee pursuant to any agreed Manufacturing and Supply Plan; and
 - 11.1.6 the negligence, intentional or wrongful acts or omissions or violations of law or regulation by Entasis, its Affiliates or its or their respective directors, officers or employees; and
 - 11.1.7 the breach by Entasis, its Affiliates or its or their respective directors, officers or employees of or the material inaccuracy of, any representation or warranty made by it in Clause 10 of this Agreement.

The foregoing indemnity obligations shall not apply to the extent that any Losses arise from or is based on any activity for which DNDi is obligated to indemnify the Entasis Indemnified Parties under Section 11.2.

DNDi Indemnities

- 11.2 DNDi shall defend, indemnify and hold harmless Entasis, its Affiliates and its and their respective directors, officers, employees and agents (the “**Entasis Indemnified Parties**”) from and against all Losses arising from or occurring as a result of a Third Party’s claim, action, suit, judgment or settlement to the extent such Losses arise out of:
 - 11.2.1 any research and development activities performed by DNDi outside of the Field;
 - 11.2.2 the negligent conduct by a DNDi Indemnified Party of the Phase III MC Trial;
 - 11.2.3 the negligent conduct of any other Clinical Trial conducted by or on behalf of DNDi in the context of the Collaboration Programme;
 - 11.2.4 the Manufacture or Commercialization of the Drug Product by or on behalf of DNDi;
 - 11.2.5 the negligence, intentional or wrongful acts or omissions or violations of law or regulation by DNDi, its Affiliates or its or their respective directors, officers or employees; and
 - 11.2.6 the breach by DNDi, its Affiliates or its or their respective directors, officers or employees of or the material inaccuracy of, any representation or warranty made by it in Clause 10 this Agreement.

The foregoing indemnity obligations shall not apply to the extent that any Losses arise from or is based on any activity for which Entasis is obligated to indemnify the DNDi Indemnified Parties under Section 11.1.

- 11.3 A person entitled to indemnification under Clause 11.1 or 11.2 (an “**Indemnified Party**”) shall give prompt written notice (the “**Indemnification Claim Notice**”) through a Party to this Agreement or

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its insurers to the person from whom indemnification is sought (including where relevant its insurers) (the “**Indemnifying Party**”) of the threat or commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought (a “**Third Party Claim**”). Each Indemnification Claim Notice shall contain a description of the claim and the amount of any Losses claimed. The Indemnified Party shall promptly provide to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received in respect of any such Losses.

- 11.4 If required, the Indemnifying Party shall notify the insurers of the Third Party Claim and shall permit them to exercise their rights of subrogation.
- 11.5 Within thirty (30) days after receipt of an Indemnification Claim Notice, the Indemnifying Party shall notify the Indemnified Party in writing whether it intends to control the defence of the Third Party Claim using its legal representatives in which case shall have sole control and responsibility for dealing with the Third Party Claim, including the right to settle the claim provided that:
- 11.5.1 the Indemnified Party shall be consulted and may retain its own legal representatives for proceedings at its own cost and expense; and
- 11.5.2 for Losses which are not solely monetary and for which the Indemnified Party has acknowledged in writing an obligation to indemnify or if the Indemnified Party will be subject to injunctive relief, prior written consent of the Indemnified Party will be required to settlement (such consent not to be unreasonably withheld).
- 11.6 If the Indemnifying Party does not assume control of such defence, the Indemnified Party may control such defence provided that the Indemnified Party shall not admit any liability with respect to, or settle, compromise or discharge any such Third Party Claim without the prior written consent of the Indemnifying Party (not to be unreasonably withheld). The Indemnifying Party shall not be liable for any settlement or other disposition of Losses by an Indemnified Party with respect to any Third Party Claim that is entered into without such consent.
- 11.7 If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party that is a Party to this Agreement shall, and shall cause each Indemnified Party to reasonably cooperate in the defence or prosecution thereof and shall provide all records, information and testimony, witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making the Indemnified Party, its Affiliates and its and their respective directors, officers, employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided, and the Indemnifying Party shall reimburse the Indemnified Party for all of its related reasonable out-of-pocket expenses.
- 11.8 The Party controlling the defence shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defence thereof and shall consider in good faith reasonable recommendations made by the other Party with respect thereto.

Insurance

- 11.9 Each Party shall maintain at its own cost sufficient insurance to cover its liabilities set out in this Clause 11. Subject to applicable law, the foregoing requirement may be met by way of self-insurance. Upon request from the other Party, each Party shall communicate to the other any

24 | Page

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insurance policies covering its responsibilities under this Agreement and copies of relevant insurance certificates.

Limitation of Liability

- 11.10 EXCEPT WITH RESPECT TO THIRD PARTY CLAIMS FOR WHICH A PARTY IS REQUIRED TO INDEMNIFY THE OTHER PARTY PURSUANT TO CLAUSE 11.1 OR 11.2, IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY LOSSES SUFFERED OR INCURRED BY THE OTHER PARTY OR ITS AFFILIATES FOR ANY DIRECT OR INDIRECT LOSS OF PROFITS, BUSINESS, REVENUE OR GOODWILL OR ANY OTHER LOSSES OF A SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL OR PUNITIVE NATURE INCLUDING, WITHOUT LIMITATION, INDIRECT OR CONSEQUENTIAL ECONOMIC LOSS OR LOSS OF BUSINESS VALUE.
- 11.11 Nothing in this Agreement shall be taken to exclude or limit either Party's liability to the extent that such liability cannot be excluded or limited in law including for fraud or fraudulent misrepresentations.

12. TERM AND TERMINATION

- 12.1 This Agreement shall be effective from the Effective Date and, subject to earlier termination in accordance with its terms, it shall remain in force and effect for the duration of the Term. For the avoidance of doubt, at the expiry of the Term in each country of the DNDi Territory and the Entasis Territory, the licences granted by each Party to the other shall become perpetual.
- 12.2 Each Party shall have the right to terminate this Agreement, without prejudice to any other rights it may have, on ninety (90) days' written notice if the other Party is in material breach any of its representations, warranties or obligations hereunder and such breach is either not capable of being remedied, or if capable of being remedied, is not remedied if within thirty (30) days following receipt of the written notice notifying the breaching Party of such breach. If the breach relates to only one country or a group of countries in the Territory of the non-breaching Party, the terminating Party may apply such termination right in relation to the relevant country or countries or to this Agreement as a whole if such breach relates to three or more countries or is unrelated to any specific countries. If the other Party in good faith disputes such material breach or disputes the failure to rectify material breach and provides written notice of that dispute to the other Party within the foregoing timeframe, the matter will be referred for dispute resolution pursuant to Clause 17.2, and the Party wishing to terminate may not do so until it has been determined under Clause 17.2 that the other Party is in material breach of this Agreement and further fails to cure such breach within thirty (30) days after conclusion of that dispute resolution procedure.
- 12.3 This Agreement may be terminated by either Party upon written notice to the other Party, with immediate effect, in the that any of the following events occurs in relation to the other Party:
- 12.3.1 a notice has been issued to convene any meeting for the purpose of passing a resolution or seeking a petition to wind up or liquidate that Party, or to seek bankruptcy or official administration, or such a resolution having been passed or such a petition having been issued (except in relation to a solvent reconstruction or reorganisation of that Party);
- 12.3.2 an involuntary petition in an insolvency proceeding is filed against a Party and is not dismissed or stayed within ninety (90) days of filing thereof; or

25 | Page

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- 12.3.3 a trustee in bankruptcy, receiver, administrative receiver, receiver and manager, court appointed receiver, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party or over any part of that Party's assets or any third party takes steps to appoint such an officer in respect of that Party; or
- 12.3.4 a Party takes any step, (including starting negotiations), with a view to readjustment, rescheduling or deferral of any part of that Party's indebtedness including a moratorium with creditors, or proposes or makes and general assignment, composition or arrangement with or for the benefit of all or some of that Party's creditors or makes or suspends or threatens to suspend making payments to all or some of that Party's creditors or the Party submits to any type of voluntary arrangement with creditors.
- 12.4 This Agreement may be terminated by the Parties upon mutual written agreement.
- 12.5 Either Party may terminate this Agreement at any time after completion or earlier termination of the Phase III MC Trial with twelve (12) months' prior notice.
- 12.6 Entasis may terminate this Agreement if DNDi has not achieved the first dosing of the first patient in the Phase III MC Trial within eighteen (18) months after the Effective Date. The foregoing termination right shall not apply if there is a delay in the first dosing of the first patient in the Phase III MC Trial due to:
- 12.6.1 any act or omission of Entasis or Entasis's Affiliates or Entasis's CSPs;
- 12.6.2 the outcome of any development activities that are required to be conducted prior to the Phase III MC Trial;
- 12.6.3 delays caused by Drug Regulatory Authorities; or

12.6.4 any Force Majeure event beyond the reasonable control of DNDi.

Consequences of Termination

12.7 In the event of termination by Entasis pursuant to Clause 12.2 (following a final determination by an arbitrator of material breach) or 12.6:

- 12.7.1 the licenses granted by Entasis to DNDi under Clauses 7.3, 7.5, 7.9 and 7.10, as applicable, shall automatically terminate in so far as they relate to the terminated countries and revert to Entasis and any sublicenses granted thereunder shall automatically terminate and revert to Entasis;
- 12.7.2 if the entire Agreement is terminated, DNDi shall return to Entasis, or at its request destroy, all Confidential Information and materials received from Entasis pursuant to this Agreement (including in the possession of a Sublicensee);
- 12.7.3 DNDi shall transfer, or have transferred, to Entasis copies of all relevant Marketing Authorisations in so far as they relate to the terminated countries and, if the entire Agreement is terminated, other documents held by DNDi in relation to the Drug Product within thirty (30) days of termination and shall do all things and execute all documents necessary to give effect to such transfers. If such transfer does not comply with legal requirements for the given country, DNDi shall use reasonable efforts to ensure that Entasis has the benefit of the Marketing Authorisations and consent to any Drug Regulatory Authority to the cross-referencing in the relevant countries to the data and information on

26 | Page

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file with such Drug Regulatory Authority as may be necessary to facilitate the granting of a second Marketing Authorisation for the Drug Product in the relevant countries. In such circumstances DNDi will, in so far as legally permissible cancel the first Marketing Authorisation for the Drug Product in a country, on the granting of the second Marketing Authorisation. DNDi will further, at its sole cost and expense, complete whatever procedures are necessary or desirable and do all such other acts and things necessary or desirable to enable Entasis (either itself or in conjunction with a Third Party) to develop, Manufacture, and Commercialise the Drug Product in the relevant countries.

- 12.7.4 the licenses granted by DNDi to Entasis pursuant to Clauses 7.3, 7.7, 7.9, and 7.10 shall survive and become perpetual, worldwide, fully paid up, exclusive, and irrevocable; and
 - 12.7.5 DNDi shall provide the necessary training to any Third Party appointed by Entasis to implement the development of the Drug Product, regulatory activities, Manufacture and Commercialisation or to ensure continuity in the supplies of the Drug Product.
- 12.8 In the event of termination by DNDi pursuant to Clause 12.2 (following a final determination by an arbitrator of material breach):
- 12.8.1 the licenses granted by Entasis to DNDi under Clauses 7.3, 7.5, 7.9 and 7.10, as applicable in so far as they relate to the terminated countries, shall become perpetual and irrevocable;
 - 12.8.2 the licenses granted by DNDi to Entasis under Clauses 7.3, 7.7 and 7.9 and 7.10, as applicable in so far as they relate to the terminated countries, shall continue;
 - 12.8.3 to the extent Entasis has not obtained or is not in the process of obtaining Marketing Authorisations in the Field with the FDA, DNDi may file for the first Marketing Authorisation for the Drug Product in the Field with the FDA; provided, that DNDi gives Entasis sixty (60) days' notice that DNDi plans to file such Marketing Authorisation application. To the extent DNDi obtains Marketing Authorisation from either the FDA, DNDi shall and hereby does grant Entasis an exclusive, royalty-bearing license and right of reference, with the right to grant sublicenses and further rights of reference through multiple tiers, under such Marketing Authorisation with the FDA to Commercialise the Drug Product in the Field in the Entasis Territory. If DNDi obtains a Marketing Authorisation with the FDA and Entasis elects to Commercialize the Drug Product in the United States, then Entasis will pay DNDi a three percent (3%) royalty on net sales (to be defined by the parties at the time of such termination) of Drug Product in the Field in the United States until such time as DNDi recoups one hundred

percent (100%) of its out-of-pocket development and regulatory filing costs incurred by DNDi for the Marketing Authorization with the FDA as of the effective date of termination; and

12.8.4 Clause 7.6 shall cease to apply.

12.9 In the event of termination by either Party pursuant to Clause 12.3:

12.9.1 the licenses granted by the insolvent Party to the solvent Party under this Agreement shall become perpetual and irrevocable;

12.9.2 the Parties will negotiate in good faith to address concerns relating to sublicensees in the insolvent Party's territory; and

12.9.3 if DNDi terminates pursuant to Clause 12.3, to the extent Entasis has not obtained or is not in the process of obtaining Marketing Authorisations in the Field with the FDA, DNDi may

27 | Page

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file for the first Marketing Authorisation for the Drug Product in the Field with the FDA; provided, that DNDi gives Entasis sixty (60) days' notice that DNDi plans to file such Marketing Authorisation; provided, further, that DNDi shall and hereby does grant Entasis an exclusive, perpetual, sublicenseable (through multiple tiers), royalty free license to use data contained in and reference any Marketing Authorisations from the FDA obtained by DNDi; and

12.9.4 if Entasis is the insolvent Party Clause 7.6 shall cease to apply.

12.10 In the event of termination by the Parties pursuant to Clause 12.4, all rights and licenses granted under this Agreement will terminate and each Party shall return to the other, or at the other's request destroy, all Confidential Information and materials received from the other Party pursuant to this Agreement (including in the possession of a Sublicensee).

12.11 In the event of termination by either Party pursuant to Clause 12.5, the licenses granted to the terminating Party shall terminate and revert to the non-termination Party, and the licenses granted by the terminating Party to the non-terminating Party under this Agreement shall become perpetual and irrevocable. If Entasis is the terminating Party, at DNDi's request, Entasis will give DNDi an exclusive first right for a period of ninety (90) days to discuss an opportunity for DNDi to commercialize the Drug Product in one or more countries in the Entasis Territory on mutually acceptable terms. Further, to the extent Entasis has not obtained or is not in the process of obtaining Marketing Authorisations in the Field with the FDA by the end of such ninety (90) day period (or such longer period as the parties may agree), DNDi may file for the first Marketing Authorisation for the Drug Product in the Field with the FDA; provided, that DNDi gives Entasis sixty (60) days' notice that DNDi plans to file such Marketing Authorisation application. To the extent DNDi obtains Marketing Authorisation from the FDA, unless it is agreed that DNDi will commercialize the Drug Product in the United States, DNDi shall and hereby does grant Entasis an exclusive (except with respect to DNDi as agreed by the Parties after termination), royalty-bearing license and right of reference, with the right to grant sublicenses and further rights of reference through multiple tiers, under such Marketing Authorisation with the FDA to Commercialise the Drug Product in the Field in the Entasis Territory. If DNDi obtains a Marketing Authorisation with the FDA and Entasis elects to Commercialize the Drug Product in the United States, then Entasis will pay DNDi a three percent (3%) royalty on net sales (to be defined by the parties at the time of such termination) of Drug Product in the Field in the United States until such time as DNDi recoups fifty percent (50%) of its out-of-pocket regulatory filing costs incurred by DNDi for the Marketing Authorization with the FDA as of the effective date of termination.

Survival

12.12 Notwithstanding the expiration or termination of this Agreement, and except as provided expressly herein, the provisions of Clauses 1 (to the extent defined terms are contained in the following surviving Clauses), 6.3, 7.1, 7.2, 7.3, each of 7.5, 7.6, 7.7, 7.8, 7.9, 7.10, and 7.14 solely to the extent required under clauses 12.7—12.11, 11.1 (with respect to any matter, fact, or circumstance arising or existing prior to the termination or expiration of this Agreement), 11.2 (with respect to any matter, fact, or circumstance arising or existing prior to the termination or expiration of this Agreement), 11.3, 11.4, 11.5, 11.6 (except as otherwise specified in Clause 12.8 and 12.9), 11.7, 11.8, 11.9 (for a reasonable period of time following expiration or termination), 11.10, 11.11, 12.1 (as applicable), 12.7 (as applicable), 12.8 (as applicable), 12.9 (as

applicable), 12.10 (as applicable), 12.11 (as applicable), this Clause 12.12, 13, 15.1, 16.1, 16.3, 16.7, 16.9, 16.11 (to the extent required under Clauses 12.7—12.11), 16.12, 16.13, and 17 shall remain in full force effect.

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13. CONFIDENTIALITY AND RESTRICTED USE

- 13.1 Except as specifically set forth elsewhere in this Agreement, each Party shall use only for purposes of this Agreement, and, except as permitted in this Agreement, shall keep confidential and not communicate to any Third Party, all of the Confidential Information received or otherwise learned pursuant to this Agreement including without limitation Confidential Information exchanged prior to the Effective Date relating to the subject matter of this Agreement.
- 13.2 Each Party shall communicate the Confidential Information of the other Party only to its employees and Third Parties (including, but not limited to actual and potential funding partners, consultants, CSPs and Sublicensees) who need to know such Confidential Information in order to perform this Agreement and who have agreed to abide by confidentiality and restricted use obligations at least as stringent as those set forth herein (the “**Permitted Recipients**”). Each Party shall be responsible to the other Party for any breach by its Permitted Recipients of such obligations.
- 13.3 The confidentiality and restricted use obligations set forth herein shall not apply to Confidential Information with respect to which the receiving Party can reasonably prove:
- 13.3.1 was already lawfully in such Party’s possession at the time of its disclosure hereunder, and not subject to any obligation of confidentiality or restricted use;
 - 13.3.2 is in the public domain at the time of disclosure or becomes in the public domain after disclosure to the receiving Party through no action, fault or omission of the receiving Party;
 - 13.3.3 is lawfully received by the receiving Party from a Third Party, provided that such Third Party is not subject to any obligation of confidentiality or restricted use with respect thereto;
 - 13.3.4 is independently developed by the receiving Party without using any of the Confidential Information received hereunder;
 - 13.3.5 that the receiving Party is required to disclose pursuant to applicable law, regulation or decision or order of any competent court, tribunal, governmental authorities or Drug Regulatory Authority, provided that the receiving Party has promptly disclosed such obligation to the disclosing Party and cooperates with the disclosing Party in efforts to (i) limit the extent of such disclosure to what is required to comply with the applicable law, regulatory, or decision, and (ii) obtain confidential treatment of the Confidential Information required to be disclosed.
- 13.4 The obligations of confidentiality and restricted use in this Clause 13 shall remain in force for the Term of this Agreement and for seven (7) years following disclosure of the relevant Confidential Information.

14. SCIENTIFIC PUBLICATIONS

- 14.1 Notwithstanding Clause 13, and in accordance with DNDi’s mission statement on providing access to the public of its research, DNDi and Entasis will encourage publications in scientific journals, abstracts or conferences of the scientific data and/or results of the Collaboration Programme pursuant to this Clause 14.
- 14.2 Each Party shall submit to the other Party prior to publication any draft publication relating to the Collaboration Programme for review at least twenty-eight (28) days prior to the intended date of publication, and permit it to submit comments which the publishing Party shall reasonably take into account, or object to such publication on the grounds that it discloses patentable inventions or discloses confidential technology of a Party. Should Patent Rights be sought by a Party upon any data in the draft publication, publication can be delayed by a maximum period of ninety (90) days

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to allow for drafting of the Patent Rights application. Each Party will, on the reasonable request from the other Party, remove from any proposed manuscript or presentation any Confidential Information of the other Party provided that neither Party will be prevented from publishing Confidential Information of the other Party (and in particular clinical data) to the extent that publication of such Confidential Information is required for any Regulatory Dossier or in order to obtain a Marketing Authorisation.

- 14.3 Both Parties will ensure that all written communications, including those that originate from one of their respective partners, indicate that the Drug Product was jointly developed through collaboration between DNDi and Entasis.

15. PUBLICITY

- 15.1 Except as required by applicable law or the rules of any stock exchange, neither Party shall make any public disclosure concerning this Agreement or the subject matter hereof without the prior written consent of the other Party, which shall not be withheld unreasonably.
- 15.2 Notwithstanding Clause 15.1, either Party may disclose the information set forth on Schedule 7 (the “**Disclosable Information**”) without the prior written consent of the other Party, provided that the disclosing Party gives the other Party a copy of or reference (e.g., link to internet site) to such disclosure at the time of disclosure. For the avoidance of doubt, any press release shall require the prior written consent of the non-disclosing Party, even if such press release is limited to the Disclosable Information.

16. MISCELLANEOUS

- 16.1 Notifications and Communications. All notifications and other communications contemplated by this Agreement shall be sent in writing to the Parties at the following addresses:

For DNDi:

15 Chemin Louis-Dunant
CH-1202 Geneva, Switzerland
Attention: Jean-Pierre Paccaud
With copy to: the GARDP R&D Director

For Entasis:

35 Gatehouse Drive
Waltham, MA 02451
United States of America
Attn: Michael Gutch

or to such other address as the recipient may notify to the other Party in accordance with this Clause 16.1. Unless otherwise set forth herein, all such notifications and communications must be sent by registered letter with return receipt, and shall be deemed delivered on the date on the return receipt (if delivered by registered mail with return receipt requested).

- 16.2 Entire Agreement; Modification. This Agreement, including the recitals and the Schedules, is the entire agreement, and supersedes all prior agreements, written or oral, between the Parties with respect to the subject matter hereof. No modification of this Agreement shall be effective unless set forth in a writing signed by both Parties.

30 | Page

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- 16.3 Invalidity. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any applicable present or future law, the illegality, invalidity or unenforceability of such provision shall not affect the validity of this Agreement as a whole, unless such provision is of such essential importance for this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without such provision. Where possible, the Parties shall negotiate in good faith a provision to replace such illegal, invalid or unenforceable provision that is as close to the intent of the original provision as legally possible. All other provisions of this Agreement shall remain valid and in force.

- 16.4 Assignment. Neither Party may transfer or assign to a Third Party any of its rights or obligations under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. It is understood, however, that either Party may freely transfer or assign or subcontract any of its rights and obligations under this Agreement to any of its Affiliates. Furthermore, it is understood, that subject to Clause 12.7 either Party may freely transfer or assign or subcontract any of its rights and obligations under this Agreement to any direct or indirect successor to all or substantially all of its business by means of merger, divestment, acquisition, contribution of assets or any other restructuring operation. DNDi may further transfer any of its rights and obligations pursuant to this Agreement to any legal entity that may be set up for the purpose of the business of GARDP (a “**GARDP Entity**”). DNDi and the GARDP Entity shall provide notice to Entasis of such transfer or assignment to which Entasis shall be deemed to agree by executing this Agreement. Entasis shall, on request and at the cost of DNDi and/or the GARDP Entity enter into any additional documentation that may be required to give effect to or implement any such assignment or transfer.
- 16.5 Force Majeure. Neither Party shall be liable for any default or delay in performing its obligations hereunder if such default or delay is caused by an event of Force Majeure. The Party claiming Force Majeure must promptly inform the other Party of such event and, in accordance with the other Party, must take commercially reasonable endeavours to limit the consequences of such Force Majeure event. If a Party is unable to fulfil any relevant obligation under this Agreement due to any such cause, and this situation continues for a period of six (6) consecutive months, then the other Party may, with immediate effect, terminate this Agreement immediately. In such circumstances the terms set out in Clause 12.7 or 12.8 (as appropriate) shall apply to the Party being terminated.
- 16.6 Regulatory Advantages. The Parties acknowledge that both Parties are actively contributing to the Collaboration Programme hereunder. Consequently, in the event that any advantage may be received from any Drug Regulatory Authority resulting from obtaining any Marketing Authorisation hereunder and arising from the classification of the Drug Product on the WHO essential medicines list the Parties shall discuss in good faith to find a way to share the repercussions of such advantage in an equitable manner.
- 16.7 Audit. Each Party agrees to permit any auditor or an independent public accountant designated by any funding entity of the Collaboration Programme and reasonably acceptable to the Parties to have access, during the Term of this Agreement and for a period of six (6) years from expiry or earlier termination, during regular business hours and upon at least (10) days’ written notice, to its records and books to the extent necessary to determine compliance with the requirements of this Agreement and the Collaboration Programme. The Parties will further agree to appropriate audit rights for the purpose of the Manufacturing and Supply Plan.
- 16.8 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized representative of each Party.

31 | Page

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

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- 16.9 Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of any Party or its agents or employees except in writing expressly waiving such provision and signed by a duly authorised officer or director of the waiving Party.
- 16.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which need not contain signature on behalf of more than one Party but all such counterparts will, taken together, constitute one and the same agreement. A signed agreement received by a Party hereto and received by way of a pdf submitted electronically will be deemed an original, and binding upon the Party signing it.
- 16.11 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 16.12 Independent Contractors. The relationship between Entasis and DNDi created by this Agreement is one of independent contractors and neither Party shall have the power or authority to bind or obligate the other. There is no employer-employee relationship, principal-agent relationship, or partnership relationship between Entasis and DNDi or any of their representatives.
- 16.13 No Strict Construction; Headings. This Agreement has been prepared jointly and shall not be construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, regardless of which Party may be

deemed to have authored the ambiguous provision. The headings of each Clause in this Agreement have been inserted for reference only and are not intended to limit or expand the meaning or language in the particular Clause.

17. GOVERNING LAW AND JURISDICTION

- 17.1 This Agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter of formation shall be governed by, subject to and construed and enforced in accordance with the laws of [*], without giving effect to any conflicts or choice of law rules.
- 17.2 Subject to Clause 8.11, the Parties shall use reasonable endeavours to resolve amicably any dispute between the Parties arising out of or in connection with this Agreement by referral to the Executive Director of GARDP for DNDi and the Chief Executive Officer for Entasis who shall use reasonable efforts to meet in person within thirty (30) days from written notice of dispute received by one Party from the other. Should such matter remain unresolved at the end of that period, such dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with such rules. The place of arbitration shall be Geneva, Switzerland and the language of the proceedings shall be English.
- 17.3 Notwithstanding the dispute resolution procedures set forth in Clause 17.2, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder.
- 17.4 Notwithstanding Clauses 17.1 and 17.2, any dispute concerning the ownership or inventorship of any Patent Rights arising hereunder in any given jurisdiction shall be determined by the courts of the jurisdiction in question.

{SIGNATURE PAGE FOLLOWS}

32 | Page

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

Entasis Therapeutics Limited

Drugs for Neglected Diseases initiative

By: /s/ Manos Perros
Name: Manos Perros
Title: Chief Executive Officer

By: /s/ Manica Balasegaram
Name: Dr. Manica Balasegaram
Title: DIRECTOR, GARDP

By: /s/ Jean-Pierre Paccaud
Name: Dr. Jean-Pierre Paccaud
Title: BD and CORPORATE STRATEGY DIRECTOR

33 | Page

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Schedule 1: Development Plan

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34 | Page

[*] = Twelve pages of certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Schedule 2: Territories

Entasis Territory

The following countries constitute the Entasis Territory:

[*]

DNDi Territory

All countries in the world (other than each Additional Country as defined below) that are not specified as being in the Entasis Territory.

Additional Countries

Additional Countries shall be [*] (each an “Additional Country”).

Each Additional Country shall be considered as falling within DNDi’s Territory if, at the time of [*], such Additional Country has either (i) provided investment into development of the API or the Drug Product in the Field by way of funds or contributions in kind with a value of at least EUR [*] or (ii) entered into a binding written commitment (to provide such funds or contributions in kind with a value of at least EUR [*] during the time the Parties are conducting activities under the Development Plan. Each Additional Country shall be considered as falling within Entasis’s Territory should such foregoing funding condition not be met for such Additional Country.

If an Additional Country is included in DNDi’s Territory at the time of [*], then DNDi shall use commercially reasonable endeavours to obtain a Marketing Authorisation in the Field in such Additional Country. If DNDi has not obtained Marketing Authorization in the Field in such Additional Country within [*], then Entasis will be entitled to transfer that such Additional Country to the Entasis Territory.

If an Additional Country is included in Entasis’s Territory at the time of [*], then Entasis may seek a Marketing Authorisation in the Field in such Additional Country. If Entasis has taken no action to seek Marketing Authorization in the Field in such Additional Country within [*], then DNDi will be entitled to request that such Additional Country be transferred to the DNDi Territory.

35 | Page

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Schedule 3: Entasis Patent Rights

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36 | Page

[*] = Seven pages of certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Schedule 4: Regulatory Plan

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37 | Page

[*] = Three pages of certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Schedule 5: TPP

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38 | Page

[*] = One page of certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Schedule 6: API

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39 | Page

[*] = One page of certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

Schedule 7: Disclosable Information

The Agreement covers and relates to:

- treatment of gonorrhoea caused by *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and/or *Mycoplasma genitalium*
- with drug products containing zoliflodacin
- commercialization by Entasis in certain high-income countries; and commercialization by DNDi in all other countries worldwide
- joint drug development including formulation and clinical and non-clinical studies and subsequent registration
- each party's commitment to ensure access to the Product.

40 | Page

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Drugs for Neglected Diseases *initiative*



ENTASIS THERAPEUTICS LIMITED

1 Ashely Road, 3rd Floor

Altrincham, Cheshire WA14 2DT

11 January 2019

Purpose: Novation of contract

Dear Manos Perros,

We refer to the contract between ENTASIS THERAPEUTICS LIMITED ("**ENTASIS**") and the Drugs for Neglected Diseases initiative ("**DNDi**") for a collaboration agreement relating to the development, manufacture and commercialization of zoliflodacin, dated 4 July 2017 ("**Contract**").

The GARDP Foundation, a Swiss charitable foundation having its principal office at 15 Chemin Louis-Dunant, 1202 Geneva, Switzerland (the "**GARDP Foundation**") has now been established and operationalised. In accordance with section 16.4 of the Contract, DNDi now wishes to transfer its rights, obligations and liabilities under the Contract to the GARDP Foundation under the terms set out below.

With effect from January 2019 ("**Effective Date**"):

- DNDi transfers all its rights and obligations under the Contract to the GARDP Foundation.
- The GARDP Foundation will perform the Contract and be bound by its terms in every way as if it were the original party to it in place of DNDi.
- ENTASIS will perform the Contract and be bound by its terms in every way as if the GARDP Foundation were the original party to it in place of DNDi.

In addition, also with effect from the Effective Date:

- Each of ENTASIS and DNDi releases and discharges the other from all claims and demands under or in connection with the Contract, whether arising before, on, or after the Effective Date, and in each case whether known or unknown to the releasing party.
- Each of ENTASIS and the GARDP Foundation will have the right to enforce the Contract and pursue any claims and demands under it against each other with respect to matters arising before, on or after the Effective Date, as if GARDP were the original party to the Contract instead of DNDi.
- The GARDP Foundation agrees to indemnify DNDi against any losses, damages or costs suffered or incurred by DNDi under or in connection with the Contract after the Effective Date. This indemnity shall apply even if DNDi has been negligent.

The Contract will in all other respects continue on its existing terms.

From the Effective Date, each of ENTASIS and the GARDP Foundation should deal solely with each other in respect of the Contract; all invoices and correspondence relating to the Contract should be sent to the GARDP Foundation at the address set out below, marked for the attention of Jean-Pierre PACCAUD, BD Director.

If you have any questions concerning the transfer, please contact GARDP Legal Department at [***] or Fiona Ross, Senior Legal Counsel for DNDi on [***] or at [***].

This letter and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the law of England and Wales.

Please sign each of the three (3) originals of this letter to acknowledge your agreement to the novation of the Contract with effect from the Effective Date on the terms set out above, and return two (2) originals to the attention of GARDP FOUNDATION, Legal Department, at the following address: 15 Chemin Louis Dunant, 1202 GENEVA, SWITZERLAND.

Yours faithfully

/s/ Bernard Pecoul

Name: BERNARD PECOUL

Title: EXECUTIVE DIRECTOR

for and on behalf of the **GARDP Foundation**

Signed /s/ Dr. Manica Balasegaram

Name: Dr.MANICA BALASEGARAM

Title: EXECUTIVE DIRECTOR

for and on behalf of **ENTASIS**

Signed /s/ Manos Perros

Name :MANOS PERROS

Title: CHIEF EXECUTIVE OFFICER