

**DRAFT FOR DISCUSSION PURPOSES ONLY**

**DEVELOPMENT COLLABORATION AND LICENSE  
AGREEMENT  
(HEREINAFTER THE “AGREEMENT”)**

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This **DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT** is made on < add date > (“**Effective Date**”)

**BETWEEN**

**Drugs for Neglected Diseases initiative**, a Swiss foundation with its registered offices at 15, chemin Camille-Vidart, 1202 Geneva, Switzerland (“**DNDi**”);

**AND**

< add name of partner >, a company incorporated under the laws of < add applicable incorporation laws > having its registered office at < add registered address > (“**Partner**”),

(each individually referred to as a “**Party**”, and collectively as the “**Parties**”).

**RECITALS**

Terms written in initial capital letters and used in this “**Recitals**” section of this Agreement and not otherwise defined shall have the meanings set out in Section 1 of this Agreement.

- A. **WHEREAS**, DNDi is a not-for-profit entity whose mission is to develop safe, effective, field-adapted and affordable new treatments for people suffering from neglected diseases, and ensure equitable access to such treatments (the “**Mission**”);
- B. **WHEREAS**, acting in the public interest, DNDi bridges existing research and development (“**R&D**”) gaps for these diseases by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry and other relevant partners;
- C. **WHEREAS**, Partner is < add Partner’ introduction, mission here >;
- D. **WHEREAS**, Partner has advanced a Molecule with potential activity in the Field; and
- E. **WHEREAS**, Partner and DNDi desire to collaborate to undertake a development and distribution program with respect to such Molecule, which includes clinical development, manufacture and distribution of a Product on an Affordable Basis in the Territory.

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

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**1. DEFINITIONS**

- 1.1. **Access and Implementation Plan** shall mean a written plan setting forth the mutually agreed strategy based on needs while ensuring access to the Product on an Affordable Basis in the Field in the Territory.
- 1.2. **Affiliate** shall mean with respect to a Party, any legal entity that directly or indirectly controls, is controlled by, or is under common control with such Party. For this definition, the term “**control**” (with correlative meanings for “**controlled by**” and “**under common control with**”) shall refer to the power to direct the management or policies of an entity, whether through ownership of shares, voting rights, securities, by contract or otherwise.
- 1.3. **Affordable Basis** shall mean pricing a Product at the lowest sustainable level which may include only:
  - a) full production costs, as optimised without compromising the quality of the Product; and
  - b) direct distribution costs, and
  - c) a reasonable margin, not to exceed **< to be completed >** percent of the foregoing costs, for the selling Party.
- 1.4. **Agreement** shall mean this Development Collaboration and License Agreement, including any exhibits, appendices, Annexes and schedules hereto, as well as any future written amendments agreed and signed by the Parties in accordance with the terms herein.
- 1.5. **Applicable Laws** shall mean current local and international laws, regulations, regulatory requirements and authorisations, decisions and guidance of regulatory authorities, professional association codes or other requirements applicable in the context of this Agreement, including Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice and Good Distribution Practice.
- 1.6. **Collaboration Technology** shall mean any Technology that is made, developed, conceived and reduced to practice by either Party (or on its behalf) during the performance of the Development and Distribution Program. Collaboration Technology includes Partner Collaboration Technology and DNDi Collaboration Technology.
- 1.7. **Collaboration Plans** shall mean the Development Plan(s), the Access and Implementation Plan(s) and any other plan(s) mutually agreed by the Parties in connection with this Agreement.
- 1.8. **Confidential Information** shall mean any and all non-public information and data, chemical structures, Know-How, all other scientific, preclinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, which is provided through any means of communication by, or on behalf of, one Party to the other Party in connection with this Agreement.
- 1.9. **Contract Service Provider or CSP** shall mean any Third-Party service provider or Affiliate contracted by either Party to perform certain aspects of the Development and Distribution Program.

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- 1.10. **Development and Distribution Program** shall mean the activities to be conducted in connection with the development of a Molecule with the objective of generating a Product in the Field, covering Phase 1, Phase 2 and Phase 3 clinical studies as well as certain preclinical regulatory studies, pharmaceutical development; and all activities needed to manufacture the Product on an industrial scale, to obtain all Regulatory Approvals for the Product in the Field and to distribute the Product, with a priority on distribution in the Territory on an Affordable Basis, including post-registration activities such as pharmaco-vigilance studies.
- 1.11. **Development Plan** shall mean a detailed written plan(s) setting forth the mutually agreed strategy, design and product development activities in the Development and Distribution Program (including each Party's contributions, milestones and timelines). The Development Plan is set forth herein as **Annex 1**, as may be revised and approved from time to time.
- 1.12. **Disclosable Information** shall have the meaning ascribed to such term in Section 20.2.
- 1.13. **DNDi Background Technology** shall mean any Technology that:
- a) is owned by or licensed to DNDi or its Affiliates by any Third Party with a right to sublicense;
  - b) exists as of the Effective Date or is made, developed or conceived and reduced to practice thereafter by DNDi (or on its behalf) or its licensor outside the scope of this Agreement; and
  - c) is necessary or useful for the Partner to perform the activities under the Development and Distribution Program and to exercise the licenses granted hereunder.
- 1.14. **DNDi Collaboration Technology** shall mean any Technology that is made, developed, conceived and reduced to practice by DNDi (or on its behalf) during the performance of the Development and Distribution Program.
- 1.15. **Effective Date** shall mean the date set forth at the head of this Agreement.
- 1.16. **Field** shall mean potential treatments for the following diseases: **< complete list >** and any other diseases that the Parties mutually agree to add to the Field in writing by amendment to this Agreement.
- 1.17. **Force Majeure** shall mean any event that is beyond the reasonable control of a Party, and that prevents or substantially interferes with the performance by such Party of any of its obligations under this Agreement.
- 1.18. **Good Clinical Practice** shall mean current Good Clinical Practices, i.e. a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected, as defined in the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) Guideline for Good Clinical Practice (ICH E6).
- 1.19. **Good Distribution Practice** shall mean current Good Distribution Practices required with respect to the supply a Product by the guidelines on Good Distribution Practice of:

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- a) medicinal products for human use in the form of European Commission Guideline 2013/C 343/01; and
  - b) active substances for medicinal products for human use in the form of European Commission Guideline 2015/C95/01.
- 1.20. **Good Laboratory Practice** shall mean the current complete set of the series on the Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice guidelines, the requirements as specified in Directive 2004/10/EC, the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines, or equivalents, such as those promulgated by the WHO/TDR in countries where ICH guidelines are not in effect < delete as appropriate >, the Party's own standard operating procedures and any other Applicable Laws as in effect during the Term that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived, thereby ensuring that studies submitted to a regulatory authority are of sufficient quality and rigour and are verifiable.
- 1.21. **Good Manufacturing Practice** shall mean current Good Manufacturing Practices, required with respect to the Development and Distribution Program by Annex 13 (Investigational Medicinal Products) to Volume 4 of EudraLex: "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use", the applicable current EU Directives, ICH Guidelines and World Health Organization (WHO) Guidelines, in effect at any time during the Term. < adapt according to the intended regions or countries of use for the product or place of vendor >
- 1.22. **Guest(s)** shall have the meaning ascribed to such term in Section 15.10.
- 1.23. **JDC Member** shall have the meaning ascribed to such term in Section 15.4.
- 1.24. **Joint Development Committee or JDC** shall have the meaning ascribed to such term in Article 15.
- 1.25. **Know-How** shall mean all non-public proprietary information including, without limitation, trade secrets, formulae, practices, methods, knowledge, processes, experiences, test data (including pharmacological, toxicological and clinical information), analytical and quality control data, and manufacturing data, whether patentable or not.
- 1.26. **Marketing Authorisation** shall mean all approval(s), registration(s) and authorisation(s) (including WHO prequalification(s) of medicines or equivalent) necessary to be obtained from applicable Regulatory Authorities to lawfully import, promote, distribute and sell a final Product in the Field.
- 1.27. **Mission** shall have the meaning ascribed to such term in the Recitals.
- 1.28. **Molecule** shall mean < code name of the Molecule >; free from encumbrances, and any polymorphs, prodrugs, active metabolites and/or pharmaceutically acceptable salts and any other molecule as may be agreed between the Parties in writing from time to time.

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- 1.29. **Partner Background Technology** shall mean any Technology that:
- a) is owned by or licensed to Partner or its Affiliates by any Third Party with a right to sublicense;
  - b) exists as of the Effective Date or is made, developed, conceived and reduced to practice thereafter by Partner (or on its behalf) or its licensor outside the scope of this Agreement; and
  - c) is necessary or useful for DNDi to perform the activities under the Development and Distribution Program and to exercise the licenses granted hereunder.
- 1.30. **Partner Collaboration Technology** shall mean any Technology that is made, developed, conceived and reduced to practice by Partner (or on its behalf) during the performance of the Development and Distribution Program.
- 1.31. **Patent Rights** shall mean any:
- a) national, regional and international patents and patent applications (provisional and non-provisional);
  - b) 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 therefrom;
  - c) counterparts, substitutions, restorations, extensions (including, without limitation, patent term extensions), supplementary protection certificates, registrations, confirmations, validations and renewals of any of the foregoing; and
  - d) invention certificates and other government grants for the protection of inventions or industrial designs.
- 1.32. **Permitted Recipients** shall have the meaning ascribed to such term in Section 18.3.
- 1.33. **Pharmacovigilance Agreement** shall mean a separate agreement to be entered into the Parties specifying the procedures and timelines for exchanges of safety information or data to ensure compliance with Applicable Laws pertaining to safety reporting on Product and their related activities. A copy of the fully signed Pharmacovigilance Agreement will be added herein as **Annex 2** and shall constitute an integral part of this Agreement.
- 1.34. **Product** shall mean any pharmaceutical drug candidate or drug product, which contains the Molecule alone or in combination with any other active pharmaceutical ingredient(s), including fix-dose and loose-dose combinations, any co-formulation, co-packaged product, or bundled product.
- 1.35. **Project Leader** shall have the meaning ascribed to such term in Section 15.1.
- 1.36. **PRV** shall mean the Food and Drug Administration (“**FDA**”) priority review voucher program in the United States of America.
- 1.37. **Quality Agreement** shall mean a separate written and approved technical formal agreement between the Parties, which defines in detail the Good Manufacturing Practice responsibilities,

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including the quality measures, of each Party. A copy of the fully signed Quality Agreement will be added herein as **Annex 3** and shall constitute an integral part of this Agreement.

- 1.38. **Reasonable Efforts** shall mean with respect to the performance of a Party's activities under the Development and Distribution Program, the efforts and resources typically used in comparable development and distribution programs for products at a similar stage in development to ensure continuous progress of the timelines.
- 1.39. **Regulatory Advantage** shall mean the PRV or any equivalent incentive program to the PRV from a Regulatory Authority regarding a Product.
- 1.40. **Regulatory Approval** shall mean any approval (excluding price and reimbursement approvals), license, registration or authorisation (including a Marketing Authorisation) of any Regulatory Authority that is necessary for the development, manufacture, use, storage, import, transport, sale or distribution of a Product in such jurisdiction.
- 1.41. **Regulatory Authority** shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with responsibility for granting any Regulatory Approval, including the FDA and the European Medicine Agency ("EMA").
- 1.42. **Regulatory Dossier** shall mean all regulatory documents and filings registered with a Regulatory Authority for a Marketing Authorisation containing the administrative, safety, efficacy, quality, non-clinical and clinical data and CMC data for the Product as it may change from time to time.
- 1.43. **Regulatory Responsibilities Plan** shall mean the split of regulatory responsibilities of the Parties and alignment on expectations on sharing of information as set out in **Annex 4** hereto.
- 1.44. **Regulatory Strategy** shall mean the strategy for obtaining a Marketing Authorisation with the aim of ensuring equitable and affordable access to such Product in the Territory at the earliest possible date, consistent with the Access and Implementation Plan.
- 1.45. **Rights of Reference** shall mean, with regard to a Party, a grant of rights (including through a Third Party) that allows the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in a Regulatory Dossier (and any data contained therein) filed with another Regulatory Authority by or on behalf of the other Party (its Affiliate or sublicensee).
- 1.46. **Specifications** shall mean, collectively, the list of quality tests and acceptance criteria set forth in the Regulatory Dossier relating to a Product, filed with the competent Regulatory Authority and pursuant to Good Manufacturing Practice.
- 1.47. **Technology** shall mean Patent Rights, Know How, proprietary reagents, rights in designs, database rights, copyright and related rights, moral rights, 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.

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- 1.48. **Term** shall have the meaning ascribed to such term in Section 23.1.
- 1.49. **Territory** shall mean all countries in which one or more of the diseases of the Field is endemic, as listed and revised by the WHO from time to time; and any additional countries that might be added subject to the written agreement of the Parties.
- 1.50. **Third Party** shall mean any person, organisation or entity other than the Parties and their Affiliates.

**2. OBJECTIVE OF THIS AGREEMENT**

The objective of this Agreement is to set forth:

- a) the principles of the collaboration between DNDi and Partner in the performance of the Development and Distribution Program;
- b) the roles and responsibilities of each Party in the implementation of the Development and Distribution Program; and
- c) the conditions pursuant to which a Party shall provide to the other Party the right to use its Technology in order to perform the Development and Distribution Program.

**3. DEVELOPMENT AND DISTRIBUTION PROGRAM**

- 3.1. DNDi and Partner shall engage in the Development and Distribution Program upon the terms and conditions set forth in this Agreement. Each Party shall carry out its roles and activities in accordance with the Collaboration Plans. In the event of a conflict between any of the Collaboration Plans and this Agreement, the terms of this Agreement shall govern.
- 3.2. The Development Plan shall include, but not be limited to, the following matters:
- a) the Molecule to be developed, and related information to be transferred and developed;
  - b) < the disease of the Field targeted >;
  - c) an outlined description of the planned development activities;
  - d) the allocation of activities between the Parties;
  - e) the relevant timelines, including expected start and end dates; and
  - f) the content and form of required reports and deliverables.
- 3.3. The Access and Implementation Plan will be drawn up in good faith at a high-level at the beginning of the Development and Distribution Program and will be developed by the Parties in more detail at a later stage.
- 3.4. The Collaboration Plans may be approved and revised by the JDC, at decision points as new data becomes available and inclusive of scientific consultations with the Regulatory Authorities, in accordance with the provisions of Article 15.
- 3.5. During the Term, each Party shall use Reasonable Efforts to conduct, advance and complete the activities assigned to it in a timely way and as soon as reasonably practical, including devoting such employees/consultants/CSPs with sufficient skills and experience, and facilities and equipment as are reasonably necessary to complete its obligations under the Collaboration

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Plans. In particular, the Parties shall use Reasonable Efforts to develop, obtain Regulatory Approval(s) for and, following Marketing Authorisation, use all Reasonable Efforts to provide an adequate supply of Product on an Affordable Basis in the Field in the Territory and provide a strong supply network to support such distribution.

**4. COMPLIANCE**

- 4.1. In the performance by it or on its behalf of any activities under the Development and Distribution Program or any other activities contemplated hereunder (including the exercise of any rights licensed hereunder), each Party shall comply with all Applicable Laws and its own standard operating procedures. Each Party shall be responsible for obtaining all applicable Regulatory Approvals that may be necessary for it to perform its activities.
- 4.2. The Parties shall comply with all Applicable Laws for the care, welfare and ethical treatment of animals in the country where the animal studies are being performed. The Parties further agree to comply with the “3Rs” Principles – reducing the number of animals used, replacing animals with non-animal methods whenever possible and refining the research techniques used. All work shall be conducted in adherence to the core principles for animals identified below. Local customs, norms, practices or laws may be additive to the core principles, but the Parties shall comply, as a minimum, with these core principles:
- a) providing laboratory animals access to species-appropriate food and water;
  - b) providing laboratory animals access to species-specific housing, which is maintained at species-appropriate conditions, taking into account such factors as temperature and humidity;
  - c) providing laboratory animals access to humane care and a program of veterinary care;
  - d) providing laboratory animals housing that minimizes the development of abnormal behaviours;
  - e) adhering to principles of replacement, reduction and refinement in the design of *in vivo* or *ex vivo* studies;
  - f) submitting the study design and purpose for review by an institutional ethical review panel;
  - g) committing to minimizing pain and distress experienced by laboratory animals during *in vivo* and *ex vivo* studies;
  - h) performing work by staff trained to conduct the procedures for which they are responsible;
  - i) ensuring training is documented and verified; and
  - j) implementing processes to minimize animal use.
- 4.3. Each Party shall have the right to conduct quality assurance assessments of the other Party’s processes and systems, if necessary, audits and inspections of laboratory, clinical trial and manufacturing sites, and any associated vendors or laboratories involved in the Development Plans.
- 4.4. A Party’s failure to abide by the provisions of this Article 4 shall be deemed a material breach of this Agreement.

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**5. PARTNER'S CONTRIBUTIONS TO THE DEVELOPMENT PLAN**

- 5.1 Partner shall:
- a) carry out the activities assigned to it in the Development Plan and as agreed between the Parties from time to time, mainly:
    - a. < complete >;
    - b. < complete >; and
  - b) contribute to the management of the activities by participating to the JDC.
- 5.2 Partner shall supply to DNDi, upon request and free of charge, pursuant to Good Manufacturing Practice, Good Distribution Practice and its internal quality guidelines and practices including the requirements of the Quality Agreement, such quantities of Molecule, Product < and comparator products > as deemed necessary for DNDi to perform its activities under the Collaboration Plan(s).
- 5.3 Partner shall grant the license rights set forth under Article 17.

**6. DNDI'S CONTRIBUTIONS TO THE DEVELOPMENT PLAN**

- 6.1 DNDi shall:
- a) coordinate and conduct, through its CSPs, all activities assigned to it in the Development Plan, mainly:
    - a. < complete >;
    - b. < complete >; and
  - b) DNDi shall participate in the management of the activities through the JDC.
- 6.2 DNDi shall grant the license rights set forth under Article 17.

**7. REGULATORY STRATEGY AND REGISTRATION**

Regulatory Strategy for Obtaining a Marketing Authorisation.

- 7.1. The Regulatory Strategy (including timelines and milestones) for the registration of the Product shall be defined by the Parties, following the high-level Access and Implementation Plan. Upon agreement on the Regulatory Strategy for a country, the Parties shall jointly establish a detailed Access and Implementation Plan for such country to ensure availability of the Product through public and private distribution channels in the Territory on an Affordable Basis.

The Regulatory Strategy will for the time being be based on the process under Article 58 of Regulation (EC) No. 776/2004 and on the local registration requirements in the Territory. Any other regulatory mechanism that could facilitate registration of a Product in the Field in the Territory shall be considered by the Parties and could possibly lead to a change in the Regulatory Strategy upon written agreement between the Parties.

- 7.2. The Party responsible for a relevant clinical trial shall lead and be responsible for the Regulatory Strategy of such clinical trial in consultation with the other Party.

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- 7.3. Partner shall be responsible for obtaining and maintaining Marketing Authorizations for the Product covering the Territory.
- 7.4. The roles and responsibilities of the Parties are defined by the Parties in the Regulatory Responsibilities Plan. In case of contradictions between the Regulatory Responsibilities Plan and the terms of the main body of this Agreement, the terms of the main body of this Agreement shall prevail. The Parties shall also undertake their roles and activities at all times with the goal of making a Product available on an Affordable Basis in the Field in the Territory as early as possible.
- 7.5. If, for purposes of a Marketing Authorisation in the United States, the FDA requests changes to the Development Plan, the Parties shall discuss such changes in good faith to ensure that the FDA's proposals do not interfere with the Regulatory Strategy and will not materially delay the clinical development of the Product that was discussed under the Regulatory Strategy.
- 7.6. The Parties shall act in good faith to develop the Regulatory Dossier of the Product according to the agreed Regulatory Strategy. Partner shall permit DNDi to review and make suggestions in relation to the Regulatory Dossier prior to submission to the Regulatory Authority and reasonably consider such suggestions.
- 7.7. Partner shall update DNDi as to the status of each Regulatory Dossier and will provide DNDi through the JDC with a report on its exchanges with the applicable Regulatory Authority.
- 7.8. Support for Registration. DNDi shall use its Reasonable Efforts to assist Partner in obtaining the Marketing Authorisation of the Product for use in the Field in the Territory, and in answering questions from any Regulatory Authority with respect to the Product.
- 7.9. As soon as feasible, the Parties shall prepare a Product needs' forecast for the Territory and attach the same to this Agreement as **Annex 5**. Such forecast shall not be binding but shall serve as a reference to support decisions on the Regulatory Strategy and the Access and Implementation Plan.

**8. REGULATORY ADVANTAGE**

- 8.1. The Parties acknowledge that both Parties will actively contribute to the Development and Distribution Program and agree to share the economic benefits of any Regulatory Advantage.
- 8.2. In the event Partner (or any of its Affiliates) obtains a Regulatory Advantage from the Marketing Authorisation of a Product:
  - a) **< to complete >**.

**9. MANUFACTURE AND SUPPLY**

- 9.1. The Parties shall undertake the following roles and activities for product manufacture and supply.

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Manufacture of the Product.

- 9.2. Partner shall manufacture, scale up, package, label and supply the Product(s) pursuant to all Applicable Laws, to make it accessible as outlined in the Access and Implementation Plan.
- 9.3. Partner represents that it has known sources of supply and sufficient production capacities to ensure a continuity of supply of the Product(s) to the Territory in reasonable quantities as may be requested under normal conditions.
- 9.4. Partner shall inform DNDi, as soon as possible, of all proposed changes in the manufacturing of any of the Product required by the Regulatory Authorities or any other events, which may result in a disruption in the supply of such materials. Partner will use Reasonable Efforts to carry out this change as quickly as possible to satisfy as much as possible the orders of the Product from the Territory.
- 9.5. Partner shall undertake Reasonable Efforts to optimize the manufacture of the Product, so as to make possible a final price ensuring the widespread use of the Product consistent with the Access and Implementation Plan. Partner commits to pass on any significant reduction in the production costs of such materials to the benefit of the sale price.

Product Distribution and Pricing.

- 9.6. Partner shall be responsible for the distribution, either directly or through any Third Party it may appoint, of the Product in accordance with this Agreement. Following receipt of the applicable Marketing Authorisation, Partner shall make the Product available in the Territory on an Affordable Basis.
- 9.7. In the event that the Product is not achieving the Access and Implementation Plan, which may be attributable to the price of the Product, then DNDi may request and Partner shall disclose to DNDi the composition of the price of the Product, including any allowed Third Party or Affiliate margin and cost mark-up, so that the Parties can resolve the elements of pricing in good faith.
- 9.8. Partner shall transfer manufacturing technology in full to one or more Third Party manufacturers if such transfer reduces the cost of the Product in accordance with a technology transfer plan mutually agreed upon by the Parties which shall include, at a minimum the terms attached hereto as Annex 6, provided that (i) such Third Party manufacturers' quality standards meets Good Manufacturing Practice; and (ii) the transfer will not delay access to the Product in the Territory.

Price Audit and Adjustment.

- 9.9. DNDi may mandate an independent and experienced auditor to verify the conformity of Partner's current prices of the Product with the Affordable Basis definition. Partner undertakes to provide the independent auditor with all relevant data, methods and information that are required to allow the independent auditor to carry out its mandate. The conclusion of the independent auditor will be binding on the Parties. The fees and expenses of such auditor shall be paid by DNDi, unless the examination results in a determination that the current price of the Product was overstated by more than ten percent (10%) for the period examined, in which case Partner shall pay the fees and expenses of such auditor.

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**10. SAFETY REPORTING AND RECALLS**

- 10.1. The Party that is the sponsor of any clinical trial performed under this Agreement shall remain fully responsible for ensuring safety reporting through individual and aggregate reports to Regulatory Authorities and other entities in countries for which it is responsible as required by Applicable Laws.
- 10.2. As long as DNDi is conducting clinical trials with a Product anywhere in the world, the Parties will promptly exchange all relevant information that relates to the safety of such Product and, especially, all adverse drug reactions. Within a period of six (6) months from the Effective Date, and/or before enrolment of the first patient in a Product-related clinical trial, the Parties will conclude a Pharmacovigilance Agreement to govern the investigation of and action to be taken with regard to Product related adverse experience reports, such that each Party can comply with its legal obligations worldwide.
- 10.3. Each Party shall be responsible for conducting, in accordance with all Applicable Laws, all withdrawals or recalls of the Product used in its respective clinical trials and shall comply at all times with all legal requirements on recalls. Each Party shall inform the other of any withdrawals or recalls and will provide the other with reasonable notice of the circumstances of any intended withdrawal or recall in an appropriate time.
- 10.4. During the post-registration phase, Partner (as the Marketing Authorisation holder) shall be fully responsible for ensuring safety reporting of individual and aggregate reports to the relevant Regulatory Authority and other entities as required by Applicable Laws and regulations.

**11. CONTRACT SERVICE PROVIDERS (“CSPs”)**

- 11.1. Each Party shall have the right to subcontract activities under the Collaboration Plans to CSPs. Each Party’s written agreement with CSPs shall be consistent with the terms of this Agreement.
- 11.2. Each Party shall ensure that its CSPs allocate sufficient time, effort, equipment, instruments and facilities to the Development and Distribution Program and utilize personnel with sufficient skills and experience as are required to satisfy the requirements and standards for activities under the Development and Distribution Program.
- 11.3. Each Party may sublicense its rights under Article 17 to a CSP, but only to the extent necessary to enable such CSP to carry out such Party’s duties under the Collaboration Plans.
- 11.4. Each Party shall remain responsible for the acts or omissions of its CSP(s) as if such acts or omissions had been performed by such Party.

**12. COSTS AND EXPENSES; PAYMENTS**

Except as otherwise specified in this Agreement, the Development Plan, or the Access and Implementation Plan, each Party shall be solely responsible for all of its own costs and expenses associated with the performance of its activities under the Collaboration Plans including, without limitation, expenses related to the attendance of its representatives at JDC meetings and neither

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Party shall make any payment or pay any financial contribution to the other Party in consideration of the other Party's performance under this Agreement.

**13. INFORMATION EXCHANGE**

- 13.1. Each Party shall inform the other Party regularly through the JDC of the progress of its activities under this Agreement in good faith to ensure the Collaboration Plans can be executed efficiently.
- 13.2. Each Party has been provided and will keep providing to the other, with technical information and data necessary for the purpose of the Development and Distribution Program in its possession, including without limitation letters of reference granting the other Party the Rights of Reference to the Regulatory Dossier filed with a Regulatory Authority.
- 13.3. For the purpose of supporting DNDi's advocacy effort, Partner shall provide DNDi within sixty (60) days following the end of each calendar year with a report on the number of units of the Product sold worldwide, and in particular in the Territory, and the sale prices of such units.

**14. RECORDS**

Each Party shall ensure that all records related to activities conducted by it or on its behalf are maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with Applicable Laws, which shall reasonably reflect all work done and results achieved under this Agreement. Such records shall be retained by the Parties for such period as may be required by Applicable Laws.

**15. GOVERNANCE STRUCTURE**

Project Leaders.

- 15.1. Each Party shall appoint a project leader for the duration of the Collaboration Plans (each, a "Project Leader"). Each Party may replace its Project Leader from time to time by giving a written notice to the other Party in relation to such change.
- 15.2. The Project Leaders shall be responsible for:
  - a) being the primary points of contact for the Collaboration Plans;
  - b) designing, updating, refining and revising the Collaboration Plans;
  - c) facilitating the efficient implementation, coordination and monitoring of the operational activities set out in the Collaboration Plans;
  - d) providing information to the Parties with respect to specific activities conducted under the Collaboration Plans; and
  - e) assisting with the analysis and interpretation of data resulting from the Collaboration Plans.

Joint Development Committee.

- 15.3. The Parties shall set up the JDC within thirty (30) days after the Effective Date.
- 15.4. The JDC shall be composed of < the Project Leaders and two (2) permanent representatives of each Party > (each, a "JDC Member"). Each JDC Member shall have appropriate technical

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credentials, experience and knowledge. Either Party may replace any or all of its JDC Members at any time upon prior written notice to the other Party. If a Party's JDC Member is unable to attend a meeting, that Party may designate an alternate representative for such particular meeting.

- 15.5. The role of the JDC is to serve as an information exchange platform, to leverage the respective competencies and contributions of each Party to optimally conduct the Collaboraton Plans, and to oversee the performance of the Collaboraton Plans. It shall notably:
- a) review and approve any Collaboration Plans, updates and amendments thereto, or the discontinuation thereof;
  - b) monitor the workflow and overall progress under the Collaboration Plans;
  - c) discuss strategic issues that could influence the implementation of the Collaboration Plans, the Regulatory Strategy and manufacturing and supply strategy; and
  - d) take such other actions as are expressly delegated to the JDC in this Agreement or as the Parties may mutually agree in writing.

For the avoidance of doubt, the JDC has no authority to amend, or to waive compliance with, any term or condition of this Agreement.

- 15.6. The JDC shall be chaired by < > during < add phases > and by < > during < add phases >. The Chair shall be responsible for administering the work of the JDC, including organizing JDC meetings, setting the agenda for such meetings and distributing it to the JDC Members no less than < one (1) week > before any JDC meeting. The Chair shall also be responsible for preparing and circulating draft minutes from each JDC meeting to the JDC Members, facilitating the exchange of information, reviews of results and monitoring the contributions by each Party.
- 15.7. The JDC shall meet at such times as are agreed to by the JDC Members, but at least < four (4)> times per year. Such meetings may be held in person or by means of telecommunication (telephone, video, or web conferences) at a mutually agreed time and place. The first meeting shall take place within < thirty (30) > days after the Effective Date.
- 15.8. A quorum of the JDC shall exist whenever at least < one representative appointed by each Party > is present at a meeting.
- 15.9. The minutes shall be kept of all JDC meetings and sent to all JDC Members for review and approval within < seven (7) > days after each meeting. Minutes shall be deemed approved unless any JDC Member objects to the accuracy of such minutes by providing written notice to the other JDC Members within < fourteen (14) > days after receipt of the minutes. In the event that any such objection is not resolved by the JDC, such minutes shall be amended to reflect such unresolved dispute.
- 15.10 The Parties may invite, from time to time, guests (from either Party as well as external consultants or advisors), who shall be under an obligation of confidentiality no less stringent than the terms set forth in this Agreement, to attend any meeting of the JDC in an advisory capacity within their respective competences as deemed necessary for the advancement of the Collaboration Plans (such additional representative(s), "**Guest(s)**"). For clarity, any

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Guest(s) shall not vote or otherwise participate in the decision-making process of the JDC. Expenses related to the attendance of any Guest(s) to a JDC meeting shall be borne solely by the Party inviting such Guest(s).

- 15.11 For the avoidance of doubt, the Parties may also engage in informal scientific discussions and exchanges of correspondence outside of the scheduled JDC meetings, as needed.

Decision-Making.

- 15.12. The JDC shall take decision by consensus. Any differences of opinion between the Parties relating to the Collaboration Plans shall be discussed in good faith within the JDC.
- 15.13. If the JDC is unable to reconcile the opinions within thirty (30) days, then the Parties shall submit the difference of opinion to each Party's senior executive officer, which, in the case of Partner, shall be **< complete >**, and, in the case of DNDi, shall be the Executive Director, to enable a compromise between different views with respect to such issue.
- 15.14. If such senior executives of the Parties cannot successfully reconcile the difference of opinion within a ten (10) day period after the moment of formal submission to them, then the Party that has been allocated responsibility for the matter at issue will have the final decision, provided that any such decision will not result in an increase of the other Party's financial burden.
- 15.15. The Parties acknowledge and agree that the JDC is strictly for the purposes of decision-making and governance of the Collaboration Plans. Without limiting the generality of the foregoing, any dispute relating to the interpretation of this Agreement, the performance or alleged non-performance of a Party's obligations under this Agreement, or any other alleged breach of this Agreement shall be decided in accordance with the terms of Article 32.

**16. OWNERSHIP OF TECHNOLOGY**

- 16.1. All rights in, title to and interest in the DNDi Background Technology and DNDi Collaboration Technology shall be owned by DNDi.
- 16.2. All rights in, title to and interest in the Partner Background Technology and Partner Collaboration Technology shall be owned by Partner.
- 16.3. For the avoidance of doubt, any Regulatory Dossier developed by Partner for Regulatory Approval shall be the property of Partner, subject to the rights of DNDi to the Technology contained in such dossier, as described in this Agreement.
- 16.4. Both Parties agree, where applicable and to the extent that they are able, (a) to not seek or (b) to waive, regulatory exclusivity in relation to any data relating to the Product and arising directly or indirectly from the Marketing Authorization of the Product.
- 16.5. Each Party shall take all necessary and proper acts to effectuate the ownership provisions provided in this Article 16.

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16.6. It is understood that, as of the Effective Date, DNDi's policy with regard to Technology is that it should be accessible to all interested persons to foster DNDi's Mission.

**17. GRANT OF LICENSE RIGHTS**

Grants to DNDi.

17.1. Partner hereby grants to DNDi a non-exclusive, worldwide, perpetual, irrevocable, fully paid, royalty-free license, with the right to sublicense to Third Parties under Partner's rights to and interests in Partner Background Technology and Partner Collaboration Technology:

- a) to the extent necessary or useful to perform the Development and Distribution Program;  
and
- b) for non-commercial research purposes.

17.2. During the Term, Partner shall promptly communicate and make available to DNDi, in a continuous manner and as it becomes available, all Partner Background Technology and Partner Collaboration Technology, and all corresponding freedom to operate searches and analyses in its possession.

Grants to Partner.

17.3. DNDi hereby grants to Partner a non-exclusive, worldwide, perpetual, irrevocable, fully paid, royalty-free license under DNDi's rights to and interests in DNDi Background Technology and DNDi Collaboration Technology:

- a) to the extent necessary or useful to perform the Development and Distribution Program;
- b) to commercialize the Product in the Field outside of the Territory at a price to be determined by Partner that allows a purchaser in a particular sector to buy such Product in sufficient quantities to meet its public health or individual needs. In consideration of the license grants outside the Territory, Partner shall compensate DNDi, such amount of compensation to be mutually agreed upon by the Parties based on good faith negotiations. It is DNDi's intent to invest any such compensation in access to medicines programs; and
- c) for non-commercial research purposes.

17.4. Partner may grant sublicenses to Third Parties under the licenses granted herein, subject to each such sub-licensee undertaking in writing to assume Partner's obligation herein to commercialize the Product in the Field on an Affordable Basis in the Territory.

17.5. During the Term, DNDi shall promptly communicate and make available to Partner, in a continuous manner and as it becomes available, all DNDi Background Technology and DNDi Collaboration Technology.

General terms.

17.6. The rights granted under this Article 17 and Section 24.2c) include Rights of Reference to the relevant part of the other Party's Regulatory Dossier to the extent needed for the conduct of the Development and Distribution Program; or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder. With respect to such Rights of Reference, the Party granting such rights shall reasonably assist and cooperate with the requesting Party to effect such Rights of Reference,

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including by making written authorizations and other filings with the applicable Regulatory Authority.

- 17.7. Notwithstanding any other provision of this Agreement, the licenses under this Article 17 (except the licences for non-commercial research purposes) are subject to Section 17.8 and Article 24.
- 17.8. In the event that Partner Background Technology or DNDi Background Technology includes Technology in-licensed from a Third Party by Partner or DNDi, as the case may be, the Party granting a license under Sections 17.1 and 17.3 above shall include in such license the grant of a sublicense of such Third Party rights:
- a) to the extent permitted under the agreement between such Party and such Third Party; and
  - b) on the same terms and conditions licensed to such Party by such Third Party.
- In the event that the sublicense is more limitative than the terms of licenses under Sections 17.1 and 17.3 then the Party granting a license under Sections 17.1 and 17.3 above shall use Reasonable Efforts, at the other Party's written request, to procure that such Third Party grants to such other Party a non-exclusive license under such Third Party's relevant Technology for the purposes described in Sections 17.1 and 17.3.
- 17.9. Except as explicitly set forth in this Agreement, neither Party shall acquire any license or other interest, by implication or otherwise, in any Technology, including the Molecule, of the other Party disclosed to it under this Agreement.

**18. CONFIDENTIALITY**

- 18.1. Each Party shall, and shall cause its officers, directors and employees to keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement (including exercising any license granted herein) or expressly permitted by the disclosing Party.
- 18.2. Notwithstanding the foregoing, the confidentiality and non-use obligations under Section 18.1 shall not apply to any information that is, as documented by the receiving Party's written records or other competent proof:
- a) in the possession of the receiving Party prior to disclosure by the disclosing Party, and not through a prior disclosure by the disclosing Party;
  - b) properly in the public domain prior to disclosure or becomes part of the public domain through no breach of this Agreement by the receiving Party;
  - c) subsequently disclosed to the receiving Party by a Third Party free of any obligation of confidence to the disclosing Party; or
  - d) independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information.
- 18.3. Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

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- a) made to governmental or other regulatory agencies in order to obtain or enforce Patent Rights or to gain or maintain Regulatory Approvals, but such disclosure may be made only to the extent reasonably necessary to obtain Patent Rights or authorisations and otherwise to exercise the licenses granted in this Agreement, in accordance with Applicable Laws;
- b) deemed necessary by the receiving Party to be disclosed to Affiliates (including their officers, directors and employees) or Third Parties (including actual and potential consultants, CSPs, funding partners, sublicensees and agents) who need to know such information to the extent necessary to conduct development and distribution activities (the “**Permitted Recipients**”), on the condition that such Permitted Recipients agree to be bound by confidentiality and non-use obligations at least as stringent as the confidentiality and non-use obligations contained in this Agreement, provided, however, that no such agreement shall be required of any funding party that as a matter of organizational policy does not enter into such agreement; the receiving Party shall be liable for any damage caused by or resulting from any unauthorised disclosure and use of the disclosing Party’s Confidential Information by such Permitted Recipients;
- c) made pursuant to DNDi Policy on Sharing and Secondary Use of Human Subject Research Data (attached hereto as **Annex 7**); or
- d) required to be disclosed to comply with Applicable Laws or to comply with a valid and enforceable order of a court of valid jurisdiction or by a binding decision of any governmental body having jurisdiction, provided that the receiving Party shall:
  - i. if legally permitted to do so, provide the disclosing Party with prior written notice of such disclosure requirement as soon as it becomes aware thereof;
  - ii. assist the disclosing Party, at the disclosing Party’s sole expense, in obtaining a protective order precluding or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purpose of which it is required; and
  - iii. limit the disclosure of Confidential Information to that information that is legally required to be disclosed in response to such court or governmental order.

18.4. These obligations set out in this Article 18 shall remain in force for a period of **< seven (7) >** years from disclosure of the Confidential Information, which obligation will survive the earlier termination or expiration of this Agreement.

**19. SCIENTIFIC PUBLICATIONS**

19.1. Notwithstanding Article 18 above and in accordance with DNDi’s Mission on providing free access to the public of its research as per its Scientific and Clinical External Communications Policy (as published in DNDi’s website), as well as the requirements of several donors to DNDi, DNDi and Partner will publish the scientific data and/or results of the Development and Distribution Program in scientific journals, abstracts, conferences, databases, as well as present such data at professional meetings. The Parties shall first seek to publish such data jointly. Should either Party opt not to participate in the publication, the other Party shall be free to publish the data in accordance with the terms of this Article 19.

19.2. Independent draft manuscripts of written publications or oral presentations that include any part of the results of the Development and Distribution Program or Confidential Information

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shall be sent to the other Party for review at least twenty-eight (28) days prior to the contemplated publication and eight (8) days for abstracts and presentations. Within this period, the other Party shall be entitled to object to the proposed publication or presentation on the grounds that it contains or refers to a patentable subject matter. Should patenting be sought by a Party, the other Party shall refrain from making any publication or presentation for an additional period of ninety (90) days from the date of the patenting Party's objection to allow the filing of Patent Rights.

- 19.3. In case of collective publication, the citation order and respective functions of the authors from the Parties (e.g. first author, last author and corresponding author) shall be determined in accordance with DNDi Scientific and Clinical External Communications Policy.
- 19.4. The Parties shall ensure that any publication agreement or copyright transfer agreement allows peer-reviewed manuscripts and scientific data to be published in an open access journal (e.g. PLOS) or database.
- 19.5. In any publication relating to the Development and Distribution Program, each Party shall acknowledge the contributions of both Parties to such program.

## **20. PUBLICITY**

- 20.1. Except as required by Applicable Laws 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.
- 20.2. Prior to the Effective Date, the Parties shall agree on a set of information concerning this Agreement and its subject matter that may be disclosed without prior consent, other than in the form of a press release (e.g., on a Party's website, in its annual reports, its newsletters, etc.) (the "**Disclosable Information**"), 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. The Disclosable Information is attached to the Agreement in **Annex 8**.
- 20.3. For the avoidance of doubt, any press release related to the subject matter of this Agreement shall require the prior written consent of the non-disclosing Party, even if such press release is limited to the Disclosable Information. The Parties agree that any draft press release shall be sent to the other Party for review at least four (4) working days prior to the contemplated day of publication.

## **21. REPRESENTATIONS AND WARRANTIES**

- 21.1 DNDi represents and warrants the following:
  - a) it is duly authorized to enter into this Agreement and perform its obligations hereunder;
  - b) to its knowledge as of the Effective Date:
    - i. it is either the owner or licensee of all rights to the DNDi Background Technology;
    - ii. it has the full right, power and authority to grant all of the rights granted to Partner hereunder and the use of the DNDi Background Technology as contemplated under this Agreement does not infringe any Technology of any Third Party;

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- iii. it has not granted and will not grant to any Third Party any of its rights relating to DNDi Background Technology or DNDi Collaboration Technology that would conflict with, limit or adversely affect the rights granted to Partner hereunder; and
- iv. it has not received any claim and/or been party to any proceeding of any nature by any Third Party claiming the existence of any such infringement. During the Term, DNDi shall notify Partner in writing promptly upon learning of any such actual or threatened claim or proceeding.

21.2 Partner represents and warrants the following:

- a) it is duly authorized to enter into this Agreement and perform its obligations hereunder;
- b) to its knowledge as of the Effective Date:
  - i. it is the sole and exclusive owner or licensee of all rights to the Partner Background Technology;
  - ii. it has the full right, power and authority to grant all of the rights granted to DNDi hereunder and the use of the Partner Background Technology as contemplated under this Agreement does not infringe any Technology of any Third Party;
  - iii. has not granted and will not grant to any Third Party any of its rights relating to Partner Background Technology or Partner Collaboration Technology that would conflict with, limit or adversely affect the rights granted to DNDi hereunder; and
  - iv. it has not received any claim and/or been party to any proceeding of any nature by any Third Party claiming the existence of any such infringement. During the Term, Partner shall notify DNDi in writing promptly upon learning of any such actual or threatened claim or proceeding.

21.3 Each Party represents and commits that:

- a) the negotiation and the performance of this Agreement did not and shall not give rise to any act of corruption or fraud;
- b) it has anti-fraud and anti-corruption mechanisms in place which are effectively implemented throughout the term of this Agreement;
- c) it has complied, and will continue to comply, with all applicable local, national and international laws and regulations prohibiting the provision of resources and support to individuals and organisations associated with terrorist or anti-social groups including, without limitation, applicable economic sanctions or trade embargoes;
- d) it does not itself appear on any listed sanctions; and
- e) in the case of the Partner, it will promptly notify DNDi on its integrity line (<https://dndi.integrityline.org/>) or by email at [ethics@dndi.org](mailto:ethics@dndi.org) of:
  - i. any serious suspicion or proven case of fraud or corruption impacting directly or indirectly DNDi; or
  - ii. any breach or suspected breach of this Section 21.3.

21.4 A breach of Section 21.3 shall be considered as a fundamental breach of this Agreement in which event the non-breaching Party shall be entitled to terminate this Agreement immediately on provision of notice.

21.5 Each Party acknowledges that it has a duty of care to ensure honest and ethical behaviour. Each Party agrees to abide by the high standards of behaviour described in **Annex 9**, or represents and

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warrants that it has its own policies which are substantially equivalent and that such policies are currently applied.

**22. LIMITATION OF LIABILITY**

22.1. IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY LOSS OF PROFITS AND LOST REVENUE, OR ANY OTHER DAMAGES OF SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE NATURE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE, PROVIDED THAT THIS LIMITATION OF LIABILITY SHALL NOT APPLY TO THIRD PARTY CLAIMS FOR WHICH A PARTY IS REQUIRED TO INDEMNIFY THE OTHER PARTY, OR TO THE EXTENT THAT IT WOULD BE INVALID BY LAW.

**23. TERM AND EARLY TERMINATION**

23.1. The term of this Agreement shall begin on the Effective Date and continue for **< add period >** years from the date of obtaining the first Marketing Authorisation in the first country of the Territory, unless earlier terminated by either Party in accordance with the provisions of this Agreement or extended by mutual written agreement of the Parties (the “**Term**”).

23.2. Either Party may terminate this Agreement in its entirety or with respect to any Product at any time upon twelve (12) months’ written notice to the other Party, without thereby incurring any liability to the other Party. For the avoidance of doubt, termination by a Party because it is not satisfied with the results of its safety data assessment shall not impact the continuation of the development of the Product(s) by the other Party.

23.3. Either Party may terminate this Agreement in its entirety at any time, as follows:

- a) if the other Party is in material breach of this Agreement, upon thirty (30) days’ written notice stating its intent to terminate if such breach has not been cured within such thirty (30) day period;
- b) with immediate effect if the other Party is declared insolvent or has an administrator or receiver appointed over all or any part of its assets;
- c) with immediate effect if the other Party is in breach of Section 21.3; or
- d) in case of a Force Majeure event with respect to the other Party pursuant to Article 29.

23.4. If in the reasonable opinion of DNDi, Partner fails to use Reasonable Efforts to promote access to the Product in the Territory in accordance with the timelines and milestones agreed by the Parties under the Access and Implementation Plan(s), DNDi shall give notice to Partner requiring curing such failure. If, in the reasonable opinion of DNDi, Partner fails to present an acceptable plan within sixty (60) days and report reasonable progress within one hundred and eighty (180) days after receiving written notice with respect to the default, DNDi shall have the right to terminate this Agreement in respect to such Product with immediate effect by giving written notice to Partner.

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23.5. Any termination notice sent pursuant to this Article 23 shall specify the specific Section of this Article 23 pursuant to which such termination is made; if no Section is so specified, then termination shall be deemed to be pursuant to Section 23.2.

**24. EFFECT OF EXPIRATION OR EARLY TERMINATION**

24.1. Upon termination by DNDi pursuant to Section 23.2 or termination by Partner pursuant to Section 23.3:

- a) DNDi's activities shall discontinue immediately or as soon as practical;
- b) the licenses granted to Partner under Section 17.3 shall survive;
- c) the licenses granted to DNDi under Section 17.1 shall automatically terminate;
- d) DNDi shall return or cause to be returned to Partner all Partner's Confidential Information, Partner Background Technology, including any unused supplies of Product, and Partner Collaboration Technology within thirty (30) days after the effective date of such termination, or certify the destruction thereof as specified by Partner;
- e) DNDi shall promptly notify its CSPs and sublicensees, if any, of any termination of sublicenses granted by DNDi under this Agreement and take all actions necessary to effectuate termination of such sublicenses;
- f) DNDi shall make available to and/or transfer to Partner, copies of such information, documentation and materials in its possession relating to the Development and Distribution Program so that Partner may proceed with further research and development, manufacture, registration and/or commercialisation of the Product; and
- g) in the case of termination by DNDi under Section 23.2 with respect to any part of the Development Plan or Access and Implementation Plan (as opposed to the Agreement in its entirety), the provisions of sub-sections a) to f) of this Section 24.1 shall apply only with respect to such terminated part of the Collaboration Plans.

24.2. Upon termination by Partner pursuant to Section 23.2 or termination by DNDi pursuant to Section 23.3 or Section 23.4:

- a) Partner's activities shall discontinue immediately or as soon as practical;
- b) the licenses granted to DNDi under Section 17.1 shall survive;
- c) Partner shall grant to DNDi a non-exclusive, perpetual, irrevocable, fully paid, royalty-free license, with the right to sublicense, under Partner's rights to and interests in Partner Background Technology and Partner Collaboration Technology, to sell, offer to sell, import and distribute the Product within the Field outside of the Territory;
- d) the licenses granted to Partner under Section 17.3 shall automatically terminate;
- e) Partner shall return or cause to be returned to DNDi all DNDi's Confidential Information, DNDi Background Technology and DNDi Collaboration Technology within thirty (30) days after the effective date of termination, or certify the destruction thereof as specified by DNDi;
- f) Partner shall promptly notify all sublicensees and CSPs, if any, of any termination of sublicenses granted by Partner under this Agreement and take all actions necessary to effectuate termination of sublicenses;
- g) Partner shall make available to and/or transfer to DNDi, copies of such information, documentation and materials in its possession relating to the Development and Distribution Program so that DNDi may proceed with further research and development, manufacture, registration and/or commercialisation of the Product. In particular, Partner

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shall transfer, to the extent owned, licensed or controlled by Partner, copies of the Partner Collaboration Technology, and provide the necessary training (including on-site), free of charge, to any Third Party appointed by DNDi on Product manufacture. To ensure continuity in the supplies of the Product, Partner shall continue to manufacture and supply the Product in accordance with the terms of this Agreement until such time as the technology transfer to the Third Party appointed by DNDi is complete and such Third Party is manufacturing and supplying the Product. Partner shall transfer all existing stocks of the Product to the Third Party following the completion of such technology transfer and launch of manufacture and supply by such Third Party as described in the preceding sentence;

- h) Partner shall transfer to DNDi the Regulatory Dossier and any supporting documentation, including the Marketing Authorization(s) and Regulatory Approvals in its possession; and
- i) in the case of termination by Partner under Section 23.2 with respect to any part of the Development Plan or the Access and Implementation Plan (as opposed to the Agreement in its entirety), the provisions of sub-sections a) to h) of this Section 24.2 shall apply only with respect to such terminated part of the Collaboration Plans.

24.3. For the avoidance of doubt, upon expiration of this Agreement, the license grants to each Party in Article 17 shall survive until discontinuation of the relevant R&D, manufacture or distribution activities by the licensee Party.

24.4. All rights and licenses granted under or pursuant to this Agreement by DNDi or Partner are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party’s possession, shall be promptly delivered to it:

- a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party’s written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement; or
- b) if not delivered under subsection a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

24.5. In the event of expiration or early termination of this Agreement for any reason, the following provisions shall survive: Articles 8, 16, 17, 18, 19, 20, 21, 22, 23 24 and 32; as well as any other obligation which by its nature is intended to survive.

24.6. Expiration or early termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration.

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**25. RIGHTS AND REMEDIES**

The rights and remedies provided under this Agreement are in addition to, and not exclusive of, any rights or remedies provided by law.

**26. INDEPENDENT CONTRACTORS**

Nothing in this Agreement shall be deemed to constitute a partnership or joint venture between the Parties or to constitute any Party as the agent or the employee of the other Party. Neither Party shall have authority to bind or act on behalf of the other Party.

**27. WAIVER**

No waiver of any term or condition of this Agreement in any instance shall be deemed to be or construed as a further or continuing waiver of such term or condition or of any other term or condition of this Agreement.

**28. FURTHER ASSURANCE**

28.1. The Parties shall perform any other activities necessary for the successful achievement of the objectives of this Agreement, provided that the Parties shall evaluate and agree on the costs of performing such activities, the financing thereof, and allocation of roles and responsibilities.

28.2. The Parties shall sign all documents or acts and provide all assurances necessary to give full effect to the terms of this Agreement.

**29. FORCE MAJEURE**

29.1. Neither Party shall be liable for failure or delay in performing its obligations herein and neither Party shall be deemed to be in breach of its obligations if such failure or delay occurs by reason of such Force Majeure event.

29.2. The Party claiming Force Majeure shall promptly inform the other Party of such event, by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effects. The Party claiming Force Majeure shall take all measures necessary to limit the consequences of such Force Majeure event.

29.3. The non-performing Party shall use Reasonable Efforts to limit the suspension of performance to no greater scope and no longer duration than is necessary and to resume performance of its obligations hereunder as soon as reasonably possible.

29.4. 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 hereto shall have the right to terminate this Agreement immediately upon written notice to the other Party.

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**30. NO ASSIGNMENT**

- 30.1 Neither Party may transfer or assign to a Third Party this Agreement, in whole or in part, without the prior written consent of the other Party, which consent shall not be unreasonably withheld.
- 30.2 It is understood, however, that either Party may freely transfer or assign any of its rights and obligations under this Agreement to any of its Affiliates, provided that such Affiliate agrees to be bound by the terms of this Agreement.
- 30.3 Furthermore, it is understood, that either Party may freely transfer or assign any of its rights and obligations under this Agreement to any direct or indirect successor to its business by means of merger, divestment, acquisition, contribution of assets or any other restructuring operation.

**31. NOTICES**

- 31.1 All notices or communications to be given under this Agreement shall be addressed in writing in English and sent by certified mail, return receipt requested, or recognised courier service, properly addressed, or by email with confirmed receipt, to the other Party at the addresses set forth below or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Article 31.
- 31.2 Notices shall be deemed effective upon:
- a) the date received if sent by certified mail or recognised courier; or
  - b) the date of confirmed receipt if sent by email.

**For DNDi:**

*In relation to technical and strategic issues:*

< add full name of contact >  
< add full address of contact >  
< add telephone number of contact >  
Email: < add email address of contact >

*In relation to legal issues:*

< add full name of contact >  
< add full address of contact >  
< add telephone number of contact >  
Email: < add email address of contact >

**For Partner:**

*In relation to technical and strategic issues:*

< add full name of contact >  
< add full address of contact >  
< add telephone number of contact >  
Email: < add email address of contact >

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**FOR DISCUSSION PURPOSES ONLY AND SUBJECT TO APPROVAL**

*In relation to legal issues:*

< add full name of contact >

< add full address of contact >

< add telephone number of contact >

Email: < add email address of contact >

**32. GOVERNING LAW, DISPUTE RESOLUTION AND EQUITABLE RELIEF**

- 32.1. This Agreement shall be governed by, subject to, construed and enforced in accordance with the laws of Switzerland, without giving effect to any conflicts of law rules.
- 32.2. Except as provided in Sections 15.12 to 15.15, any disputes arising between the Parties in connection with the validity, interpretation, performance or termination of this Agreement 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.
- 32.3. Prior to initiating arbitration, the Parties shall make a good faith attempt to resolve amicably any dispute arising under this Agreement. The contact persons indicated in Article 31 shall first attempt to resolve the matter by negotiation, and shall attend to at least one meeting for this purpose. In case this effort is unsuccessful, within fifteen (15) calendar days from the first discussion, the Parties shall each designate a person senior to the contact persons indicated in Article 31 to make a further attempt to resolve the dispute. If the dispute is not resolved within fifteen (15) calendar days thereafter, either Party may, by written notice to the other Party, initiate arbitration proceedings as provided in Section 32.2. Notwithstanding this Section 32.3, each Party shall be free to seek a preliminary injunction in court at any time.
- 32.4. Notwithstanding Sections 32.2 and 32.3, a breach by either Party of this Agreement may cause irreparable damage and the non-breaching Party may not be adequately compensated by monetary damages. In the event of a breach, or threatened breach, the non-breaching Party shall be entitled to seek from any court of competent jurisdiction equitable relief, whether preliminary or permanent, without the need to show irreparable harm or the inadequacy of monetary damages as a remedy and without the requirement of having to post a bond or other security. Nothing in this Section 32.4 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

**33. ENTIRE AGREEMENT, AMENDMENTS AND SEVERABILITY**

- 33.1. This Agreement sets forth the entire understanding between the Parties as to its subject matter and supersedes any prior oral or written understanding or agreement relating thereto.
- 33.2. This Agreement may be amended only in writing with the signature of a duly authorised representative of each Party.

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33.3. The provisions of this Agreement are severable, and if any provisions hereof shall be determined to be invalid or unenforceable by a court of competent jurisdiction, the remaining provisions shall continue in full force and effect.

**34. COUNTERPARTS AND TRANSMISSION IN PORTABLE DOCUMENT FORMAT**

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

34.2. For the convenience of the Parties, an executed copy of this Agreement may be transmitted by email in portable document format (PDF) and such .pdf file shall be deemed equivalent to an original.

**IN WITNESS WHEREOF**, each of the Parties has caused this Agreement to be executed by its authorised representative in its name and on its behalf.

< **add full name of Partner** >

Name:

Title:

Signature:

.....

**Drugs for Neglected Diseases initiative**

Name:

Title:

Signature:

.....

Name:

Title:

Signature:

.....

Name:

Title:

Signature:

.....

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**ANNEX 1 - DEVELOPMENT PLAN (AND CONSEQUENT ACCESS AND IMPLEMENTATION PLAN)**

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**ANNEX 2 - DULY EXECUTED PHARMACOVIGILANCE AGREEMENT**

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**ANNEX 3 – DULY EXECUTED QUALITY AGREEMENT**

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**ANNEX 4 - REGULATORY RESPONSIBILITIES PLAN**

- Split of regulatory responsibilities
- Sharing of information
- Attendance to meetings with Regulatory Authorities
- Format of data for regulatory submissions

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**ANNEX 5 – PRODUCT NEEDS’ FORECAST FOR THE TERRITORY**

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**ANNEX 6 – TECHNOLOGY TRANSFER**

1. Partner shall grant to any third party manufacturer (each manufacturer, a “Technology Transferee”) a non-exclusive, royalty-free license under Partner’s rights to and interest in all Technology controlled by Partner that is necessary or useful for the manufacture of the Product (such Technology, the “Manufacturing Technology”).
2. Partner shall disclose to each Technology Transferee all Manufacturing Technology so as to enable such Technology Transferee to manufacture the Product at facilities designated by such Technology Transferee.
3. Partner shall provide technical assistance (including on-site assistance) to each Technology Transferee, free of charge, as reasonably requested by such Technology Transferee in connection with the transfer of the Manufacturing Technology.

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**ANNEX 7 - POLICY ON SHARING AND SECONDARY USE OF HUMAN SUBJECT RESEARCH DATA**

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**ANNEX 8 - DISCLOSABLE INFORMATION**

- This Agreement covers:
  - < add disclosable information agreed between the Parties >
- Access to the Product
- Affordable Price

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**ANNEX 9 – ETHICAL BEHAVIOUR**

Each Party respects all human beings and expects everyone working for or with it to share the following principles on honest and ethical behaviour:

- **Equality, Diversity, and Inclusion:** each Party holds the principles and practices of equal opportunity and workforce diversity high in its working environment. Each Party :
  - does not tolerate discrimination especially against any characteristics protected by law (e.g., age, marital status or civil partnership, disability, ethnicity, gender reassignment, physical/mental health condition, physical appearance, political affiliation, cultural belief, pregnancy/maternity/paternity, race, religion, sex or sexual orientation);
  - respects cultural differences and values diversity;
  - supports full contribution of everyone in interactions.
  
- **Safeguarding:** neither Party tolerates persecution in any form. Each Party is committed to
  - provide a safe and trusted environment for staff;
  - treat staff with dignity and respect;
  - protect vulnerable groups (e.g., people who are ill or immunocompromised, children, pregnant women, elderly people or those who are unable to take care of or protect themselves);
  - prevent any form of abuse of power/authority, disrespect, harassment and bullying, exploitation, sexual misconduct and inappropriate behaviour of a sexual nature or threats to commit any of these.

In absence of safeguarding policy, Partner is encouraged to apply, with appropriate adaptations, DNDi's Guidelines for the prevention of sexual misconduct, published on its website (<https://dndi.org/wp-content/uploads/2019/12/DNDi-Guidelines-Prevention-Sexual-Misconduct-2019.pdf>).

Each Party ensures, notably through training, that those standards of behaviour are well communicated, understood and accepted.

Each Party shall provide a structure and a procedure that ensure secure reporting channels and proper handling and sanctioning of discrimination, abuse or exploitation.

No staff of either Party shall be discharged, demoted or otherwise discriminated in retaliation for raising, in good faith, a concern about compliance issues or cooperating with an investigation on an alleged breach of compliance.

Partner and its staff may report any kind of actual or potential ethical or legal concern, especially where it may adversely impact patients or any vulnerable person on DNDi Integrity Line (<https://dndi.integrityline.org/>) which offers confidentiality and anonymity as an option.