
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO SECTION 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of October 2021

Commission File Number: 001-39950

Evaxion Biotech A/S

(Exact Name of Registrant as Specified in Its Charter)

**Dr. Neergaards Vej 5f
DK-2970 Hoersholm
Denmark
(Address of principal executive offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Entry Into Material Agreement

On October 21, 2021, Evaxion Biotech A/S (the “Company”) entered into a Clinical Trial Collaboration and Supply Agreement (the “Agreement”), with MSD International GmbH and MSD International Business GmbH, subsidiaries of Merck & Co., Inc., (known collectively as MSD outside the United States and Canada), to evaluate in a new Phase 2b clinical trial, the combination of the Company’s patient specific neoepitope cancer immunotherapy compound, EVX-01, with MSD’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) compound, a humanized anti-human PD-1 monoclonal antibody. A copy of the Company’s press release announcing the Agreement is attached hereto as Exhibit 99.1.

The information furnished pursuant to this Form 6-K, including Exhibit 99.1 attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

The foregoing summary of the Agreement is qualified in its entirety by the full text of the Agreement, a copy of which is filed as Exhibit 99.2 attached hereto with certain portions subject to confidential treatment.

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release Announcing execution of Clinical Trial Collaboration and Supply Agreement by and among Evaxion Biotech A/S, MSD International GmbH and MSD International Business GmbH, subsidiaries of Merck & Co., Inc., (known collectively as MSD outside the United States and Canada),
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99.2*	Clinical Trial Collaboration and Supply Agreement by and among Evaxion Biotech A/S, MSD International GmbH and MSD International Business GmbH, subsidiaries of Merck & Co., Inc., (known collectively as MSD outside the United States and Canada),
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* Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[****]”) because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Evaxion Biotech A/S

Date: October 25, 2021

By: /s/ Lars Staal Wegner, M.D.
Lars Staal Wegner, M.D.
Chief Executive Officer



Evaxion Biotech Announces Clinical Collaboration to Evaluate Lead Product Candidate with KEYTRUDA[®] (pembrolizumab) in Patients with Melanoma

Copenhagen, Denmark, October 25, 2021(GLOBE NEWSWIRE) – Evaxion Biotech A/S (NASDAQ: EVAX), a clinical-stage biotechnology company specializing in the development of AI-driven immunotherapies to improve the lives of patients with cancer and infectious diseases, announced today that it has entered into a clinical trial collaboration and supply agreement with subsidiaries of Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the United States and Canada), to evaluate the combination of Evaxion’s cancer immunotherapy EVX-01 with MSD’s anti-PD-1 therapy KEYTRUDA[®] (pembrolizumab) in a new Phase 2b study.

The planned multicenter Phase 2b trial will enroll patients with metastatic melanoma stage III and stage IV and will investigate the personalized neoepitope immunotherapy EVX-01 in combination with KEYTRUDA[®]. It is expected to be initiated in Q4 2021. Under terms of the agreement, Evaxion will be responsible for the conduct of the study; MSD will supply all of the necessary KEYTRUDA[®] and will continue to collaborate as the data mature.

Lars Wegner, CEO of Evaxion, said: “We are extremely proud to collaborate with MSD, one of the world’s premier immuno-oncology companies, on our upcoming Phase 2b trial with EVX-01. The promising Phase 1/2a data, which we reported in July, showed that EVX-01 may be able to improve the treatment landscape in melanoma and potentially other cancers. Now that checkpoint inhibitors including KEYTRUDA[®] have become the standard of care for these patients, we are excited about the potential additive benefits of our drug candidate to further improve treatment and to strengthen the evidence supporting our platform and clinical pipeline. Furthermore, this collaboration will also reduce the cost of conducting our Phase 2b trial on EVX-01.”

The ongoing Phase 1/2a trial is investigating EVX-01, a novel personalized cancer neoepitope immunotherapy based on Evaxion’s proprietary PIONEER[®] AI technology, for the treatment of patients with melanoma.

KEYTRUDA[®] is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Kenilworth, NJ, USA.

About Evaxion

Evaxion Biotech A/S is a clinical-stage AI-immunology[™] platform company decoding the human immune system to discover and develop novel immunotherapies to treat cancer, and vaccines against bacterial diseases and viral infections. Based on its proprietary and scalable AI-immunology core technology, Evaxion is developing a broad pipeline of novel product candidates which currently includes three patient-specific cancer immunotherapies, two of which are in Phase 1/2a clinical development. In addition, Evaxion is advancing a portfolio of vaccines, currently in preclinical development, to prevent bacterial and viral infections.

For more information

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Source: Evaxion Biotech

Forward-looking statement

This announcement contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this announcement regarding the Company's future operations, plans and objectives are forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this announcement about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by, or including words such as "target," "believe," "expect," "hope," "aim," "intend," "may," "might," "anticipate," "contemplate," "continue," "estimate," "plan," "potential," "predict," "project," "will," "can have," "likely," "should," "would," "could", and other words and terms of similar meaning or the negative thereof. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with the Company's financial condition and need for additional capital; risks associated with the Company's development work; cost and success of the Company's product development activities and preclinical and clinical trials; risks related to commercializing any approved pharmaceutical product developed using the Company's AI platform technology, including the rate and degree of market acceptance of the Company's product candidates; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture; risks associated with the Company's inability to enter into partnerships; risks related to government regulation; risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's ADSs and ordinary shares, risks associated with the pandemic caused by the coronavirus known as COVID-19 and other risks and uncertainties affecting the Company's business operations and financial condition.

Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results, performance, or achievements to be materially different from the expected results, performance, or achievements expressed or implied by such forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, see the risks described in the "Risk Factors" section included in the Company's Form 20-F for the year end December 31, 2020 and the Company's current and future reports filed with, or submitted to, the U.S. Securities and Exchange Commission (SEC). Any forward-looking statements contained in this announcement speak only as of the date hereof, and except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

Clinical Trial Collaboration and Supply Agreement

by and between

MSD International GmbH,

MSD International Business GmbH,

and

Collaborator (as defined below)

[***]

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This Clinical Trial Collaboration and Supply Agreement is entered into as of the Effective Date, by and among MSD International GmbH (“**MSDIG**”), MSD International Business GmbH (“**MSDIB**” and, collectively with MSDIG, “**MSD**”), [***]and Collaborator (as defined below), having a place of business at the Collaborator Address (as defined below). MSD and Collaborator are each referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

- A. MSD holds intellectual property rights to the MSD Compound (as defined below) and is developing the MSD Compound for the treatment of certain tumor types.
- B. Collaborator is developing the Collaborator Compound (as defined below) for the treatment of certain tumor types.
- C. Collaborator desires to sponsor the Collaborator Clinical Trial (as defined below) in which the Collaborator Compound and the MSD Compound would be dosed in Combination (as defined below).
- D. MSD and Collaborator, consistent with the terms of this Agreement, desire to collaborate as described herein, including by providing the MSD Compound and the Collaborator Compound for the MSD Compound Study (as defined below).

NOW, THEREFORE, in consideration of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, agree as follows:

1. **DEFINITIONS.**

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

- 1.1. “**Affiliate**” means, with respect to either Party, a firm, corporation or other entity that, now or hereafter, directly or indirectly owns or controls said Party, or, now or hereafter, is owned or controlled by said Party, or is under common ownership or control with said Party for so long as such control exists. The word “**control**” as used in this definition means: (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity; or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.
- 1.2. “**Agreement**” means this agreement.
- 1.3. “**Alliance Manager**” means the alliance managers appointed by the Parties in accordance with Section 2.3 (Joint Development Committee; Managers).

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 1.4. **“Applicable Law”** means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including: (i) those promulgated by any Regulatory Authority; (ii) cGMP and GCP; (iii) Data Protection Law; (iv) export control and economic sanctions regulations that prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; (v) anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; (vi) laws and regulations governing payments to healthcare providers; (vii) the listing or other rules or regulations of any stock exchange; and (viii) health, safety and environmental protections.
- 1.5. **“Applicable Manufacturer”** has the meaning ascribed to it in the Sunshine Act.
- 1.6. **“Business Day”** means any day other than a Saturday, Sunday, or a day on which commercial banks located in the country (or, in the United States, in the state) where the applicable obligations are to be performed are authorized or required by law to be closed.
- 1.7. **“cGMP”** means the Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities as applicable to the Manufacture of the Compounds.
- 1.8. **“Change of Control”** means: (a) the sale of all or substantially all of such Collaborator’s assets or business relating to the Collaborator Compound; or (b) a merger, reorganization or consolidation involving Collaborator in which the voting securities immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) any Third Party (or group of Third Parties acting in concert) becoming the beneficial owner directly or indirectly, of fifty percent (50%) or more of the total voting power of Collaborator.
- 1.9. **“Clinical Quality Agreement”** means an agreement to be entered into by the Parties pursuant to Section 2.4 (Clinical Quality Agreement) to address and govern the quality and handling of clinical drug to be supplied by the Parties for use in the MSD Compound Study.
- 1.10. **“Clinical Data”** means Collaborator Clinical Data, Joint Clinical Data and MSD Clinical Data.
- 1.11. **“Clinical Safety Data”** means all safety and tolerability data from the monotherapy portions of the Collaborator Clinical Trial or other monotherapy clinical trials involving the Collaborator Compound, including all safety reports containing information on adverse events, SAEs, and other information required by any FDA-reporting requirements, including summary tables of laboratory and radiographic data.

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- 1.12. “**CMC**” means “**Chemistry Manufacturing and Controls**” as such term of art is used in the pharmaceutical industry.
- 1.13. “**Collaborator**” means the entity specified in the “Collaborator Entity Name” row of the Information Sheet.
- 1.14. “**Collaborator Address**” means the address set forth for Collaborator in the “Collaborator Address” row of the Information Sheet.
- 1.15. “**Collaborator Background Patents**” means any patent Controlled by Collaborator or its Affiliate that: (i) has a priority claim that is earlier than the first dosing of the first patient in a Combination Arm(s); and (ii) claims or covers the Combination.
- 1.16. “**Collaborator Class Compound**” means [***].
- 1.17. “**Collaborator Clinical Data**” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the Collaborator Compound Arm(s), if any Collaborator Compound Arm(s) are included in the Collaborator Clinical Trial. Collaborator Clinical Data does not include Sample Testing Results, Joint Clinical Data or MSD Clinical Data.
- 1.18. “**Collaborator Clinical Trial**” means the clinical trial set forth in the “Collaborator Clinical Trial” row of the Information Sheet.
- 1.19. “**Collaborator Compound**” means [***].
- 1.20. “**Collaborator Compound Arm(s)**” means any portion of the Collaborator Clinical Trial where patients are intended to receive the Collaborator Compound either alone or in concomitant or sequential administration with one or more treatments, but not in Combination with the MSD Compound.
- 1.21. “**Collaborator Escalation Contact**” means the person set forth in the “Collaborator JDC Escalation Person Title” row of the Information Sheet.
- 1.22. “**Collaborator Inventions**” means [***].
- 1.23. “**Combination**” means the use or method of using the Collaborator Compound and the MSD Compound in concomitant or sequential administration (whether or not in concomitant or sequential administration with one or more other treatments). “Sequential administration” shall not include separate but sequential lines of therapy.
- 1.24. “**Combination Arm(s)**” means the portion of the Collaborator Clinical Trial where patients are intended to receive the Collaborator Compound and the MSD Compound in Combination (whether or not in concomitant or sequential administration with one or more other treatments).

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- 1.25. “**Compounds**” means the Collaborator Compound and the MSD Compound. A “**Compound**” means either the Collaborator Compound or the MSD Compound.
- 1.26. “**Confidential Information**” means any information (including personal data), Know-How or other proprietary information or materials furnished to a Receiving Party by or on behalf of a Disclosing Party in connection with this Agreement, except to the extent that such information or materials, as demonstrated by competent evidence: (i) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through a breach of this Agreement by the Receiving Party; (iv) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (v) was subsequently developed by the Receiving Party without use of the Disclosing Party’s Confidential Information. MSD Clinical Data is deemed the Confidential Information of MSD (and MSD is the “Disclosing Party” and Collaborator the “Receiving Party” with respect to the same). Collaborator Clinical Data is deemed the Confidential Information of Collaborator (and Collaborator is the “Disclosing Party” and MSD the “Receiving Party” with respect to the same). [***].
- 1.27. “**Continuing Party**” means the Party continuing prosecution or maintenance pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.28. “**Control**” or “**Controlled**” means, with respect to particular information or intellectual property, that the applicable Party or its Affiliate owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.
- 1.29. “**CTA**” means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.
- 1.30. “**Data Protection Law**” means any applicable data protection or privacy law to which a Party is subject in connection with this Agreement.
- 1.31. “**Data Protection Terms**” means Exhibit C hereto, which ensures certain protections are in place for the processing personal data in the performance of the MSD Compound Study and sets forth the Parties’ responsibilities for certain obligations, including addressing the rights of data subjects, ensuring a legal basis for processing personal data, conducting appropriate data-protection impact assessments and prior consultations with relevant supervisory authorities, complying with all personal-data breach-notification obligations, and certain other compliance obligations under Data Protection Law.

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- 1.32. **“Data Sharing Schedule”** means the schedule attached hereto as Schedule I.
- 1.33. **“Defending Party”** means a Party controlling the defense of an action pursuant to Section 14.2.3 (Procedure).
- 1.34. **“Delivery”** with respect to the MSD Compound means delivery DAP (Incoterms 2020) and, with respect to the Collaborator Compound, means when a given quantity of Collaborator Compound is packaged for shipment to an MSD Compound Study site. **“Deliver”** shall have a correlative meaning.
- 1.35. **“Disclosing Party”** means a Party (or its Affiliate) disclosing Confidential Information of such Party hereunder.
- 1.36. **“Effective Date”** means the date set forth in the “Effective Date” row of the Information Sheet.
- 1.37. **“EMA”** means the European Medicines Agency and any successor agency.
- 1.38. **“Exclusions List”** means: (i) List of Excluded Individuals and Entities on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website including 42 U.S.C. 1320a-7(<https://www.oig.hhs.gov/exclusions/index.asp>); (ii) the U.S. General Services Administrator’s list of Parties Excluded from Federal Programs – System for Award Management (<https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf>) and (iii) the debarment list promulgated under 21 U.S.C.335a (<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications>).
- 1.39. **“FCPA”** means the U.S. Foreign Corrupt Practices Act.
- 1.40. **“FDA”** means the United States Food and Drug Administration.
- 1.41. **“GCP”** means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use that may be in effect from time to time and applicable to the testing of the Compounds.
- 1.42. **“Government Official”** means: (i) any officer or employee of a government or any department, agency or instrument of a government; (ii) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (iii) any officer or employee of a company or business owned in whole or part by a government; (iv) any officer or employee of a public international organization such as the World Bank or United Nations; (v) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; or (vi) any candidate for political office; who, in each of the foregoing cases (i) through (vi), when such Government Official is acting in an official capacity or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either Party.

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- 1.43. “**IND**” means any Investigational New Drug Application as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an “Investigational Medicinal Product Dossier” in the European Union.
- 1.44. “**Information Sheet**” means the table entitled Information Sheet set forth just before the preamble to this Agreement.
- 1.45. “**Inventions**” means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together: [***].
- 1.46. “**Joint Clinical Data**” means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the Combination Arm(s); provided however, that Joint Clinical Data does not include Sample Testing Results, Collaborator Clinical Data or MSD Clinical Data.
- 1.47. “**Joint Development Committee**” or “**JDC**” means the committee to be established by the Parties pursuant to Section 2.3 (Joint Development Committee; Managers).
- 1.48. “**Joint Patent Application**” means a Patent Application filed in respect to any Joint Invention.
- 1.49. “**Joint Patent**” means a Patent that issues from a Joint Patent Application.
- 1.50. “**Joint Invention**” means [***].
- 1.51. “**Kit**” means [***]for which MSD is entitled to reimbursement pursuant to Sections 6.10 (Manufacturing Costs) or 8.9.2 (Non-Conformance).
- 1.52. “**Know-How**” means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 1.53. **“Liability”** means any loss, damage, reasonable costs and expenses (including reasonable attorneys’ fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or the Collaborator Clinical Trial.
- 1.54. **“Manufacture,” “Manufactured,” or “Manufacturing”** means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply.
- 1.55. **“Manufacturer’s Release” or “Release”** has the meaning ascribed to release of the MSD Compound in the Clinical Quality Agreement.
- 1.56. **“Manufacturing Site”** means the facilities where a Compound is Manufactured by or on behalf of a Party.
- 1.57. **“MSD”** has the meaning set forth in the preamble.
- 1.58. **“MSD Background Patents”** means [***].
- 1.59. **“MSD Clinical Data”** means all data (including raw data) and results generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of the MSD Compound Arm(s), if any MSD Compound Arm(s) are included in the Collaborator Clinical Trial [***].
- 1.60. **“MSD Compound”** means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody,.
- 1.61. **“MSD Compound Arm(s)”** means any portion of the Collaborator Clinical Trial where patients are intended to receive the MSD Compound either alone or in combination with one or more treatments but not in Combination with the Collaborator Compound.
- 1.62. **“MSD Compound Study”** means the arms of the Collaborator Clinical Trial where patients are intended to receive the MSD Compound either alone or in combination with one or more treatments (including the Collaborator Compound). The MSD Compound Study includes the Combination Arm(s) and any MSD Compound Arm(s) included in the Collaborator Clinical Trial.
- 1.63. **“MSD Inventions”** means [***].
- 1.64. **“NDA”** means a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in a country or group of countries.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 1.65. **“Non-Conformance”** means, with respect to a given unit of Compound: (i) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound; or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Article 8 (Supply and Use of Compounds) or Section 13.2 (Compounds). **“Non-Conforming”** shall have a correlative meaning.
- 1.66. **“Non-Pursuing Party”** means a Party not pursuing the filing, prosecution or maintenance of a Joint Patent Application or Joint Patent pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.67. **“Opting-out Party”** means a Party that wishes to discontinue the prosecution and maintenance of a Joint Patent Application or Joint Patent pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.68. **“Other Party”** means a Party not controlling the defense of an action pursuant to Section 14.2.3 (Procedure).
- 1.69. **“Parties”** and **“Party”** have the meanings set forth in the preamble.
- 1.70. **“Patent”** means a patent, extension, registration, supplementary protection certificate or the like that issues from a given Patent Application.
- 1.71. **“Patent Application”** means a patent application (including any provisional, substitution, divisional, continuation, continuation-in-part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of a given Invention.
- 1.72. **“PD-1 Antagonist”** means [***].
- 1.73. **“Person”** means any entity, including any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, or governmental entity.
- 1.74. **“Pharmacovigilance Agreement”** means the pharmacovigilance agreement to be executed by the Parties pursuant to Section 2.6 (Pharmacovigilance Agreement).
- 1.75. **“Project Manager”** means the Project Managers to be designated by the Parties pursuant to Section 2.3 (Joint Development Committee; Managers).
- 1.76. **“Protocol”** means the written documentation that describes the Collaborator Clinical Trial and sets forth specific activities to be performed as part of the conduct of the Collaborator Clinical Trial.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 1.77. **“Pursuing Party”** means a Party pursuing the filing, prosecution or maintenance of a Joint Patent Application or Joint Patent pursuant to Section 10.4 (Declining to File, Prosecute or Maintain).
- 1.78. **“Receiving Party”** means a Party (or its Affiliate) receiving Confidential Information of the other Party hereunder.
- 1.79. **“Regulatory Approvals”** means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from any Regulatory Authority or other competent authority for the development, registration, importation and distribution of such Compound in any jurisdiction for use in the MSD Compound Study.
- 1.80. **“Regulatory Authorities”** means the FDA, national regulatory authorities, the EMA, any successor agency to the FDA or EMA and any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction.
- 1.81. **“Regulatory Documentation”** means all submissions to Regulatory Authorities in connection with the development of a Compound, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse-event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including any documents that include Clinical Data).
- 1.82. **“Related Agreements”** means the Pharmacovigilance Agreement and the Clinical Quality Agreement.
- 1.83. **“Related Entities”** means, with respect to each of Collaborator and MSD, such Party’s Affiliates and its and their directors, officers, employees and others acting on its or their behalf.
- 1.84. **“Right of Reference”** means the “right of reference” defined in 21 CFR 314.3(ii) including, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information and data (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation filed with such Regulatory Authority with respect to a Party’s Compound.
- 1.85. **“SAE”** means a serious adverse event.
- 1.86. **“Samples”** means biological specimens collected from subjects participating in the MSD Compound Study, including any urine, blood and tissue samples.
- 1.87. **“Sample Testing”** means the analyses to be performed by each Party using the applicable Samples, as described in the Sample Testing Schedule.

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- 1.88. “**Sample Testing Results**” means the data and results arising from the Sample Testing.
- 1.89. “**Sample Testing Schedule**” means the schedule attached hereto as Schedule II.
- 1.90. “**Sensitive Information**” means [***].
- 1.91. “**Specifications**” means the requirements to which a Compound must conform. The Specifications for a Compound will be set forth in the certificate of analysis accompanying each batch of Compound supplied for use in the MSD Compound Study.
- 1.92. “**Study Completion**” means: (i) the date when the last patient enrolled in the MSD Compound Study has completed their last study-related assessment for evaluation excluding survival follow-up; or (ii) an alternative date as agreed to by the JDC.
- 1.93. “**Subcontractors**” means any and all Third Parties to whom a Party delegates any of its obligations hereunder.
- 1.94. “**Subsequent Study**” means a registrational study for the Combination in the same indication(s) and line(s) of therapy as that included in the Combination Arm(s).
- 1.95. “**Sunshine Act**” shall mean the Physician Payments Sunshine Act as amended from time to time.
- 1.96. “**Term**” means the term of this Agreement.
- 1.97. “**Third Party**” means any Person or entity other than Collaborator, MSD or their respective Affiliates.
- 1.98. “**Third-Party Infringement**” means any actual or threatened infringement or misappropriation by a Third Party of any Joint Patent or Joint Invention.
- 1.99. “**Toxicity and Safety Data**” means all clinical adverse-event information or patient-related safety data included in the Joint Clinical Data and MSD Clinical Data, as more fully described in the Pharmacovigilance Agreement.
- 1.100. “**Transparency Report**” means a transparency report in connection with reporting payments and other transfers of value made to health-care professionals, including investigators, steering-committee members, data-monitoring committee members, and consultants in connection with the MSD Compound Study in accordance with reporting requirements under Applicable Law, including the Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and a Party’s applicable policies.
- 1.101. “**VAT**” means a value-added or similar tax.
- 1.102. “**Violation**” means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (i) convicted of any of the felonies identified among the Exclusion Lists or (ii) identified or listed as having an active exclusion on any Exclusion List; or (iii) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under any Exclusion List.

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2. **PERFORMANCE OF THE AGREEMENT. RELATED AGREEMENTS.**

2.1. The Collaborator Clinical Trial. Collaborator is conducting or intends to conduct the Collaborator Clinical Trial, which Collaborator Clinical Trial has or is intended to have a Combination Arm(s). In addition, the Collaborator Clinical Trial may (or may not) have a Collaborator Compound Arm(s), an MSD Compound Arm(s), or both. The term “Collaborator Clinical Trial” as used in this Agreement refers to the Collaborator Clinical Trial as a whole, including the Combination Arm(s), and any Collaborator Compound Arm(s) or MSD Compound Arm(s) that form or are intended to form a part of the Collaborator Clinical Trial. The term “MSD Compound Study” refers to the Combination Arm(s) and any MSD Compound Arm(s) that form or are intended to form a part of the Collaborator Clinical Trial. Collaborator Clinical Trial, Collaborator Compound Arm(s), Combination Arm(s), MSD Compound Arm(s) and MSD Compound Study all refer to such arms as are intended to be conducted in accordance with the Protocol, including the Protocol as may be amended in accordance with Article 4 (PROTOCOL AND INFORMED CONSENT; CERTAIN COVENANTS).

2.2. Generally. Each Party shall: (i) contribute such resources as are necessary to conduct the activities contemplated by this Agreement; and (ii) act in good faith in performing its obligations under this Agreement and each Related Agreement to which it is a Party.

2.3. Joint Development Committee; Managers.

2.3.1. The Parties shall form the Joint Development Committee made up of an equal number of representatives of MSD and Collaborator, which shall have responsibility for coordinating all regulatory and other activities under, and pursuant to, this Agreement (except for activities under, and pursuant to, Article 10 (INTELLECTUAL PROPERTY)). The JDC will review and finalize the Protocol in accordance with Section 4.1 (Protocol). Each Party shall designate a Project Manager who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties with respect to the MSD Compound Study and shall be entitled to attend meetings of the JDC. JDC members will be agreed by both Parties.

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- 2.3.2. The JDC shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably requested by either Party, to provide an update on the progress of the MSD Compound Study. The JDC may meet in person or by means of teleconference, internet conference, videoconference or similar means. Prior to any such meeting, Collaborator's Project Manager shall provide a written update to MSD's Project Manager and Alliance Manager containing information about the overall progress of the MSD Compound Study, recruitment status, interim analysis (if available), final analysis and other information relevant to the conduct of the MSD Compound Study (and data relating to the Collaborator Clinical Trial reasonably requested by MSD and relevant to the MSD Compound Study).
- 2.3.3. In addition to a Project Manager, each Party shall designate an Alliance Manager who shall serve as the primary point of contact for any issues arising under this Agreement and shall endeavor to ensure clear and responsive communication and the effective exchange of information between the Parties. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matters either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree. In the event that an issue arises and the Alliance Managers do not, after good faith efforts, reach agreement on such issue, or if there is a decision to be made by the JDC on which the members of the JDC do not unanimously agree, the issue shall be elevated to the [***]. In the event such escalation does not result in resolution or consensus: (i) MSD shall have final decision-making authority with respect to issues related to MSD Compound; and (ii) Collaborator shall have final decision-making authority with respect to issues related to Collaborator Compound.
- 2.4. Clinical Quality Agreement. The Parties will execute the Clinical Quality Agreement prior to any supply of MSD Compound hereunder, and no later than [***]days after the Effective Date. The Clinical Quality Agreement shall, among other things: (i) detail classification of any Non-Conforming MSD Compound; (ii) include criteria for Manufacturer's Release and related certificates and documentation; (iii) include criteria and timeframes for acceptance of MSD Compound; (iv) include procedures for the resolution of disputes regarding any Non-Conforming MSD Compound; (v) detail procedures and rights with respect to audit and inspection rights for Manufacturing sites, and (vi) include provisions governing the recall of Compounds. Quality matters and the Manufacture of the MSD Compound shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement.
- 2.5. Data Protection. The Parties will comply with the Data Protection Terms set forth on Exhibit C, which are incorporated into and form a part of this Agreement.

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- 2.6. Pharmacovigilance Agreement. The Parties will execute the Pharmacovigilance Agreement prior to MSD Delivering MSD Compound to Collaborator hereunder. The Pharmacovigilance Agreement will: (i) include safety data exchange procedures; (ii) facilitate appropriate safety reviews; (iii) govern the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the MSD Compound and Collaborator Compound in the MSD Compound Study; and (iv) shall enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities, all of the foregoing in accordance with Applicable Law. For the avoidance of doubt, the obligations to provide safety data under the Pharmacovigilance Agreement will be independent of any obligations to provide safety data pursuant to this Agreement.
- 2.7. Delegation of Obligations. Each Party shall have the right to delegate any portion of its obligations hereunder only: (i) to such Party's Affiliates; (ii) to Third Parties that are set forth on Schedule III as performing MSD Compound Study activities or as conducting Sample Testing for such Party; (iii) [***]; and (iv) upon the other Party's prior consent. Notwithstanding any delegation of its obligations hereunder, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by its Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement.
- 2.8. Relationship. Without prejudice to Section 2.9 (Subsequent Study), this Agreement does not create any obligation for either Party to provide any compound other than its Compound or to provide its Compound for any activities other than the MSD Compound Study. Except as expressly set forth in Section 2.9 (Subsequent Study), nothing in this Agreement shall: [***]. Collaborator and MSD have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Collaborator Clinical Trial. Except as expressly set forth in Section 2.9 (Subsequent Study), nothing in this Agreement obligates the Parties to enter into any agreement other than the Related Agreements now or in the future.
- 2.9. Subsequent Study. [***].

3. CONDUCT OF THE MSD COMPOUND STUDY.

- 3.1. Sponsor. Collaborator shall act as the sponsor of the Collaborator Clinical Trial under its own IND for the Collaborator Compound with a Right of Reference to the IND of the MSD Compound as described in Section 3.5 (Regulatory Matters); provided, however, that in no event shall Collaborator file an additional IND for the MSD Compound Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests such an additional IND for the MSD Compound Study, the Parties shall meet and agree on an approach to address such requirement.

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- 3.2. Clinical Safety Data Review. If the Information Sheet indicates that this Agreement contains a safety gate (i.e. “Yes” is selected for the Safety Gate (Yes/No) row), then this Section 3.2 (Clinical Safety Data Review) shall apply to this Agreement. If “No” is selected, then this Section 3.2 (Clinical Safety Data Review) shall be deemed omitted from this Agreement and shall not apply. [***].
- 3.3. Performance. Collaborator shall ensure that the MSD Compound Study and all related activities are performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP.
- 3.4. Debarred Personnel; Exclusions Lists. Collaborator certifies that it has not and shall not use in any capacity the services of any person, including any subcontractor or individual, that has been excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs including Title 21 U.S.C. Section 335a or any foreign equivalent thereof. Collaborator has, as of the Effective Date screened itself, and its Affiliates’ officers and directors against the Exclusions Lists and has informed MSD whether it or any of its employees, officers or directors is or has been in Violation. Collaborator shall notify MSD in writing immediately if any suspension, proposed debarment, debarment or Violation occurs or comes to its attention with respect to any Person performing activities related to the MSD Compound Study or otherwise related to activities under this Agreement.
- 3.5. Regulatory Matters. Collaborator shall: (i) obtain all Regulatory Approvals from all Regulatory Authorities, ethics committees and institutional review boards with jurisdiction over the MSD Compound Study prior to its initiation; and (ii) follow all directions from any such Regulatory Authorities, ethics committees and institutional review boards. MSD shall have the right (but not the obligation) to participate in any discussions (including meetings) with a Regulatory Authority regarding matters related to the MSD Compound Study or the MSD Compound and to collaborate on questions posed to Regulatory Authorities regarding design and conduct of the MSD Compound Study. If a Right of Reference is necessary for the conduct of the MSD Compound Study in a given country, each Party shall provide a cross-reference letter or similar communication to the applicable Regulatory Authority as needed to effectuate the Right of Reference. [***]. MSD shall authorize the FDA and other applicable Regulatory Authorities to cross-reference the appropriate MSD Compound INDs and CTAs to provide data access to Collaborator as necessary to conduct the MSD Compound Study. If MSD’s CTA is not available in a given country, MSD [***].

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- 3.6. Documentation. Collaborator shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Collaborator shall provide to MSD all Collaborator Clinical Trial information and documentation reasonably requested by MSD to enable MSD to: (i) comply with any of its legal, regulatory or contractual obligations, or any request by any Regulatory Authority related to the MSD Compound; and (ii) determine whether the MSD Compound Study has been performed in accordance with this Agreement.
- 3.7. Copies. Collaborator shall provide to MSD copies of all Joint Clinical Data and any MSD Clinical Data in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing Schedule or mutually agreed; provided, however, that a complete copy of the Joint Clinical Data and any MSD Clinical Data shall be provided to MSD no later than [***] following MSD Compound Study Completion or any sooner termination of this Agreement. Collaborator shall ensure that: (i) all patient authorizations and consents required under Applicable Law in connection with the Collaborator Clinical Trial permit such sharing of Joint Clinical Data and any MSD Clinical Data with MSD; and (ii) it complies with Applicable Law in transferring personal data hereunder.
- 3.8. Sample Testing.
- 3.8.1. Collaborator shall provide Samples to MSD as specified in the Protocol and as agreed to by the Joint Development Committee. Each Party shall use the Samples only for Sample Testing in accordance with the Sample Testing Schedule and the Protocol. [***].
- 3.8.2. Except to the extent otherwise expressly agreed, each Party may use and disclose the Sample Testing Results owned by and shared by the other Party in accordance with the Sample Testing Schedule solely for the purposes of: [***].
- 3.9. Ownership and Use of Joint Clinical Data.
- 3.9.1. [***]. Collaborator shall maintain the Joint Clinical Data [***] in its internal database; provided, however, that at all times during the Term and for [***] days thereafter, Collaborator shall grant MSD access to all Joint Clinical Data [***]. [***].
- 3.9.2. All Collaborator Clinical Data shall be solely owned by Collaborator. [***].

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- 3.9.3. Notwithstanding the foregoing, before publication or presentation of the Joint Clinical Data in accordance with Section 12.2 (Publication), [***]; provided, however, that the foregoing shall not limit or restrict either Party's ability to: (a) use or disclose the Joint Clinical Data as may be necessary to comply with Applicable Law or with such Party's internal policies and procedures with respect to pharmacovigilance and adverse event reporting; or (b) share with Third Parties or Affiliates Toxicity and Safety Data where, because of severity, frequency or lack of reversibility, either Party needs to use such Toxicity and Safety Data with respect to its Compound or the Combination to ensure patient safety. For the purposes of this Section 3.9.3, "publication or presentation" includes any publicly-available oral presentation, journal publication, abstract, poster presentation, press release, paper, letter, or other publicly-available publication.
- 3.9.4. Notwithstanding anything to the contrary in this Section 3.9 (Ownership and Use of Joint Clinical Data), Collaborator may: [***]; and (z) Collaborator must notify MSD at least [***] before such disclosure of the reasons for the planned disclosure and provide MSD with a copy of the Clinical Data (and any related summaries or analyses) to be disclosed. Collaborator will consider MSD's comments on such Clinical Data, summaries and analyses.
- 3.10. Regulatory Submission. It is understood and acknowledged by the Parties that positive Clinical Data may be used to [***].
- 3.11. Certain Memoranda and Reports. Promptly following MSD Compound Study Completion, Collaborator shall provide to MSD an electronic draft of the [***] and an electronic draft of the [***]. MSD shall have [***] days after receipt of such results memorandum and [***] days after receipt of such final report to provide comments thereon. [***]. Collaborator shall deliver to MSD a final version of each such document promptly following finalization thereof.
- 3.12. Licensing.
- 3.12.1. [***].
- 3.12.2. [***].

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4. **PROTOCOL AND INFORMED CONSENT; CERTAIN COVENANTS.**

- 4.1. Protocol. A synopsis of the agreed initial Protocol and any agreed draft statistical analysis plan for the MSD Compound Study or Collaborator Clinical Trial are attached hereto as Exhibit A. Collaborator shall: (i) provide a draft of the Protocol (and any subsequent revisions thereof) to MSD for MSD's review and comment; (ii) consider any changes to the draft of the Protocol requested by MSD; and (iii) incorporate any changes requested by MSD with respect to MSD Compound. Collaborator shall submit the draft Protocol to the MSD for final approval; provided, that, the country or countries in which the MSD Compound Study will be performed will be reviewed and agreed upon by the JDC before MSD Compound Study initiation and any changes thereto will be subject to review and approval of MSD. To the extent the Parties cannot agree unanimously regarding the contents of the Protocol for final approval: (x) Collaborator shall have final decision-making authority with respect to matters in the Protocol related to the Collaborator Compound; (y) MSD shall have final decision-making authority with respect to matters in the Protocol related to the MSD Compound [***]; and (z) all other matters in respect of the Protocol on which the Parties cannot agree shall be resolved in accordance with Section 2.3 (Joint Development Committee; Managers). Notwithstanding anything to the contrary contained herein, each Party, in its sole discretion, shall have the sole right to determine the dose and dosing regimen for its Compound and shall have the final decision on all matters relating to its Compound and any information regarding its Compound included in the Protocol.
- 4.2. Informed Consent. Collaborator shall prepare the patient informed-consent form for the MSD Compound Study (which shall include provisions regarding the use of Samples in Sample Testing) in consultation with MSD (it being understood and agreed that the portion of the informed-consent form relating to the Sample Testing of the MSD Compound shall be provided to Collaborator by MSD and adopted by Collaborator).
- 4.3. Changes to Protocol or Informed Consent. Any proposed changes to: (i) the approved final Protocol (other than changes that are solely related to Collaborator Compound); or (ii) the informed consent form relating to the MSD Compound, including Sample Testing of the MSD Compound, shall be made only with MSD's prior written consent. Any proposed changes ([***) will be sent to MSD's Project Manager and MSD's Alliance Manager. For those changes requiring MSD's consent, [***], within [***] after MSD receives a copy of the requested changes. If Protocol revisions made in accordance with this Section 4.3 would necessitate corresponding revisions to the definitions of Collaborator Clinical Trial, Combination Arm(s) or MSD Compound Study, such definitions shall be deemed to be revised consistent with such Protocol revisions.
- 4.4. Transparency Reporting. Collaborator is solely responsible for reporting payments and other transfers of value, (including supply of MSD Compound), made to health-care professionals, including investigators, steering-committee members, data-monitoring committee members, and consultants in connection with the MSD Compound Study in accordance with reporting requirements under Applicable Law, including the Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and Collaborator's applicable policies. Promptly after the Effective Date, Collaborator will notify MSD of Collaborator's point of contact for purposes of receiving information from MSD pursuant to this Section 4.4, along with such contact's full name, email address, and telephone number. Collaborator may update such contact from time to time by notifying MSD pursuant to Article 22 (NOTICES). Where applicable, MSD will provide to such Collaborator contact all information regarding the value of the MSD Compound provided for use in the MSD Compound Study as required for such reporting. In the event that the value of the MSD Compound provided pursuant to this Section 4.4 materially changes, MSD shall notify Collaborator of such revised value and the effective date thereof.

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- 4.4.1. **Periods Collaborator is Not Required to Report.** With respect to any [***]reporting period in which Collaborator is not an entity that is required to make a Transparency Report under Applicable Law, Collaborator will: (i) notify MSD within [***]days after the commencement of such reporting period that Collaborator is not so required; and (ii) during such reporting period Collaborator will[***]. Collaborator represents and warrants that any data provided by Collaborator to MSD pursuant to this Section 4.4 will be complete and accurate to the best of Collaborator’s knowledge.
- 4.5. Financial Disclosure. To the extent required by Applicable Law, Collaborator will be responsible for preparing and submitting the Financial Disclosure Module 1.3.4 components to the FDA for any Regulatory Documentation in connection with the MSD Compound Study and Collaborator Clinical Trial.
5. **ADVERSE EVENT REPORTING.**
- 5.1. Pharmacovigilance. Collaborator will be solely responsible for safety reporting for the Collaborator Clinical Trial and related activities, all in accordance with Applicable Law.
- 5.2. Transmission of SAEs. Collaborator will transmit to MSD all SAEs from the MSD Compound Study as set forth below. All cases will be transmitted on a CIOMS-1 form in English.
- 5.2.1. For drug-related fatal and life-threatening SAEs, Collaborator will transmit a processed case within [***]days after receipt by Collaborator of notice of such SAEs.
- 5.2.2. For all other SAEs, including non-drug-related fatal and life-threatening SAEs, and newly diagnosed cancer, Collaborator will transmit a processed case within [***]days after receipt by Collaborator of notice of such SAEs.
- 5.2.3. Cases of disease progression will be handled as outlined in the Protocol, and if the Protocol specifies that such cases are collected as SAEs, Collaborator will transmit such cases to MSD within the applicable timeframe set forth in Section 5.2.1 or Section 5.2.2.
- 5.2.4. For all other reportable information that includes: (i) overdose, exposure during pregnancy or lactation; and (ii) cases of potential drug-induced liver injury where the patient was exposed to the MSD Compound (if required to be collected or identified per the Protocol), Collaborator will transmit a processed case within [***]days after receipt by Collaborator of such information.

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6. **TERM AND TERMINATION.**

- 6.1. Term. The Term shall commence on the Effective Date and shall continue in full force and effect until [***].
- 6.2. MSD Termination for Unsafe Use. In the event MSD notifies Collaborator that it in good faith believes that the MSD Compound is being used unsafely in the MSD Compound Study and the grounds for such belief, and if either MSD believes such matter is not reasonably capable of remedy or if Collaborator fails to promptly remedy such issue to MSD's reasonable satisfaction, MSD may terminate this Agreement and the supply of the MSD Compound by notice to Collaborator with immediate effect.
- 6.3. Termination for Breach. Either Party may terminate this Agreement by notice with immediate effect if the other Party commits a material breach of this Agreement and such material breach continues for[***] days after receipt of notice thereof from the non-breaching Party; provided that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement by notice effective at the expiration of such [***]-day cure period. Either Party shall have the right to terminate this Agreement by notice to the other Party with immediate effect if such other Party fails to perform any of its obligations under Section 13.4 (Anti-Corruption) or breaches any representation or warranty contained in Section 13.4 (Anti-Corruption). In addition: (i) this Agreement may be terminated by the non-breaching party for material breach of any other Clinical Trial Collaboration and Supply Agreement between the Parties (or their Affiliates) involving MSD Compound if such material breach occurred or was discovered during the Term and such material breach is not cured in accordance with the terms of such other Clinical Trial Collaboration and Supply Agreement; and (ii) in the event this Agreement is terminated pursuant to this Section 6.3, the terminating Party will have the right to terminate any or all other Clinical Trial Collaboration and Supply Agreements between the Parties by written notice given within [***]days after termination of this Agreement becomes effective pursuant to this Section 6.3.
- 6.4. Termination for Patient Safety. If either Party determines in good faith that the MSD Compound Study or Collaborator Clinical Trial may unreasonably adversely affect patient safety, such Party shall promptly notify the other Party of such determination. The Party receiving such notice may propose modifications to the MSD Compound Study or Collaborator Clinical Trial to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the proposed modifications and may instead terminate this Agreement immediately by notice to the other Party with immediate effect. Furthermore, the notifying Party may terminate this Agreement by notice to the other Party with immediate effect if, in its sole discretion, it believes that the modifications proposed by the other Party will not resolve the patient safety issue.

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- 6.5. Termination for Regulatory Action; Other Reasons. Either Party may terminate this Agreement by notice to the other Party with immediate effect in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the MSD Compound Study. Additionally, either Party shall have the right to terminate this Agreement by notice with immediate effect to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound for medical, scientific or legal reasons.
- 6.6. Return of MSD Compound. If Collaborator remains in possession (including through any Affiliate or Subcontractor) of MSD Compound at the time this Agreement expires or is terminated, Collaborator shall promptly return or destroy all unused MSD Compound as instructed by MSD in its sole discretion. Collaborator shall provide certification of any requested destruction.
- 6.7. Survival. The provisions of Sections 2.9 (Subsequent Study), 3.4 (Debarred Personnel; Exclusions Lists) through 3.9 (Ownership and Use of Joint Clinical Data)(inclusive), 6.7 (Survival) through 6.10 (Manufacturing Costs)(inclusive), 8.5 (Provision of Compounds), 8.11 (Quality Control), 8.12 (VAT), 12.2 (Publication), 13.4.6, 14.2 (Indemnification), and 14.3 (LIMITATION OF LIABILITY), and Articles 1 (DEFINITIONS), 5 (ADVERSE EVENT REPORTING), 9 (CONFIDENTIALITY) through 12 (PUBLICATIONS; PRESS RELEASES)(inclusive), 17 (ENTIRE AGREEMENT; AMENDMENT; WAIVER), and 20 (INVALID PROVISION) through 25 (CONSTRUCTION) (inclusive) shall survive the expiration or termination of this Agreement.
- 6.8. No Prejudice. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party for any breach of this Agreement. Except as set forth in Section 6.10 (Manufacturing Costs) and the foregoing sentence, the non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement.

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- 6.9. Confidential Information. Upon expiration or termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party (other than Clinical Data, Sample Testing Results and Inventions) furnished to the Receiving Party; provided, however that the Receiving Party may retain one copy of such Confidential Information in its confidential files, solely for purposes of exercising the Receiving Party's rights hereunder, satisfying its obligations hereunder or complying with any legal proceeding or requirement with respect thereto, and provided further that the Receiving Party shall not be required to erase electronic files created in the ordinary course of business during automatic system back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information so long as such electronic files are: (i) maintained only on centralized storage servers (and not on personal computers or devices); (ii) not accessible by any of its personnel (other than its information technology specialists); and (iii) not otherwise accessed subsequently except with the written consent of the Disclosing Party or as required by law or legal process. Such retained copies of Confidential Information shall remain subject to the confidentiality and non-use obligations herein.
- 6.10. Manufacturing Costs. In the event of termination by MSD pursuant to Section 6.2 (MSD Termination for Unsafe Use) or 6.3 (Termination for Breach), [***].
7. **COSTS.**
- [***] in connection with the Collaborator Clinical Trial.
8. **SUPPLY AND USE OF COMPOUNDS.**
- 8.1. Supply of the Compounds. Subject to the terms and conditions of this Agreement, each of Collaborator and MSD will use commercially-reasonable efforts to supply, or cause to be supplied, its Compound in the quantities and on the timelines set forth in Exhibit B, for use in the MSD Compound Study. If a change to the Protocol in accordance with Article 4 (PROTOCOL AND INFORMED CONSENTS; CERTAIN COVENANTS) requires an increase of the quantity of MSD Compound to be provided of more than [***], the Parties shall amend Exhibit B to reflect such changes. Each Party shall also provide the other Party a contact person for the supply of its Compound under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, if a Party is: (i) not supplying its Compound in accordance with the terms of this Agreement, then the other Party shall have no obligation to supply its Compound; or (ii) allocating under Section 8.10 (Shortage; Allocation), then the other Party may allocate proportionally.
- 8.2. Manufacturing Delay. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound hereunder.
- 8.3. Compound Commitments. Each Party agrees, [***].
- 8.4. Minimum Shelf Life Requirements. Each Party shall use commercially-reasonable efforts to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the MSD Compound Study requirements.

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8.5. Provision of Compounds.

8.5.1. MSD will Deliver the MSD Compound to the location specified by Collaborator. [***].

8.5.2. Collaborator is solely responsible for supplying (including all Manufacturing, acceptance and release testing) the Collaborator Compound for the Collaborator Clinical Trial and the subsequent handling, storage, transportation, warehousing and distribution of all such Collaborator Compound. Collaborator shall ensure that all such activities are conducted in compliance with Applicable Law and, with respect to the MSD Compound Study, the Clinical Quality Agreement.

8.6. Labeling and Packaging; Use, Handling and Storage.

8.6.1. The Parties' obligations with respect to the labeling and packaging of the MSD Compound are as set forth in the Clinical Quality Agreement. MSD shall provide the MSD Compound to Collaborator in the form of [***].

8.6.2. Collaborator shall: (i) use the MSD Compound solely for purposes of performing the MSD Compound Study; and (ii) not use the MSD Compound in any manner that is inconsistent with this Agreement or for any commercial purpose. Collaborator shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the MSD Compound, and in particular shall not analyze the MSD Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Quality Agreement.

8.7. Product Specifications. A certificate of analysis shall accompany each shipment of the MSD Compound to Collaborator. Upon request, Collaborator shall provide MSD with a certificate of analysis covering each shipment of Collaborator Compound used in the MSD Compound Study.

8.8. Changes to Manufacturing. Each Party may make changes from time to time to its Compound or the Manufacturing Site, provided that such changes shall be in accordance with the Clinical Quality Agreement.

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8.9. Product Testing; Nonconformance.

8.9.1. **After Manufacturer's Release.** After Manufacturer's Release of the MSD Compound and concurrently with Delivery of the Compound to Collaborator, MSD shall provide Collaborator with the documentation described in the Clinical Quality Agreement. Collaborator shall conduct the acceptance procedures under the Clinical Quality Agreement within the time frames set forth therein. Collaborator shall be solely responsible for taking all steps necessary to determine that MSD Compound or Collaborator Compound, as applicable, is suitable for release before making such Compounds available for human use, and MSD shall assist Collaborator as Collaborator reasonably requests in making such determination for the MSD Compound. Collaborator shall be responsible for storage and maintenance of the MSD Compound until it is tested and released, which storage and maintenance shall be in compliance with: (i) the Specifications for the MSD Compound, (ii) the Clinical Quality Agreement, (iii) Applicable Law, and (iv) any specific storage and maintenance requirements as may be provided by MSD from time to time. Collaborator shall be responsible for any failure of the MSD Compound to meet the Specifications to the extent caused after Delivery to Collaborator hereunder.

8.9.2. **Non-Conformance.**

8.9.2.1. In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.9.1 (After Manufacturer's Release)), such Party shall immediately notify the other Party. Notification related to MSD Compound shall be in accordance with the Clinical Quality Agreement. MSD shall investigate any Non-Conformance of the MSD Compound in accordance with the Clinical Quality Agreement.

8.9.2.2. In the event that all or any portion of any proposed or actual shipment of the MSD Compound is agreed to be Non-Conforming at the time of Delivery to Collaborator then MSD shall replace any such Non-Conforming MSD Compound that has not been administered. The sole and exclusive remedies of Collaborator with respect to any MSD Compound that is found to be Non-Conforming at the time of Delivery shall be: [***]. In the event MSD Compound is lost or damaged by Collaborator after Delivery, MSD shall [***]; provided that [***].

MSD shall have no obligation to [***]. Except as set forth in this Section 8.9.2.2, MSD shall have no obligation [***].

8.9.2.3. Collaborator shall be responsible for, and MSD shall have no obligation or liability with respect to, any Collaborator Compound that is found to have a Non-Conformance. Collaborator shall replace any such Collaborator Compound that has not been administered. The sole and exclusive remedies of MSD with respect to any Collaborator Compound that is found to have a Non-Conformance at the time of Delivery shall be: [***].

8.9.3. **Resolution of Discrepancies.** Disagreements regarding any determination of Non-Conformance by Collaborator shall be resolved in accordance with this Clinical Quality Agreement or, in situations where the Clinical Quality Agreement does not apply, Section 21 (GOVERNING LAW; DISPUTE RESOLUTION) of this Agreement.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 8.10. Shortage; Allocation. If a Party believes in good faith that it will not be able to fulfill its supply obligations hereunder because its Compound is in short supply, such Party will provide prompt written notice to the other Party of such shortage, the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply and the Parties will promptly discuss the situation (including allocation of Compound supplied hereunder within the MSD Compound Study). The Party experiencing the shortage shall [***].
- 8.11. Quality Control. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality-assurance and quality-control procedures as are required by the Specifications, cGMPs and (with respect only to the MSD Compound) the Clinical Quality Agreement.
- 8.12. VAT. Where MSD is treated as making a supply of goods in a particular jurisdiction for no consideration for VAT purposes, and Collaborator is treated as receiving such supply in the same jurisdiction, thus resulting in an amount of VAT being properly chargeable on such supply, Collaborator shall be obliged to pay to MSD the amount of VAT properly chargeable on such supply. Collaborator shall pay such VAT to MSD on receipt of a valid VAT invoice from MSD issued in accordance with the laws and regulations of the jurisdiction in which the VAT is properly chargeable. MSD will: (i) determine, in accordance with Applicable Law, the value of the supply that has been made and, as a result, the corresponding amount of VAT that is properly chargeable; and (ii) provide Collaborator any information or copies of documents in MSD's Control as are reasonably necessary for VAT purposes to evidence that such supply will take, or has taken, place in the same jurisdiction.

9. **CONFIDENTIALITY.**

- 9.1. Confidential Information. Subject to Section 13.4.8, Collaborator and MSD agree to hold in confidence all Confidential Information of the other Party and use such Confidential Information only to fulfill its obligations or exercise its rights hereunder. Without limiting the foregoing, the Receiving Party may not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent such disclosure is: (i) required by Applicable Law; (ii) pursuant to the terms of this Agreement; or (iii) necessary for the conduct of the MSD Compound Study, and in each case (i) through (iii) provided that the Receiving Party shall provide reasonable advance notice to the Disclosing Party before making such disclosure. For the avoidance of doubt, Collaborator may, without MSD's consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing the MSD Compound Study, the data safety monitoring and advisory boards relating to the MSD Compound Study, and Regulatory Authorities working with Collaborator on the MSD Compound Study, in each case as necessary for the performance of the MSD Compound Study and provided that such Persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 9.2. Inventions. [***].
- 9.3. Personal Identifiable Data. All Confidential Information containing personal identifiable data shall be handled in accordance with all applicable data-protection and privacy laws, rules and regulations.
- 9.4. Publicity/Use of Names. Except as set forth in Section 12.3 (Press Releases), no disclosure of the existence or terms of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter without the prior express written permission of such Person, except as may be required by Applicable Law.

10. **INTELLECTUAL PROPERTY.**

- 10.1. Joint Ownership. [***].
- 10.2. Right to Exploit. [***].
- 10.3. Prosecution. [***].
- 10.4. Declining to File, Prosecute or Maintain. [***].
- 10.5. Prohibition of Patenting. [***].
- 10.6. Patent Enforcement.

10.6.1. Each Party shall promptly notify the other of any Third-Party Infringement of which such Party becomes aware.

10.6.2. [***].

10.6.3. [***].

10.6.4. [***].

10.6.5. [***].

- 10.7. Inventions Owned by Each Party. [***].
- 10.8. Mutual Freedom to Operate. [***].

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

10.9. Termination. Any and all licenses granted under [***] shall terminate upon the expiration or earlier termination of this Agreement and shall not survive such expiration or termination; provided, however that the license granted in [***] shall survive such expiration or termination except that if a Party terminates the Agreement pursuant to [***], then only the grant to the terminating Party from the non-terminating Party shall survive.

10.10. Ownership of Other Inventions. [***].

11. **REPRINTS; REFERENCES IN PUBLICATION.**

Consistent with Applicable Law (including copyright law), each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences or symposia relating to the MSD Compound Study that disclose the name of a Party, provided, however, that such use does not constitute an endorsement of any commercial product or service by the other Party.

12. **PUBLICATIONS; PRESS RELEASES.**

12.1. Clinical Trial Registry. Collaborator shall register the MSD Compound Study and Collaborator Clinical Trial with the clinical trials registry located at www.clinicaltrials.gov, shall list MSD as a collaborator with respect to the Collaborator Clinical Trial, and shall timely publish the results following completion of the MSD Compound Study, after taking appropriate action to secure any intellectual property rights arising from the MSD Compound Study. The results of the MSD Compound Study will be published in accordance with the Protocol.

12.2. Publication. Each Party shall use reasonable efforts to publish or present scientific papers with respect to the MSD Compound Study in accordance with accepted scientific practice. The Parties agree that, prior to submission of the results of the MSD Compound Study for publication or presentation or any other dissemination of such results (including oral dissemination), the publishing Party shall invite the other to comment on the content of the material to be published, presented, or otherwise disseminated according to the following procedure:

12.2.1. At least [***] days prior to submission for publication of any paper, letter or any other publication, or [***] days prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the full details of the proposed publication, presentation, or dissemination in an electronic version as an email attachment. Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation/dissemination for an additional [***] days to allow for actions to be taken to preserve rights for patent protection.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 12.2.2. The publishing Party shall reasonably consider any request by the other Party made within the periods set forth in Section 12.2.1 to modify the publication and the Parties shall work together to timely resolve any issue regarding the content for publication. Notwithstanding the foregoing, MSD Clinical Data shall be subject to final review and approval by MSD, not to be unreasonably withheld.
- 12.2.3. The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.
- 12.3. Press Releases. Unless otherwise required by Applicable Law, neither Party shall make any other public announcement concerning this Agreement without the prior written consent of the other Party. To the extent a Party desires to make such public announcement, such Party shall request permission of the other Party and provide the other Party with a draft thereof for review and comment at least [***] prior to the date on which such Party would like to make the public announcement.
13. **REPRESENTATIONS AND WARRANTIES; DISCLAIMERS.**
- 13.1. Due Authorization. Each of Collaborator and MSD represents and warrants to the other that: (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.
- 13.2. Compounds.
- 13.2.1. Collaborator Compound. Collaborator hereby represents and warrants to MSD that:
- (i) Collaborator has the full right, power and authority to grant all of the licenses granted to MSD under this Agreement; (ii) Collaborator Controls the Collaborator Compound; and (iii) at the time of Delivery of the Collaborator Compound, such Collaborator Compound shall have been Manufactured and supplied in compliance with its Specifications and all Applicable Law.
- 13.2.2. MSD Compound. MSD hereby represents and warrants to Collaborator that: (i) MSD has the full right, power and authority to grant all of the licenses granted to Collaborator under this Agreement; (ii) MSD Controls the MSD Compound; and (iii) at the time of Delivery of the MSD Compound, such MSD Compound shall have been Manufactured and supplied in compliance with its Specifications, the Clinical Quality Agreement, and all Applicable Law.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

13.3. Results. Neither Party undertakes that the MSD Compound Study shall lead to any particular result, nor is the success of the MSD Compound Study guaranteed. Neither Party shall be liable for any use that the other Party may make of the Joint Clinical Data or shared Sample Testing Results, nor for advice or information given in connection therewith.

13.4. Anti-Corruption.

13.4.1. The Parties acknowledge that the corporate policies or Codes of Conduct of Collaborator and MSD and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. Each Party agrees to conduct the business contemplated herein in a manner that is consistent with all Applicable Law, including the FCPA.

13.4.2. Each Party represents and warrants that it and its Related Entities have not, and covenants that it and its Related Entities will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

13.4.3. Neither Party shall contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.4.4. Each Party represents and warrants that it: (i) is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; (ii) has not employed or subcontracted with any Person for the performance of the MSD Compound Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs; and (iii) has conducted anti-corruption and bribery (e.g. FCPA) due-diligence review of all Third Parties it may hire to act on its behalf in connection with its performance under this Agreement.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 13.4.5. Each Party represents and warrants that, except as disclosed to the other in writing prior to the Effective Date, such Party: (i) does not have any interest that directly or indirectly conflicts with its proper and ethical performance of this Agreement; (ii) shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (iii) has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of any due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures to the other Party as are necessary to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that prior to hiring or retaining any Government Official to assist in its performance of this Agreement it shall obtain the written consent of the other Party and complete a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official consistent with industry standards. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.
- 13.4.6. Each Party shall have the right during the Term, and for a period of [***] following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.4. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit.
- 13.4.7. Each Party shall use commercially-reasonable efforts to ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.
- 13.4.8. Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of this Section 13.4, such other Party may make full disclosure of such belief and related information (including, if necessary, Confidential Information) needed to support such belief at any time and for any reason to any competent government bodies and agencies, and to anyone else such Party determines in good faith has a legitimate need to know.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 13.4.9. Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to their performance of any obligations or activities under this Agreement. Each Party shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.
- 13.4.10. Each Party shall have the right to terminate this Agreement immediately in accordance with Section 6.3 (Termination for Breach) in the event of any violation of this Section 13.4 by the other Party.
- 13.5. **DISCLAIMER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, MSD MAKES NO WARRANTIES, EXPRESS OR IMPLIED WITH RESPECT TO THE MSD COMPOUND, AND COLLABORATOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE COLLABORATOR COMPOUND, IN EACH CASE INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**
14. **INSURANCE; INDEMNIFICATION; LIMITATION OF LIABILITY.**
- 14.1. Insurance. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, a Party shall provide evidence of such insurance.
- 14.2. Indemnification.
- 14.2.1. Indemnification by Collaborator. Collaborator agrees to defend, indemnify and hold harmless MSD, its Affiliates, and its and their employees, directors, Subcontractors and agents from and against any Liability, except to the extent that such Liability was directly caused by: (i) negligence or willful misconduct on the part of MSD (or any of its Affiliates, or its and their employees, directors, Subcontractors or agents); (ii) a breach of this Agreement by MSD; or (iii) a violation of Applicable Law by MSD.
- 14.2.2. Indemnification by MSD. MSD agrees to defend, indemnify and hold harmless Collaborator, its Affiliates, and its and their employees, directors, Subcontractors and agents from and against any Liability to the extent such Liability was directly caused by: (i) negligence or willful misconduct on the part of MSD (or any of its Affiliates, or its and their employees, directors, Subcontractors or agents); (ii) a breach of this Agreement by MSD; or (iii) a violation of Applicable Law by MSD.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

- 14.2.3. Procedure. The obligations of MSD and Collaborator under this Section 14.2 (Indemnification) are conditioned upon the delivery of written notice to the indemnifying Party of any potential Liability within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; provided that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner). The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Defending Party shall keep the Other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld, conditioned or delayed. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.
- 14.2.4. MSD Compound Study Subjects. Neither Party shall offer compensation on behalf of the other Party to any MSD Compound Study subject or bind the other Party to any indemnification obligations in favor of any MSD Compound Study subject.
- 14.3. **LIMITATION OF LIABILITY**. IN NO EVENT SHALL EITHER PARTY, ITS AFFILIATES AND ITS OR THEIR EMPLOYEES DIRECTORS, SUBCONTRACTORS OR AGENTS) BE LIABLE TO THE OTHER PARTY UNDER ANY THEORY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES, ANY PUNITIVE DAMAGES, ANY LOST PROFIT, LOST SALE OR LOST OPPORTUNITY DAMAGES (WHETHER SUCH CLAIMED DAMAGES ARE DIRECT OR INDIRECT), ARISING DIRECTLY OR INDIRECTLY OUT OF OR RELATED TO THIS AGREEMENT, THE ACTIVITIES TO BE CONDUCTED BY THE PARTIES HEREUNDER OR THE COLLABORATOR CLINICAL TRIAL (INCLUDING THE MSD COMPOUND STUDY). SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH IT IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT WITH RESPECT TO USE, DISCLOSURE, LICENSE, ASSIGNMENT OR OTHER TRANSFER OF JOINT CLINICAL DATA, CONFIDENTIAL INFORMATION, JOINTLY-OWNED INVENTIONS AND SAMPLE TESTING RESULTS.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

15. **USE OF NAME.**

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement without the other Party's prior written consent.

16. **FORCE MAJEURE.**

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, fire, strike, acts of terror, governmental action and governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed. The non-performing Party shall notify the other Party of such any such event within [***] days after such occurrence by giving notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

17. **ENTIRE AGREEMENT; AMENDMENT; WAIVER.**

- 17.1. This Agreement, together with the Appendices, Exhibits and Schedules hereto and the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. In the event of a conflict between a Related Agreement and this Agreement, the terms of this Agreement shall control except: (i) in the event of any inconsistencies between the terms of this Agreement and the Data Protection Terms, the Data Protection Terms shall control; (ii) in the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement that relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), the terms of the Pharmacovigilance Agreement shall control. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

18. **ASSIGNMENT AND AFFILIATES.**

Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign all or any part of this Agreement without the other Party's consent: (i) to one or more of its Affiliates, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided in each case, that such Affiliates agree to be bound by this Agreement; or (ii) in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether by merger, acquisition or similar transaction or series of related transactions. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of the Agreement. Any assignment not in accordance with this Article 18 shall be null, void and of no legal effect.

19. **CHANGE OF CONTROL.**

If Collaborator undergoes a Change of Control in which the acquiring party owns or controls [***], then upon MSD's request, [***].

20. **INVALID PROVISION.**

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

21. **GOVERNING LAW; DISPUTE RESOLUTION.**

21.1.1. The Parties shall attempt to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

21.1.2. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

22. NOTICES.

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile or email (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Collaborator, to the address(es) set forth in the Collaborator Notice Block on the Information Sheet.

If to MSD, to:

MSD International GmbH

[***]

MSD International Business GmbH

[***]

With copies (which shall not constitute notice) to:

[***]

[***]

[***]

23. RELATIONSHIP OF THE PARTIES.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or bind the other Party, except with the other Party's express prior written consent. All Persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

24. **COUNTERPARTS AND DUE EXECUTION.**

This Agreement and any amendment may be executed in any number of counterparts (including by facsimile or electronic transmission), each of which shall be deemed an original, but all of which together constitute one and the same instrument, notwithstanding any electronic transmission, storage or printing of this Agreement. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage or printing of this Agreement. For clarity, facsimile signatures and signatures transmitted by PDF shall be treated as original signatures.

25. **CONSTRUCTION.**

Except where the context otherwise requires, wherever used, the singular includes the plural and vice versa, the use of any gender will be applicable to all genders, and the word “**or**” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “**including**” as used herein shall be deemed to be followed by the phrase “**without limitation**” or like expression. The term “**will**” as used herein means shall. The terms “**hereof**”, “**hereto**”, “**herein**” and “**hereunder**” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement. References to “**Article**,” “**Section**”, “**Exhibit**” or “**Schedule**” are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. A reference to any statute, law, rule, regulation or directive will be construed as a reference to such statute, law, rule, regulation or directive as amended, extended, repealed and replaced or re-enacted from time to time. A definition of or reference to any agreement, instrument or document herein shall refer to such agreement, instrument or other document as it may be amended, supplemented or otherwise modified from time to time (subject to any restrictions on such amendments, supplements or modifications set forth herein). Any reference to “agree,” “consent,” “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging). Except where the context otherwise requires, references to this “**Agreement**” shall include the appendices and schedules attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank. Signature page follows.]

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

Evaxion Biotech A/S

By: _____ /s/ Lars Wegner
Lars Wegner _____ 20th of October 2021
Name
CEO
Title

MSD International GmbH

By: _____ /s/ Franz Escherich
Franz Escherich _____
Name
Director
Title

MSD International Business GmbH

By: _____ /s/ Carlos Fernandez
Carlos Fernandez _____
Name
Director
Title

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

Exhibit A

PROTOCOL SUMMARY

[***]

Exhibit B

SUPPLY OF COMPOUND

[***]

Exhibit C

DATA PROTECTION TERMS

[***]

Schedule I

DATA SHARING SCHEDULE

[***]

Schedule II

SAMPLE TESTING SCHEDULE

[***]

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.

Schedule III

THIRD PARTIES PROVIDING MSD COMPOUND STUDY ACTIVITIES

[***]

[***] = Certain confidential information contained in this document, marked by brackets, is omitted because it is not material and would be competitively harmful if publicly disclosed.
