UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 10, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	001-39717	20-2903526
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

680 East Colorado Boulevard, Suite 180
Pasadena California 91101
(Address of principal executive offices)

(631) 830-7092
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (See General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act of 1933 (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(e) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	LIXT	The NASDAQ Stock Market, LLC
Warrants to Purchase Common Stock, par value $0.0001 per share	LIXTW	The NASDAQ Stock Market, LLC

Item 1.01 Entry Into a Material Agreement.

Effective June 10, 2024, Lixte Biotechnology Holdings, Inc. (the "Company") entered into a Clinical Trial Agreement (the "Agreement") with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b/2 clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with metastatic colon cancer. Under the Agreement, the Company will provide its lead compound, LB-100, and under a separate agreement between NKI and Roche, Roche will provide atezolizumab and financial support for the clinical trial. The Company has no obligation to, and will not provide any reimbursement of clinical trial costs. Pursuant to the Agreement and the protocol set forth in the Agreement, the clinical trial will be conducted by NKI at NKI's site in Amsterdam by principal investigator Neeltje Steeghs, MD, PhD, and NKI will be responsible for the recruitment of patients. The Agreement provides for the protection of the respective intellectual property rights of each of the Company, NKI and Roche.

This Phase 1b clinical trial will evaluate the side effects and optimal dose of LB-100 combined with atezolizumab for the treatment of patients with metastatic microsatellite stable colorectal cancer. Immunotherapy using monoclonal antibodies like atezolizumab can enhance the body's immune response against cancer and hinder tumor growth and spread. LB-100 has been found to improve the effectiveness of anticancer drugs in killing cancer cells by inhibiting a protein called PP2A on cell surfaces. Blocking PP2A increases stress signals in tumor cells expressing the PP2A protein. Accordingly, combining atezolizumab with LB-100 may enhance treatment efficacy for metastatic colorectal cancer, as cancer cells with heightened stress signals are more vulnerable to immunotherapy.

This study comprises a dose escalation phase and a dose expansion phase. The objective of the dose escalation phase is to determine the recommended Phase 2 dose (RP2D) of LB-100 when combined with the standard dosage of atezolizumab. The dose expansion phase will further investigate the clinical activity, safety, tolerability, and pharmacokinetics/dynamics of the LB-100 and atezolizumab combination. The clinical trial is scheduled to open by June 30, 2024. Patient accrual is expected to take up to 24 months, with a maximum of 37 patients with advanced colorectal cancer to be enrolled in this study.

Additional information on the clinical trial is available on the clinicaltrials.gov website athttps://clinicaltrials.gov/study/NCT06012734.

The foregoing description of the terms of the Agreement does not purport to be complete and is subject to and qualified in its entirety by reference to the Agreement, a copy of which is filed with this Form 8-K and incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) The Exhibits listed on the accompanying Index to Exhibits are incorporated herein by reference.

SIGNATURES

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

Date: June 14, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: */s/ BASTIAAN VAN DER BAAN*
Bastiaan van der Baan
Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Clinical Trial Agreement dated as of June 10, 2024 between the Company and the Netherlands Cancer Institute.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Clinical Trial Agreement

Clinical Trial: Phase Ib Study With The Combination Of LB–100 (PP2A Inhibitor) And Atezolizumab (PD–L1 Inhibitor) In Metastatic Colorectal Cancer Patients – The CoLBAt Trial

Protocol: CTIS number 2023-505534-98

Investigational Product: LB–100

Effective date of agreement: date of last Party's signature on this Agreement

The undersigned,

A. **Stichting Het Nederlands Kanker Instituut – Antoni van Leeuwenhoek Ziekenhuis**, whose registered office is at Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands lawfully represented by Dr. J.M.L. Stouthard, Medical Director, (hereinafter referred to as "**Sponsor**")

and

B. **Lixte Biotechnology Holdings, Inc.**, a corporation organized under the laws of the State of Delaware, USA, whose address is at 680 E. Colorado Blvd., Suite 180, Pasadena, CA 91101, USA, lawfully represented by Bas van der Baan, CEO, (hereinafter referred to as "**Company**")

in the presence of

Sponsor's employee, **Dr. Neeltje Steeghs**, the supervisor under whose responsibility the conduct of the Clinical Trial will be carried out (hereinafter referred to as "**the Principal Investigator**")

WHEREAS, the Principal Investigator and Sponsor are concerned with the diagnosis, treatment and prevention of disease and/or clinical research for the improvement of healthcare; and

WHEREAS Sponsor is a leader in cancer immunotherapy (CIT) research and wishes to undertake a research project that involves the Investigational Product; and

WHEREAS, the Company is a pharmaceutical company involved in research, development, registration, manufacture and/or sale of medicines for use in humans;

WHEREAS, the Sponsor has facilities and personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Trial by the Principal Investigator; and

WHEREAS, the Parties are interested in research in the area of CIT, and the purpose of this Agreement is for the Parties to collaborate and provide Investigational Product or other support to enable a clinical study conducted by Sponsor in the area of CIT research; and

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into this Clinical Trial Agreement.

1. DEFINITIONS

The following words and phrases have the following meanings:

a. "**Affiliate**" means any business entity which controls, is controlled by, or is under the common control. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity or to elect or appoint 50% or more of the members of the management of such business entity;

b. "**Agent**" shall include, but shall not be limited to, any person providing services to a Party under a contract for services or otherwise, to include without limitation any pharmacist, clinical chemist, nurse or other health professional.

c. "**Agreement**" means this agreement comprising its recitals, clauses, schedules and any appendices attached to it, including the Protocol and including any amendments to the Agreement agreed between the Parties;

d. "**Auditor**" means a person who is authorised by Sponsor and/or Funder to carry out a systematic review and independent examination of clinical study related activities and documents to determine whether the evaluated Clinical Trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the Protocol, (if applicable) the standard operating procedures of Sponsor, ICH-GCP and the applicable regulatory requirements;

e. "**CCMO**" means the Dutch clinical trial authority, namely the Central Committee on Research involving Human Subjects (in Dutch: "Centrale Commissie Mensgebonden Onderzoek" or "CCMO");

f. "**Clinical Trial**" means the investigation described in the preamble above to be conducted at the Trial Site in accordance with the Protocol as defined below;

g. "**Clinical Trial Authorisation** " means a Clinical Trial authorised in accordance with the article 2 and (if applicable) 13i and 13k of the Dutch *Medical Research Involving Human Subjects Act*;

h. "**Clinical Trial Subject**" means a person enrolled to participate in the Clinical Trial;

i. "**Competent Authority**" means the authority appointed to evaluate the Clinical Trial in accordance with 13i and 13kof the Dutch *Medical Research Involving Humans Subjects Act*, based on article 9 of the European Clinical Trial Directive 2001/20/EC;

j. "**Confidential Information**" means any information, in tangible or non-tangible form, and/or physical items or materials, that is identified as confidential by a Party (the Disclosing Party) to the other Party (the Receiving Party), or that is clearly recognizable as confidential to a reasonable person with no special knowledge of Disclosing Party's activities. If Confidential Information is disclosed orally, the Confidential Information will be identified as confidential at the time of disclosure.

k. "**CRF**" means the case report form in a format prepared by Sponsor and documenting the administration of the Investigational Product to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;

l. "**eCRF**" means a CRF in electronic form;

m. "**Effective Date**" the date this Agreement comes into effect, being the date of last Party's signature on this Agreement;

n. "**Ethics Committee**" means the accredited medical research ethics committee competent to review the Clinical Trial in accordance with article 2 of the Dutch *Medical Research Involving Human Subjects Act*, and to which the Protocol has been submitted for approval;

o. "**ICF**" means the Informed Consent Form as approved by the Ethics Committee, in which the Clinical Trial Subject consents to his participation in the Clinical Trial;

p. "ICH-GCP" means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directives 2001/20/EC and 2005/28/EC of the European Parliament and the Council relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directives;

q. "**Independent Committee**" means a committee such as a Data and Safety Monitoring Board (DSMB), which is a group of individuals with pertinent expertise that have oversight of and reviews on a regular basis accumulating data from one or more ongoing clinical trials and that advise the Sponsor regarding the continuing safety of Clinical Trial Subjects and those to be recruited to the Clinical Trial, as well as the continuing validity and scientific merit of the Clinical Trial.

r. "**Investigational Product**" means Company's proprietary molecules, LB-100, as specifically identified in the attached Protocol in Annex 1;

s. "**Law**" means any applicable international, European Union and Dutch law and regulations, as well as generally accepted international conventions applicable to the performance of the Clinical Trial. Such Law including, but not limited to:

- Directives 2001/20/EC and 2005/28/EC of the European Parliament and the Council relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directives and any implementation in Sponsor's national Law,
- ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95),
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (*General Data Protection Regulation* or *GDPR*), and any applicable national implementing legislation.
- the Dutch Medical Research Involving Human Subjects Act (*Wet Medisch-wetenschappelijk Onderzoek met Mensen*or *WMO*),
- the Dutch Medical Treatment Agreements Act (*Wet op de geneeskundige behandelingsovereenkomst or Wgbo*),
- the Directives on "the assessment of Clinical Trial Agreements (2011)" and on "External Review (2012)" issued by the CCMO,
- the principles of the Dutch Code of Conduct regarding the adequate procurement, management and use of bodily human tissue published by the Federation of Dutch Medical Scientific Societies, and
- the Declaration of Helsinki, the most recent version;

References to EU Council Directives and Dutch Law include any amendments or replacements of such Law.

t. "**Party**" means the Sponsor or the Company and "**Parties**" shall mean both of them;

u. "**Personal Data**" means personal data as defined in the GDPR (General Data Protection Regulation), i.e. any information relating to an identified or identifiable Clinical Trial Subject.

v. "**Principal Investigator**" means the person who will take primary responsibility for the conduct of the Clinical Trial at the Trial Site or any other person as may be agreed between the Parties as a replacement;

w. "**Protocol**" means the document signed by the Principal Investigator, as defined in the cadre on page 1 of this Agreement, detailing all aspects of the Clinical Trial, a copy of which is at Annex 1 to this Agreement. The Protocol includes all amendments thereto for which Clinical Trial Authorisation has been obtained;

x. "**Research Staff**" means the persons who will undertake the conduct of the Clinical Trial at the Trial Site on behalf of the Principal Investigator and under the supervision of the Principal Investigator;

y. "**Roche**" and/or **"Funder"** means F. Hoffmann-La Roche Ltd., which is contributing its proprietary molecules, atezolizumab, for use in the Clinical Trial and is financially supporting this Clinical Trial;

z. "**Samples**" are human biological specimens (including without limitation tissues, bone marrow, cells, serum, blood and other bodily fluids) and any associated health related personal data that may be provided or used in conjunction with such specimens in the Clinical Trial under this Agreement or the Agreement between Roche and Sponsor, and further includes without limitation any tangible material directly or indirectly derived from any such biological specimens;

aa. "**Sample Data**" means all scientific and technical data (in whatever form or format) generated through use of Samples, including without limitation, examination, assay analysis or other manipulations.

bb. "**Site Parties**" shall refer to the Principal Investigator and the Sponsor jointly;

cc. "**Sponsor**" means the Party commissioning for the Clinical Trial to be conducted, acting as "**verrichter**" as defined in Article 1.1(f) of the WMO ;

dd. "**Study Data**" means all scientific and technical data (in whatever form or format) generated under and in conjunction with the Clinical Trial, including without limitation raw data, and Sample Data;

ee. "**Target**" means the estimated number of Clinical Trial Subjects to be included in the Clinical Trial as referred to in clause 5.2;

ff. "**Timelines**" means the dates set out in Annex 2 hereto as may be amended by agreement between the Sponsor and the Principal Investigator and "**Timeline**" shall mean any one of such dates;

gg. "**Trial Monitor**" means one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with GCP and the Protocol and to conduct source data verification;

hh. "**Trial Site(s)**" means the premises at the Sponsor where the Clinical Trial will be conducted;

2. OBLIGATIONS

2.1. The Parties agree to perform the Clinical Trial in accordance with the terms and conditions of this Agreement.

2.2. The Parties represent and warrant that they each have the authority to enter into this Agreement. Sponsor shall ensure the performance of the responsibilities assigned to the Principal Investigator under this Agreement and by no means shall the Principal Investigator be liable hereunder in person. The Sponsor will ensure the availability of and/or access to any resources necessary to perform the Clinical Trial at the Trial Site, including departments, facilities and Research Staff and support personnel, and the Sponsor certifies that Principal Investigator holds the necessary registration and has the necessary qualifications, expertise and time to perform the Clinical Trial.

2.3. The Sponsor shall notify the Company if the Principal Investigator ceases to be associated with the Sponsor where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and Sponsor shall use all reasonable endeavours to find a qualified successor acceptable to the Company, provided that the Company will not unreasonably withhold its approval of the proposed replacement of the Principal Investigator.

2.4. The Site Parties acknowledge that Company and their respective Affiliates and/or subsidiaries need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom ("**Bribery Act**"); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America ("**FCPA**") and (iii) any other applicable anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***). A summary of the key principles underlying the Bribery Act and the FCPA is set out in Annex 3. The Sponsor and the Principal Investigator shall not and shall not permit or induce employees, Agents, consultants or other representatives, whether directly or indirectly, to engage in any activity that is prohibited by the Applicable Anti-Corruption Legislation including bribery, kickbacks, payoffs or other corrupt business practices, as outlined in the summary in Annex 3. Company shall be responsible for keeping the summary up to date in case of any changes to the Bribery Act and the FCPA.

3. CLINICAL TRIAL GOVERNANCE AND COMPLIANCE

3.1. The Sponsor shall be responsible for obtaining and maintaining Clinical Trial Authorisation for the Clinical Trial and substantial amendments to the Protocol.

3.2. In the event of any substantial amendments being made to the Protocol, the amendments shall be signed by the Principal Investigator and shall be implemented by the Research Staff as required by the Sponsor after approval of the amendments by the Competent Authority and a favourable opinion of the Ethics Committee.

3.3. The Clinical Trial shall be performed at the Trial Site. The Principal Investigator shall be responsible for obtaining authorization from the representatives of the Trial Site to perform the Clinical Trial at the Trial Site, which shall include the engagement of the Research Staff and, to the extent applicable, other departments.

The Sponsor shall be responsible for submitting the Clinical Trial for listing on a free, publicly accessible clinical study registry like www.clinicaltrials.gov.

3.4. The Parties shall, and shall require their respective Agents and Research Staff to, conduct the Clinical Trial in accordance with:

a. the Agreement;

b. the Protocol;

c. the terms and conditions of the Clinical Trial Authorisation granted by the Competent Authority and the opinion of the Ethics Committee; and

d. the applicable Law.

3.5. The Site Parties shall make and retain records regarding the Clinical Trial as required by the Protocol, applicable Law, and in accordance with the Sponsor's standard archiving procedures. Sponsor will retain such records for a minimum of time as put out in the applicable Law.

3.6. The Site Parties shall notify Company immediately (not later than one (1) business day) of any serious adverse events in accordance with the Protocol and applicable Law, and will cooperate with Sponsor in connection with any reports or filings related to such serious adverse event.

4. LIABILITIES, INDEMNIFICATION AND INSURANCE

4.1. Subject to the limitations set out hereinafter, Company shall indemnify (in Dutch "*schadeloosstellen*") and hold harmless (in Dutch "*vrijwaren*") Sponsor, its employees, Agents, the Principal Investigator and the Research Staff (the "Indemnitees") against all claims, demands, actions or proceedings (to include any settlements or ex gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise): (i) by or on behalf of any Clinical Trial Subject in connection with personal injury or death – including also costs for medical treatment in relation to such injury or death – arising out of the administration or use of the Investigational Product during or as a result of the Clinical Trial, or of any clinical intervention or procedure provided for or required by the Protocol, to which the Clinical Trial Subject would not have been exposed but for its use of the Investigational Product and its participation in the Clinical Trial. In addition, Company shall compensate Sponsor and/or the Principal Investigator for reasonable and necessary costs and expenses incurred for medical treatment of Clinical Trial Subjects who have suffered such personal injury as a result of the administration or use of the Investigational Product;. or (ii) by or on behalf of any Clinical Trial Subject or by a data protection authority for a Personal Data breach, as defined in applicable Law, which is attributable to Company or its Affiliates.

4.2. Company's indemnification and defence of the Indemnitees and compensation of Sponsor and/or the Principal Investigator shall not apply to any claim or proceeding pursuant to clause 4.1, and Company shall not be liable

a. to the extent that said personal injury (including death) is caused by (i) any of the Indemnitees' failure to comply with this Agreement or (ii) administration or use of atezolizumab. For clarity, clause 4.1 shall not apply to, and Company shall have no obligation to indemnify, defend and hold harmless any Indemnitees, or to compensate Sponsor or the Principal Investigator, in connection with any claims, demands, actions or proceedings or any medical treatment to the extent related to or arising out of the administration or use of atezolizumab (including with respect to any clinical intervention or procedure to which a Clinical Trial Subject would not have been exposed but for its use of atezolizumab).; or

b. to the extent that said personal injury (including death) is caused by gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch: *bewuste roekeloosheid of opzettelijk handelen of nalaten*) of any of the Indemnitees, unless the clinical trial insurance of Company is providing coverage for the claim;

c. if any of the Indemnitees shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it, without the prior written consent of Company, provided that this condition shall not be treated as breached by any statement properly made by any of the Indemnitees in connection with the operation of Sponsor's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such a statement is required by Law.

4.3. Company shall keep Site Parties reasonably informed of the progress of any such claim or proceeding.

4.4. The Parties will each use their reasonable endeavours to inform each other promptly of any circumstances reasonably thought likely to give rise to any claim or proceeding resulting from the Clinical Trial of which it is directly aware. Parties shall keep each other reasonably informed of developments in relation to any such claim or proceeding. The Parties will use reasonable efforts to consult with each other on the nature of any defence to be advanced.

4.5. Sponsor, Principal Investigator and Company will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding made or brought by or on behalf of Clinical Trial Subjects (or their dependants) or by a data protection authority.

4.6. Nothing in this clause 4 shall operate so as to restrict or exclude the liability of any Party vis-à-vis the Clinical Trial Subjects in relation to their death or personal injury caused by the negligence of that Party or their servants or employees (including Research Staff or Agents) or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded by law.

4.7. In no circumstances shall any Party be liable to the other in contract or otherwise howsoever arising or whatever the cause thereof, for any indirect or consequential damages of any nature, such as but not limited to any loss of profit, business, goodwill, reputation, contracts, revenues or anticipated savings which arise directly or indirectly from any default on the part of Company, Sponsor or the Principal Investigator, except and to the extent such damages.

a. shall be covered under and paid out of any insurance policy of the liable party, or

b. are caused by gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch: *bewuste roekeloosheid of opzettelijk handelen of nalaten*) of any of the Indemnitees and cannot be so restricted or excluded by law.

4.8. The liability of the Site Parties for a claim or proceeding of Company under this Agreement shall be limited to the amount covered and paid out under the insurance policy taken out in accordance with clause 4.10 below; except and to the extent such claim or proceeding is made for damages caused by gross negligence, willful recklessness or willful conduct or willful misconduct (in Dutch: *bewuste roekeloosheid of opzettelijk handelen of nalaten*) of any of the Site Parties or other Indemnitees and cannot be so restricted or excluded by law.

4.9. Company will take out or maintain

a. insurance cover in respect of its potential liability for damages to Clinical Trial Subjects resulting from the Clinical Trial in accordance with the requirements set out in the (Dutch) Medical Research Involving Human Subjects Act and the Decree on Obligatory Insurance for Medical Studies involving Human Subjects unless this requirement has been waived by the Ethics Committee, and

b. further appropriate insurance cover in respect of its other potential liability under this Agreement. Company shall produce to Sponsor, on request, copies of such insurance certificates. Except for the limitations stated in clause 4.7 above, the terms of any insurance or the amount of cover shall not relieve Company of any liabilities under this Agreement.

4.10. Sponsor will take out or maintain an insurance cover in respect of the potential liability of Sponsor, the Research Staff, the Principal Investigator and any other employees and Agents involved with the conduct of the Clinical Trial pursuant to this Agreement. Sponsor shall produce to Company, on request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect during the term of this Agreement and any period thereafter as may be required by mandatory law. Except for the limitations stated in clause 4.7 and 4.8 above, the terms of any insurance or the amount of cover shall not relieve Sponsor of any liabilities under this Agreement. Where the Sponsor cannot cover Agents under its insurance, it shall verify that such Agents have sufficient insurance and inform the Sponsor of such insurance upon request.

5. CLINICAL TRIAL SUBJECT RECRUITMENT AND ENROLLMENT

5.1. The Sponsor shall make sure that the Clinical Trial Subjects (and/or their legal representatives) will, in accordance with applicable Law, be duly informed and that each give his informed consent prior to his participation in the Clinical Trial.

5.2. The Sponsor, through its Principal Investigator, shall use reasonable endeavours to recruit the Target within the Timelines as specified in Annex 2.

5.3. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment or enrolment of the Clinical Trial Subjects, the Principal Investigator shall without undue delay inform the Company in writing. In each such event the Parties shall discuss the consequences of the delay and each Party shall undertake reasonable endeavours to agree on measures to handle the delay.

6. QUALITY ASSURANCE AND CONTROL

6.1. The Site Parties shall ensure that all procedures defined in the Protocol are complied with, so that all data generated at the Trial Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Clinical Trial as the case may be) and will ensure that the content of the CRFs or e-CRFs will accurately reflect source documents.

6.2. The Site Parties will permit the Company to examine the conduct of the Clinical Trial and the Trial Site upon thirty (30) days advance written notice and in the company of a Site Party's representative, during regular business hours at mutually agreed times, and at Company's sole expense to determine that the Clinical Trial is being conducted in accordance with the Protocol, this Agreement and applicable Law. If the audit is not-for-cause, Company shall compensate Sponsor for their help during the audit at a rate of one-thousand five-hundred euro per day (1,500€/day).

6.3. The Parties acknowledge that Sponsor shall permit the Study Monitor, Auditor and any official with a legal right to inspect and access all relevant documentation and source data for monitoring of the progress of the Clinical Trial, the proper collection and recording of Study Data, the welfare of the Clinical Trial Subjects, and altogether the good quality of the Clinical Trial and compliance with applicable Law and, if applicable and communicated to the Site Parties in writing, Sponsor's standard operating procedures. For the avoidance of any doubt, the Sponsor shall be responsible for the confidential handling of all Personal Data of Clinical Trial Subjects and other patients, which the Trial Monitor and any Auditor comes across with during its monitoring or auditing activities.

6.4. The Parties shall permit authorized representatives of the Ethics Committee and Competent Authorities to have access to, copy and verify information relating to the Clinical Trial, as required by and in accordance with applicable Law. Furthermore Company acknowledges and agrees that the Sponsor executive management (or a local review board appointed by such management) will have the right to audit the performance of the Clinical Trial at the Trial Site. Parties acknowledge that the Clinical Trial is subject to inspection by regulatory authorities worldwide and that such inspections may occur after the completion of the Clinical Trial.

7. INVESTIGATIONAL PRODUCTS

7.1. The Parties acknowledge and agree that the Sponsor's pharmacy will be responsible for certain tasks in relation to the handling of the Investigational Product. Any agreements between the pharmacy and any of the Parties will be in writing and must be in accordance with the Sponsor's internal policies.

7.2. Subject to the foregoing, the Company will provide the Principal Investigator and the pharmacy with all necessary information on the Investigational Product(s), quality and handling instructions thereof and sufficient quantities needed to conduct the Clinical Trial free of charge.

7.3. The Site Parties shall not use or permit the Research Staff or any third party to use the Investigational Product for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement all unused Investigational Product shall, at the Company's option, either be returned to the Company or disposed of in accordance with the Protocol or the Company's written instructions.

8. CONFIDENTIALITY AND DATA PROTECTION

8.1 ***Medical Confidentiality Data protection and data controlling***

a. In line with the current position of the CCMO, the Sponsor and Company are considered joint controllers for the processing of the Personal Data and will both handle all Personal Data in accordance with the GDPR and any other to the performance of the Clinical Trial applicable laws or regulations covering the protection of Personal Data (collectively "Data Protection Law").

b. Company and Sponsor will act in accordance with the Data Protection Law. Sponsor and Company will fully cooperate with each other as joint controllers and shall take the necessary measures in order to comply with the Data Protection Law, such cooperation shall duly reflect the respective roles and relationships of the joint controllers vis-à-vis the Clinical Trial Subjects as data subjects, in particular as regards the exercising of the rights of these data subjects and the joint controllers' respective duties to provide the information referred to in Articles 13 and 14 of the GDPR. Each joint controller shall maintain a record of processing activities under its responsibility. To the extent that processing of Personal Data involves the disclosure, grant of access or other transfer of Personal Data to any person located in any country or territory outside the European Economic Area which does not benefit from an adequacy decision from the European Commission ("EEA Restricted Transfer"), Company and Sponsor shall enter into Module One of the standard contractual clauses approved by the European Commission pursuant to implementing Decision (EU) 2021/914 ("SCCs"), which are set out in Annex 5 to this Agreement.

In the event law and interpretation by the CCMO and/or a relevant data protection authority or a court decision should prescribe or indicate another qualification of the roles of the parties in clinical trial agreements, the Parties hereto shall consult with each other and shall adapt the qualification of their roles and change arrangements as may be deemed appropriate.

c. Both Sponsor and Company shall implement appropriate technical and organizational measures to meet the requirements of the GDPR.

d. If Sponsor or Company becomes aware of a Personal Data breach, that Party discovering such breach shall promptly notify the other Party/ies. In such a case Sponsor and Institution will fully cooperate with each other to fulfil the (statutory) notification obligations timely. A Personal Data breach refers to: a Personal Data breach as meant in article 4 paragraph 12 GDPR and further determined by articles 33 and 34 of the GDPR.

8.2. When based outside the EU, Company will appoint a representative in the EU in order to fulfil its duties under GDPR. For processing of their Personal Data consent will be obtained by Sponsor from Clinical Trial Subjects. All processing of Personal Data will be in accordance with the GDPR.

8.3. The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects.

8.4. Company acknowledges that Clinical Trial Subjects – and/or their legal representatives on their behalf – may withdraw or change their initial informed consent. The procedure followed upon a withdrawal of a Clinical Trial Subject's consent will be according to the instructions in the Protocol and the ICF and in accordance with the (Data Protection) Law.

8.5. Company shall refrain from tracing and/or identifying any Clinical Trial Subject, except where Company is under a legal obligation to do so. In the event any Clinical Trial Subject, for any other than aforementioned reason, becomes identifiable to Company, Company agrees to preserve, at all times, the confidentiality of information pertaining to such Clinical Trial Subjects.

Confidential Information

8.6. The Receiving Party shall ensure that only those of its officers and employees (and those of its Affiliates and members of the Research Staff) and Agents directly concerned with the purposes of this Study and the carrying out of this Agreement or otherwise as expressly permitted by this Agreement, have access to the Confidential Information of the Disclosing Party. The Receiving Party shall take all practicable steps to ensure that such persons abide by the same obligations of confidentiality as apply to the Receiving Party under this Agreement. The Receiving Party undertakes to treat as strictly confidential and not to disclose to any third party (except Agents and to the extent as necessary in carrying out the rights granted in clause 9 below, bona fide collaboration partners and licensees, but in each case only if the receiving party is bound to confidentiality obligations substantially similar to those set forth in this Agreement) any Confidential Information of the Disclosing Party, except where disclosure is required by a regulatory authority or by law, in which case the Receiving Party shall inform the Disclosing Party of such requirement and the information to be disclosed and Disclosing Party take reasonable steps to limit the scope of such disclosure. Notification will be within a reasonable time prior to being required to make the disclosure or if such time is not available, immediately upon becoming known of the requirement to disclose Confidential Information. The Receiving Party undertakes not to make use of any Confidential Information of the Disclosing Party, other than in accordance with this Agreement, without the prior written consent of the Disclosing Party.

8.7. The obligations of confidentiality and non-use set out in clause 8.6 shall not apply to information which as evidenced by written records:

a. is or becomes part of the public domain by any means other than a wrongful act or breach of this Agreement by the Receiving Party;

b. was or becomes in the Receiving Parties' lawful possession prior to the disclosure without restriction on disclosure;

c. has been independently developed by the Receiving Party without the use of Confidential Information of the Disclosing Party;

d. has been obtained by the Receiving Party from a third party who is not subject to a duty of confidentiality; or

e. is published in accordance with clause 11 hereof.

Principal Investigator and Research Staff's Personal Data

8.8. Prior to and during the course of the Clinical Trial, Company may request to collect Personal Data which may be subject to the GDPR relating to the Clinical Trial from the Sponsor, including from its investigators, sub-investigators, other Sponsor staff or personnel involved in the conduct of the Study. Sponsor agrees to help Company obtain any express consents, as may be necessary in accordance with GDPR, for the processing of any Personal Data collected by the Company from its Principal Investigator, sub-investigators, other Sponsor staff and personnel involved in the conduct of the Clinical Trial. Company warrants the correct handling of this data, according to the GDPR.

9. INTELLECTUAL PROPERTY

9.1. "**Background IP**" means any intellectual property, whether patentable or not and whether or not the subject of a patent or pending patent application, that existed prior to the date of this Agreement. For avoidance of doubt, Background IP does not include LB-100 IP, Atezolizumab IP, Mingled IP, or Other New IP (terms as defined in this Agreement). As between the Parties, each Party remains the sole owner of its Background IP. To the extent necessary for the performance of the Clinical Trial and to the extent that a Party is legally able to do so, each Party hereby grants the other Party, with the right to sublicense to third parties participating in the Clinical Trial, a royalty-free, non-exclusive, non-transferable license to use the granting Party's Background IP solely for the purpose of carrying out the Clinical Trial, and for no other purposes.

9.2. "**Atezolizumab IP**" means any invention arising out of the performance of the Protocol and Clinical Trial under this Agreement relating solely to atezolizumab, including without limitation the use, method or mode of administration, formulation, dosing schedule and indications for atezolizumab. For avoidance of doubt, Atezolizumab IP does not include Background IP, LB-100 IP, Mingled IP, or Other New IP. All rights to Atezolizumab IP shall be the sole and exclusive property of Roche. A separate contract between Roche and Sponsor shall govern the ownership of and rights to use any Atezolizumab IP as between Roche and Sponsor. Company shall have no license, rights, title or interest in or to any Atezolizumab IP unless agreed by, and set forth in a separate agreement between, Company and Roche.

9.3. "**LB-100 IP**" means any invention arising out of the performance of the Protocol and Clinical Trial under this Agreement relating solely to LB-100, including without limitation the use, method or mode of administration, formulation, dosing schedule, and indications for LB-100. For avoidance of doubt, LB-100 IP does not include Background IP, Atezolizumab IP, Mingled IP, or Other New IP. Roche shall have no license, rights, title or interest in or to any LB-100 IP unless agreed by, and set forth in a separate agreement between, Company and Roche.

9.4. "**Mingled IP**" means any invention arising out of the performance of the Protocol and Clinical Trial under this Agreement solely relating to the combination of atezolizumab and LB-100 that cannot otherwise be claimed as Atezolizumab IP or LB-100 IP, including without limitation methods for co-administration, co-formulation, dosing schedule for a combination of atezolizumab and LB-100, and indications for a combination of atezolizumab and LB-100 (each optionally in further combination with other molecules). For avoidance of doubt, Mingled IP does not include Background IP, Atezolizumab IP, LB-100 IP, or Other New IP. All Mingled IP shall be jointly owned by Sponsor, Company and Roche. However, Sponsor hereby grants Company and Roche, under Sponsor's rights therein, subject to clause 9.7, (i) a paid-up, royalty-free, exclusive, sublicenseable, worldwide license to use Mingled IP to make, have made, use, import and export, sell, offer for sale, and have sold LB-100 and atezolizumab, respectively, and, subject to clause 9.7, (ii) an option to negotiate a co-exclusive license (exclusive as to Company and Roche) to use Mingled IP for any other purpose under terms to be negotiated in good faith upon request by Company and/or Roche. Roche, Company and Sponsor agree to use good faith efforts to negotiate commercially reasonable terms for any co-exclusive license. Company/Roche shall exercise its option by providing a written option exercise notice to Sponsor within six (6) months of receipt of written notice from Sponsor of filing of a patent application claiming such Mingled IP. In the event that Company fails to provide such option exercise notice to Sponsor or elects in writing not to obtain the co-exclusive license, in either case prior to expiration of such six (6) month period, then Company's option shall expire with respect to said Mingled IP upon expiration of such six (6) month period.

9.5. "**Biomarker IP**" means any invention arising out of the performance of the Protocol and Clinical Trial under this Agreement that encompasses methods of predicting responsiveness to the application of a drug used in the Clinical Trial in selecting patients for treatments, and any diagnostic method or product related thereto. For the avoidance of doubt, Biomarker IP shall not include LB-100 IP, Atezolizumab IP, Mingled IP or Other New IP. Biomarker IP shall be the sole property of the Sponsor. Sponsor hereby grants Company, subject to clause 9.7, (i) an exclusive, perpetual, paid-up, royalty-free, sub-licensable, worldwide license to make, use, have made, use, sell, offer for sale or import, products, services, or processes embodying or made in accordance with any Biomarker IP relating solely to LB-100 as evidenced by the Study Data, records and clinical data available at the time of the invention ("**LB-100 Biomarker IP**") and, subject to clause 9.7, (ii) an option to obtain an exclusive license to use LB-100 Biomarker IP for all other purposes under terms to be negotiated in good faith by Company and Sponsor upon request by Company. Company shall exercise its option by providing a written option exercise notice to Sponsor within six (6) months of receipt of written notice from Sponsor of generation of such invention related to such LB-100 Biomarker IP. In the event that Company fails to provide such option exercise notice to Sponsor or elects in writing not to obtain the exclusive license, in either case prior to expiration of such six (6) month period, then Company's option shall expire with respect to said LB-100 Biomarker IP upon expiration of such six (6) month period. The Parties agree to use good faith efforts to negotiate commercially reasonable terms for any exclusive license. If no agreement is reached within six (6) months from the exercise of the option then Sponsor may at its own discretion license LB-100 Biomarker IP to third parties, subject to Company's rights under this Agreement.

A separate contract between Roche and Sponsor shall govern the rights of use to any Biomarker IP relating solely to Atezolizumab as evidenced by the Study Data, records and clinical data available at the time of the invention ("**Atezolizumab Biomarker IP**") as between Roche and Sponsor. Company shall have no license, rights, title or interest in or to any Atezolizumab Biomarker IP unless agreed by, and set forth in a separate agreement between, Company and Roche.

Sponsor shall promptly disclose to Company and Roche any Biomarker IP that solely relates to the combination of atezolizumab and LB-100 that cannot otherwise be claimed as Atezolizumab Biomarker IP or LB-100 Biomarker IP ("**Mingled Biomarker IP**"). Sponsor hereby grants Company under Sponsor's rights in Mingled Biomarker IP, subject to clause 9.7, (i) a paid-up, royalty-free, perpetual, exclusive, sub-licensable, worldwide license to use Mingled Biomarker IP to make, have made, use, sell, offer for sale, have sold, import, and export LB-100 and (ii) an option to obtain a co-exclusive (exclusive as to Company and Roche) license to use Mingled Biomarker IP for any other purpose under terms to be negotiated in good faith upon request by Company and/or Roche.

Company/Roche shall exercise its option by providing a written option exercise notice to Sponsor within six (6) months of receipt of written notice from Sponsor of generation of such invention related to such Mingled Biomarker IP. In the event that Company fails to provide such option exercise notice to Institution or elects in writing not to obtain the exclusive or co-exclusive license, in either case prior to expiration of such six (6) month period, then Company's option shall expire with respect to said Mingled Biomarker IP upon expiration of such six (6) month period. The Parties agree to use good faith efforts to negotiate commercially reasonable terms for any exclusive or co-exclusive license. If no agreement is reached within six (6) months from the exercise of the option then Sponsor may at its own discretion license Mingled Biomarker IP to third parties, subject to Company's and/or Roche's rights under this Agreement.

9.6. "**Other New IP**" means any invention arising out of the performance of the Protocol and Clinical Trial under this Agreement that does not involve or relate to LB-100 IP, Atezolizumab IP, Mingled IP, LB-100 Biomarker IP or Atezolizumab Biomarker IP or Mingled Biomarker thereof and includes without limitation assay methods, means for collection and storage of patient data, and diagnostic kits and assays. For avoidance of doubt, Other New IP does not include Background IP, Atezolizumab IP, LB-100, Mingled IP or Biomarker IP. Other New IP shall be the sole property of Sponsor. Sponsor hereby grants Company, subject to clause 9.7, (i) a paid-up, royalty-free, perpetual, non-exclusive, sub-licensable, worldwide license to make, use and import, but not to sell, offer for sale or export, Other New IP for internal, non-commercial research and development purposes only and (ii) an option to obtain a co-exclusive (exclusive as to Company and Roche) license to use Other New IP for all purposes under terms to be negotiated in good faith upon request by Company and/or Roche. Company/Roche shall exercise its option by providing a written option exercise notice to Sponsor within six (6) months of receipt of written notice from Sponsor of generating of such invention related to such Other New IP. In the event that Company fails to provide such option exercise notice to Sponsor or elects in writing not to obtain the co-exclusive license, in either case prior to expiration of such six (6) months period, then Company's option shall expire with respect to said Other New IP upon expiration of such six (6) month period. The Parties agree to use good faith efforts to negotiate commercially reasonable terms for any co-exclusive license. If no agreement is reached within six (6) months from the exercise of the option then Sponsor may at its own discretion license Other New IP to third parties, subject to the rights of Company set out in this Agreement.

9.7. Sponsor and Principal Investigator shall have a paid-up, non-exclusive right to use Atezolizumab IP and LB-100 IP for internal, non-commercial research and, subject to any obligations of confidentiality, educational and patient care purposes. Sponsor retains all rights in Mingled IP, Atezolizumab Biomarker IP, LB-100 Biomarker IP and Mingled Biomarker IP to use such IP for any lawful purpose, other than the rights expressly granted to Company and to Roche.

9.8. Neither Sponsor nor any member of Sponsor shall be entitled to file patent applications for any LB-100 IP, Mingled IP, Atezolizumab Biomarker IP or LB-100 Biomarker IP. Company shall be entitled to patent LB-100 IP, and Roche, in coordination with Company in accordance with a separate agreement between Company and Roche, shall be responsible to patent Mingled IP. For the avoidance of doubt, Sponsor hereby assigns all of its rights, title and interest in (a) Atezolizumab IP to Roche, (b) in LB-100 IP to Company, and (c) in Mingled IP, taking into account the interest of Sponsor, to Company and to Roche jointly. Sponsor shall ensure that all employees and third parties participating in the Clinical Trial have assigned to Sponsor all Atezolizumab IP, LB-100 IP and Mingled IP in order to effectuate the foregoing assignments to Company and Roche. Upon request by Company and Roche, respectively, Sponsor shall cooperate and provide reasonable assistance in drafting, filing and prosecuting patent application and/or maintaining patents as defined under this clause 9.

9.9. All Study Data (including without limitation raw data and Sample Data (if any) and the Sponsor's Confidential Information shall be owned by Sponsor. Sponsor will maintain all Study Data in its database (except as otherwise specified in the imCORE Data Sharing Process).

9.10. Sponsor shall be entitled to use the Study Data and analyses of the Study Data for any lawful purpose in accordance with the terms of this Agreement (including without limitation, publication, intellectual property purposes (e.g. patent application filing) and collaboration with other partners, in each case to the extent in accordance with the terms of this Agreement). Sponsor shall also be entitled to publish Study Data and analyses thereof in accordance with clause 11 of this Agreement.

9.11. Sponsor agrees to provide Company a copy of the final Clinical Trial report. Company and its Affiliates and its collaboration partners and licensees shall be entitled to use, and Sponsor hereby grants Company and its Affiliates a fully sublicensable, royalty-free, fully paid-up, perpetual, irrevocable, transferable, worldwide right and non-exclusive license to use, the Study Data, and results from the final Clinical Trial report for any purpose. Sponsor will ensure that Study Data collected as part of the Clinical Trial comply with all applicable patient informed consent and data privacy laws and regulations (in the country and jurisdiction where collected) to allow (i) Study Data use for the specified Clinical Trial and (ii) Study Data to be shared with Company for the purposes agreed upon in this Agreement.

10. PUBLICITY

10.1. The Company will not use the logo or name of the Sponsor, nor of any member of the Research Staff, for promotional purposes, in any publicity, advertising or news release without the prior written approval of the Sponsor, such approval not to be unreasonably withheld.

10.2. The Site Parties will not, and will ensure that the Research Staff will not, use the name or logo of the Company or of any of its employees, in any publicity, advertising or news release without the prior written approval of the Company, such approval not to be unreasonably withheld.

10.3. The Site Parties will not issue and will ensure the Research Staff will not issue any information or statement to the press or public, including but not limited to advertisements for the enrolment of Clinical Trial Subjects, without, where appropriate, the review and the delivery of a favourable opinion from the Ethics Committee.

10.4. Unless required by Law, the Parties shall not disclose terms of this Agreement without the prior written approval of the other Party.

11. PUBLICATION AND AUTHORSHIP

Principles

11.1. The Company, Sponsor and Principal Investigator each acknowledge the importance of public disclosure/publication of information collected or generated as a result of or related to the Clinical Trial, and each has the right to publish under the condition that public disclosure/publication takes place under the provisions of this clause 11.

Publication by Sponsor

11.2. The Parties each acknowledge that the Sponsor and/or Principal Investigator may present at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Clinical Trial and in particular, but without limiting the foregoing, post a summary of Clinical Trial results in on-line clinical trials register(s) before or after publication by any other method, subject to clauses 11.4 through 11.7 of this Agreement and any publication policy described in the Protocol, provided any such policy does not obstruct publication unreasonably. Sponsor shall submit the main results of the Clinical Trial for publication in a peer-reviewed journal within 12 months of the availability of data from the primary analysis regardless of the Clinical Trial outcome, however Company understands that the Sponsor may not be able to publish or present the Clinical Trial results if the results are considered clinically or scientifically insignificant based on objective industry standards. The disclosure of the Company's role and participation of the representatives of the Company as a named author shall be determined in accordance with generally accepted academic standards for authorship as outlined in clause 11.7 below.

Publication by Principal Investigator

11.3. Company agrees that the Principal Investigator or any of the Research Staff who fulfills the ICMJE authorship criteria and is highly involved in the Clinical Trial, shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of its own choosing, methods and results of the Clinical Trial, subject to this clause 11 and any publication policy described in the Protocol, provided any such policy does not obstruct publication unreasonably. Principal Investigator shall appropriately disclose Company's role in the Clinical Trial in any such publication or presentation.

Review by Company of Publications

11.4. Presentations, manuscripts or other material for public dissemination by Sponsor/Principal Investigator or any Research Staff will be submitted to the Company for review at least thirty (30) days prior to submission for publication, public dissemination, or review by a publication committee. If Company does not respond within this period, Sponsor and/or Principal Investigator or Research Staff are free to proceed with the intended publication or presentation without further delay.

11.5. The Sponsor and Principal Investigator and/or Research Staff agree that all reasonable scientific comments made by the Company in relation to a proposed publication or presentation during the period referred to in clause 11.4 above shall be considered for incorporation into the publication or presentation.

11.6. During the period for review of a proposed publication referred to in clause 11.4 above, the Company shall be entitled to

a. make a reasoned request to the Sponsor/Principal Investigator and/or Research Staff that publication be delayed for an additional period of sixty (60) days (following the thirty (30) day period referred to in clause 11.4) in order to enable the Company to take steps to protect its proprietary information and/or patent application and the Sponsor/Principal Investigator and/or Research Staff shall permit such a request; and

b. cause the Sponsor/Principal Investigator and/or Research Staff to remove from the intended publication any of Company's Confidential Information received by Sponsor and/or Principal Investigator that does not constitute results of the Clinical Trial.

Acknowledgement, Authorship, copyrights and use

11.7. Sponsor shall clearly acknowledge Company's support in any type of publication. Publications will be in accordance with international recognized scientific and ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, established by the International Committee of Medical Journal Editors. Copyrights concerning publications of the Study remain with the authors of the publication, regardless of any other provisions regarding intellectual property rights. After publication or presentation, Sponsor shall promptly provide a reference citation and final copy to Company and Company shall be free to use the publication, presentation or parts thereof in any format as appropriate for internal and external usage, including without limitation to promote Investigational Product, in particular with healthcare professionals.

12. TERM AND TERMINATION

12.1. This Agreement commences on the Effective Date and shall continue in force until the earlier of:

a. completion of final Clinical Trial and completion of the obligations of the Parties under this Agreement; or

b. early termination in accordance with clause 12.2 of this Agreement;

12.2. Each Party may terminate this Agreement upon written notice to the other Party with immediate effect in the following events:

a. the approval by the Ethics Committee in charge of the Clinical Trial is not granted or irrevocably revoked;

b. it can be reasonably concluded that the Clinical Trial must be terminated in the interests of the health of the Clinical Trial Subjects;

c. it becomes apparent, following confirmation of the Ethics Committee or the Independent Committee, that continuation of the Clinical Trial cannot serve a scientific purpose, and this is notified to the Ethics Committee;

d. the Company and/or Sponsor become or is declared insolvent or a petition in bankruptcy has been filed against it or if one of them is dissolved;

e. circumstances beyond a Party's control occur that render continuation of the Clinical Trial unreasonable as outlined in Clause 14;

f. one of the Parties fails to comply with the obligations arising from the Agreement and, if capable of remedy, is not remedied within 30 days after receipt of written notice from the other Party specifying the non-compliance and requiring its remedy, unless failure to comply is not in reasonable proportion to the premature termination of the Clinical Trial.

12.3. In all circumstances causing the termination of this Agreement, the Company shall confer with the Principal Investigator and use their best endeavours to minimise any inconvenience or harm to Clinical Trial Subjects. The Parties agree that in case of termination of this Agreement, they will in good faith make arrangements concerning the continuation of the treatment of the enrolled Clinical Trial Subjects if such is in their medical best interest.

12.4. Upon notice of termination of this Agreement, the Site Parties will not recruit and/or enroll additional Clinical Trial subjects, and will cooperate with the Company in the orderly discontinuation of the Clinical Trial, including, without limitation, discontinuing Investigational Product as soon as medically appropriate.

12.5. At close-out of the Trial Site following termination or expiration of this Agreement, each Receiving Party shall upon request by the Disclosing Party immediately deliver, or destroy with confirmation thereof, if requested, to the Disclosing Party all Confidential Information, except for copies to be retained in order to comply with the Receiving Party's archiving obligations or for evidential purposes.

12.6. Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

13. FINANCIAL PROVISIONS

13.1. The Company has no obligation to, and will not, provide reimbursement in support of the Clinical Trial.

13.2. The Investigational Product will be supplied to Sponsor free of charge.

14. FORCE MAJEURE

No Party shall be liable to the other Parties or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, fire, flood, and epidemic or because of any other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and where they cease to do so. However, such non-performance or delay is excused under this provision only for the duration of the qualifying event.

15. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be exclusively governed by, and construed in all respects in accordance with the laws of The Netherlands without regard to its conflicts of laws rules. Any claims, controversies or disputes arising out of or in connection with this Agreement which cannot be settled amicably between the Parties, shall be subject to the exclusive jurisdiction of the competent court in the Netherlands.

16. MISCELLANEOUS

16.1. Neither Party may assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the other Party, provided, that Company may assign this Agreement or any of its rights or obligations hereunder without such prior written consent, but upon prior written notice to Sponsor, to (a) an organisation that, is an Affiliate whether now or in the future, controls, is controlled by or is under common control with Company (for the purposes of this Section 16.1, the terms "controls", "controlled by", and "under common control with" as used with respect to Company means the possession (directly or indirectly) of (i) fifty per cent (50%) or more of the voting stock or other equity interest of Company with the power to vote, or (ii) the power in fact to control the management decisions of Company through the ownership of securities or by contract or otherwise), provided that any such assignee is engaged in the research, development or sale of pharmaceuticals or biologics and not in activities that contravene Sponsor's mission of beating cancer; or (b) any third party which is not related in any way to the tobacco or alike industries.

16.2. Any permitted assignment or approval by a Party of an assignment, transfer or encumbrance by the other Party shall not release the assigning Party of any of its obligations under this Agreement due up until such assignment. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and assignees.

16.3. Company may not sub-contract the performance of all or any of their obligations under this Agreement without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed. Any Party who so sub-contracts shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

16.4. Nothing shall be construed as creating a joint venture, partnership or contract of employment between the Parties.

16.5. Any agreement to amend, vary or modify the terms of the Agreement in any manner shall be valid only if effected in writing and signed by duly authorized representatives of each of the Parties hereto.

16.6. Should there be any inconsistency between the Protocol and the terms of this Agreement, or any other document incorporated therein, the Protocol shall prevail in case such inconsistency concerns clinical matters, and this Agreement shall prevail in case the inconsistency concerns non-clinical matters. For the avoidance of doubt, Termination and Publication provisions of this Agreement shall always prevail above the Protocol.

16.7. Unless otherwise agreed, formal notices to the respective Parties required by this Agreement shall be given, made or served if in writing and delivered personally or sent by registered mail or by facsimile with receipts confirmed to the contact details as set out in Annex 4. Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form. Change of the contact details has to be notified to the other Party or Parties, but shall not require amendment of this Agreement.

16.8. The clauses 1 (Definitions); 4 (Liabilities, Indemnification and Insurance); 7.3 (Use of Investigational Product); 8 (Confidentiality and Data Protection); 9 (Intellectual Property); 10 (Publicity); 11 (Publication); 12.3-12.6 (Termination); 14 (Force Majeure); 15 (Governing Law and Dispute Resolution) and this clause 16.7 (Surviving Clauses) or other clauses (including but not limited to those in Annexes) contemplating performance after termination, shall survive termination or expiry of this Agreement. Notwithstanding the above, the provisions of clause 8.6 and 8.7 (Confidential Information) shall remain in force for a period of five (5) years from the date of termination or expiration of this Agreement.

16.9. Each person signing this Agreement represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Agreement. Each Party represents and warrants to the other that the execution and delivery of the Agreement and the performance of such Party's obligations hereunder have been duly authorized and that the Agreement is a valid and legal agreement binding on such Party and enforceable in accordance with its terms.

17. Conditional Approval

17.1. This Agreement is signed and entered into under the condition that recruitment and/or inclusion of Clinical Trial Subjects will not start until the Ethics Committee has granted approval for the Protocol as submitted on to the Ethics Committee.

17.2. Either Party may terminate this Agreement in accordance with clause 12 in case the Ethics Committee;

a. withholds its approval of the Protocol as submitted to the Ethics Committee;

b. makes its approval subject to modification(s) of the Protocol that requires amendment(s) of the Verklaring Geschiktheid Onderzoeksinstelling ("VGO") [Declaration Feasibility Site] and/or the Agreement.

Annexes

Annex 1: Protocol
Annex 2: Timelines
Annex 3: Bribery and Corruption Statement
Annex 4: Contact details

Signed on behalf of the **Company**

Signature: _____
Name: Bas van der Baan
Title: Chief Executive Officer

Date: _____

Signed on behalf of the **Sponsor**

Signature: _____
Name: Dr. J.M. L. Stouthard
Title: Medical Director
Date: _____

The undersigned Principal Investigator hereby declares that he/she has read the above Agreement between the Parties and that he/she acknowledges the provisions of the Agreement relative to his/her role, responsibilities and duties concerning the Clinical Trial:

Signed by the **Principal Investigator**

Signature: _____
Name: Dr. Neeltje Steeghs
Title: Medical Oncologist

ANNEX 1

PROTOCOL

Phase Ib Study With The Combination Of LB–100 (PP2A Inhibitor) And Atezolizumab (PD–L1 Inhibitor) In Metastatic Colorectal Cancer Patients – The CoLBAt Trial

Version 1.4, Dated 26-10-2023

(by reference only)

ANNEX 2

TIMELINES

First Subject Fist Visit	Q2 2024
Last Subject Last Visit	Q1 2027
Database Lock	Q2 2027
Study Closure	Q4 2027

ANNEX 3

BRIBERY AND CORRUPTION

A. The Site Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

B. The Site Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

i. securing any improper advantage; or
ii. inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

C. This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

D. Nevertheless, particular care must be exercised with dealings with public officials. The Site Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

E. The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

F. The Site Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

G. The Site Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Site Parties, in accordance with Dutch law.

H. The Site Parties shall devise and maintain a system of internal accounting controls in accordance with Dutch law, sufficient to provide reasonable assurances that –

i. transactions are executed in accordance with management's general or specific authorization;
ii. transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and
(II) to maintain accountability for assets;

iii. access to assets is permitted only in accordance with management's general or specific authorization; and
iv. the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

ANNEX 4

CONTACT DETAILS

Recipients of Notice in accordance with clause 19.6 of this Agreement:

If to **Company**

For scientific matters:

Name: Eric Forman
Address: 680 E. Colorado Blvd., Suite 180, Pasadena, CA 91101, USA
Tel.:
EMail: eforman@lixte.com

For legal matters:

Name: Eric Forman
Address: 680 E. Colorado Blvd., Suite 180, Pasadena, CA 91101, USA
Tel.:
EMail: eforman@lixte.com

For financial matters:

Name: Eric Forman
Address: 680 E. Colorado Blvd., Suite 180, Pasadena, CA 91101, USA
Tel.:
EMail: eforman@lixte.com

If to **Sponsor**/ **Principal Investigator**

For scientific matters:

Name: Neeltje Steeghs
Address: NKI-AvL, Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands
Tel.: +31 (0)20 512 2532
EMail: n.steeghs@nki.nl

For legal matters:

Name: Joanna Frambach
Address: NKI-AvL, Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands
Tel.: +31 (0)20 512 4160
EMail: contract@nki.nl

For financial matters:

Name: Paula Hoekstra
Address: NKI-AvL, Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands
Tel.: +31 (0)20 512 2373
EMail: proadmin@nki.nl

For data safety matters:

Name: Irith Kist (Data Protection Officer)
Address: NKI-AvL, Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands
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ANNEX 5

MODULE ONE OF SCCs
Controller to Controller

SECTION I

Clause 1

Purpose and scope

(a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) ([1]) for the transfer of personal data to a third country.

(b) The Parties:

(i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter 'entity/ies') transferring the personal data, as listed in Annex I.A (hereinafter each 'data exporter'), and

(ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A (hereinafter each 'data importer')

have agreed to these standard contractual clauses (hereinafter: 'Clauses').

(c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.

(d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

Clause 2

Effect and invariability of the Clauses

(a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46(2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.

[1] Where the data exporter is a processor subject to Regulation (EU) 2016/679 acting on behalf of a Union institution or body as controller, reliance on these Clauses when engaging another processor (sub-processing) not subject to Regulation (EU) 2016/679 also ensures compliance with Article 29(4) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39), to the extent these Clauses and the data protection obligations as set out in the contract or other legal act between the controller and the processor pursuant to Article 29(3) of Regulation (EU) 2018/1725 are aligned. This will in particular be the case where the controller and processor rely on the standard contractual clauses included in Decision 2021/915.

(b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

Clause 3

Third-party beneficiaries

(a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:

(i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;
(ii) Clause 8.5 (e) and Clause 8.9(b);
(iii) N/A
(iv) Clause 12(a) and (d);
(v) Clause 13;
(vi) Clause 15.1(c), (d) and (e);
(vii) Clause 16(e);
(viii) Clause 18(a) and (b).

(b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

Clause 4

Interpretation

(a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.

(b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.

(c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

Clause 5

Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 6

Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

Clause 7 – Optional

Docking clause

(a) An entity that is not a Party to these Clauses may, with the agreement of the Parties, accede to these Clauses at any time, either as a data exporter or as a data importer, by completing the Appendix and signing Annex I.A.

(b) Once it has completed the Appendix and signed Annex I.A, the acceding entity shall become a Party to these Clauses and have the rights and obligations of a data exporter or data importer in accordance with its designation in Annex I.A.

(c) The acceding entity shall have no rights or obligations arising under these Clauses from the period prior to becoming a Party.

SECTION II – OBLIGATIONS OF THE PARTIES

Clause 8

Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

8.1 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B. It may only process the personal data for another purpose:

(i) where it has obtained the data subject's prior consent;

(ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or

(iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

8.2 Transparency

(a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:

(i) of its identity and contact details;

(ii) of the categories of personal data processed;

(iii) of the right to obtain a copy of these Clauses;

(iv) where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.

(b) Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.

(c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.

(d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.3 Accuracy and data minimisation

(a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.

(b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.

(c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

8.4 Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation ([2]) of the data and all back-ups at the end of the retention period.

[2] This requires rendering the data anonymous in such a way that the individual is no longer identifiable by anyone, in line with recital 26 of Regulation (EU) 2016/679, and that this process is irreversible.

8.5 Security of processing

(a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter 'personal data breach'). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.

(b) The Parties have agreed on the technical and organisational measures set out in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.

(c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

(d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.

(e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.

(f) In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.

(g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

8.6 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter 'sensitive data'), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

8.7 Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union ([3]) (in the same country as the data importer or in another third country, hereinafter 'onward transfer') unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

(i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;

(ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;

(iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;

(iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;

(v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or

[3] The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union's internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purpose of these Clauses.

(vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.8 Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

8.9 Documentation and compliance

(a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.

(b) The data importer shall make such documentation available to the competent supervisory authority on request.

Clause 9

Use of sub-processors

N/A

Clause 10

Data subject rights

(a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. ([4]) The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

(b) In particular, upon request by the data subject the data importer shall, free of charge:

(i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);

[4] That period may be extended by a maximum of two more months, to the extent necessary taking into account the complexity and number of requests. The data importer shall duly and promptly inform the data subject of any such extension.

(ii) rectify inaccurate or incomplete data concerning the data subject;

(iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.

(c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.

(d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter 'automated decision'), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:

(i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and

(ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.

(e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.

(f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.

(g) If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.

Clause 11

Redress

(a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.

(b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.

(c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:

(i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;

(ii) refer the dispute to the competent courts within the meaning of Clause 18.

(d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.

(e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.

(f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

Clause 12

Liability

(a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.

(b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.

(c) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.

(d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.

(e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

Clause 13

Supervision

(a) [Where the data exporter is established in an EU Member State:] The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) and has appointed a representative pursuant to Article 27(1) of Regulation (EU) 2016/679:] The supervisory authority of the Member State in which the representative within the meaning of Article 27(1) of Regulation (EU) 2016/679 is established, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) without however having to appoint a representative pursuant to Article 27(2) of Regulation (EU) 2016/679:] The supervisory authority of one of the Member States in which the data subjects whose personal data is transferred under these Clauses in relation to the offering of goods or services to them, or whose behaviour is monitored, are located, as indicated in Annex I.C, shall act as competent supervisory authority.

(b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES

Clause 14

Local laws and practices affecting compliance with the Clauses

(a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.

(b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:

(i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;

(ii) the laws and practices of the third country of destination– including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards ([5]);

(iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.

(c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.

(d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.

(e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).

[5] As regards the impact of such laws and practices on compliance with these Clauses, different elements may be considered as part of an overall assessment. Such elements may include relevant and documented practical experience with prior instances of requests for disclosure from public authorities, or the absence of such requests, covering a sufficiently representative time-frame. This refers in particular to internal records or other documentation, drawn up on a continuous basis in accordance with due diligence and certified at senior management level, provided that this information can be lawfully shared with third parties. Where this practical experience is relied upon to conclude that the data importer will not be prevented from complying with these Clauses, it needs to be supported by other relevant, objective elements, and it is for the Parties to consider carefully whether these elements together carry sufficient weight, in terms of their reliability and representativeness, to support this conclusion. In particular, the Parties have to take into account whether their practical experience is corroborated and not contradicted by publicly available or otherwise accessible, reliable information on the existence or

absence of requests within the same sector and/or the application of the law in practice, such as case law and reports by independent oversight bodies.

(f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

Clause 15

Obligations of the data importer in case of access by public authorities

15.1 Notification

(a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:

(i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or

(ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.

(b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.

(c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).

(d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.

(e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

15.2 Review of legality and data minimisation

(a) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).

(b) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.

(c) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

SECTION IV – FINAL PROVISIONS

Clause 16

Non-compliance with the Clauses and termination

(a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.

(b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).

(c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:

(i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;

(ii) the data importer is in substantial or persistent breach of these Clauses; or

(iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

In these cases, it shall inform the competent supervisory authority of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.

(d) Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data. The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.

(e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

Clause 17

Governing law

These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the law of The Netherlands.

Clause 18

Choice of forum and jurisdiction

(a) Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.

(b) The Parties agree that those shall be the courts of Amsterdam, The Netherlands

(c) A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/her habitual residence.

(d) The Parties agree to submit themselves to the jurisdiction of such courts.

APPENDIX

EXPLANATORY NOTE:

It must be possible to clearly distinguish the information applicable to each transfer or category of transfers and, in this regard, to determine the respective role(s) of the Parties as data exporter(s) and/or data importer(s). This does not necessarily require completing and signing separate appendices for each transfer/category of transfers and/or contractual relationship, where this transparency can achieved through one appendix. However, where necessary to ensure sufficient clarity, separate appendices should be used.

ANNEX I

A. LIST OF PARTIES

Data exporter(s): [*Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union]*

Name: Stichting Het Nederlands Kanker Instituut – Antoni van Leeuwenhoek Ziekenhuis

Address: Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands

Contact person's name, position and contact details (e.g., email): privacy@nki.nl

Activities relevant to the data transferred under these Clauses: Clinical Trial

Role (controller/processor): Controller

Data importer(s): [*Identity and contact details of the data importer(s), including any contact person with responsibility for data protection]*

Name: Lixte Biotechnology Inc.

Address: 380 E Colorado Blvd Pasadena, USA

Contact person's name, position and contact details: Eric Forman, COO eforman@lixte.com:

Activities relevant to the data transferred under the Clauses: Clinical Trial

Role: Controller

Representative in the EU

Lixte Biotechnology Inc

Name: Bastiaan van der Baan bvanderbaan@lixte.com

Function: CEO

Address: Hogeweg 4-H, 1098CB Amsterdam, The Netherlands

Activities relevant to the data transferred under the Clauses: Clinical Trial

Role: Controller

B. DESCRIPTION OF TRANSFER

Categories of data subjects whose personal data is transferred

Clinical Trial Results

Categories of personal data transferred

Anonymized Data

Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.

None

The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).

One off

Nature of the processing

Regulatory Filing

Purpose(s) of the data transfer and further processing

Regulatory Filing

The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period.

Data will be retained in line with regulatory requirements and regulatory filing

For transfers to (sub-) processors, also specify subject matter, nature and duration of the processing

Regulatory Filing

C. COMPETENT SUPERVISORY AUTHORITY

Identify the competent supervisory authority/ies in accordance with Clause 13

Autoriteit Persoonsgegevens

ANNEX II

TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA

Measures for Ensuring Ongoing Confidentiality, Integrity, Availability, and Resilience of Processing Systems and Services:

1. **Physical Access Control Measures:**
    - Lixte has implemented strict access controls to physical locations where personal data is processed. Physical data is stored at the office of the Chief Operating Officer in locked cabinets.
    - Lixte's Pasadena rented office space is equipped with security personnel, surveillance cameras, and secure entry points like key card access.
2. **Electronic Access Control Measures:**
    - Lixte has ensured robust authentication mechanisms (e.g., multi-factor authentication) for accessing electronic systems.
    - Lixte has implemented role-based access control (RBAC) to limit data access to authorized personnel only.
3. **Internal Access Control Measures:**
    - Lixte has defined and enforces user rights for data access and amendment.

- Lixte regularly reviews and updates access permissions based on role changes or employment status.

4. **Isolation Control Measures:**

   - Lixte has isolated data in secure environments to prevent unauthorized access.
   - Lixte uses virtual private networks (VPNs) and encryption as necessary to protect data in transit and at rest.

5. **Data Transfer Control Measures:**

   - Lixte uses secure data transfers using encryption protocols (e.g., TLS).
   - Lixte has systems in place to maintain an audit trail of all data transfers, including details of the data, recipients, and purposes.

6. **Data Entry Control Measures:**

   - Lixte and its Clinical Research Organization partners have implemented logging mechanisms to track data entry and modifications.
   - Lixte and its Clinical Research Organizations have ensured accountability by associating data entry with specific users.

7. **Availability Control:**

   - Lixte has systems in place to deploy redundant systems and data backups to ensure data availability.
   - Lixte regularly tests backup and restoration procedures to verify data integrity and accessibility.

Organizational Measures:

1. **Measures for Ensuring the Ability to Restore the Availability and Access to Personal Data in a Timely Manner in the Event of a Physical or Technical Incident:**

   - Lixte has established disaster recovery plans and business continuity strategies.
   - Lixte conducts regular drills and simulations to ensure preparedness.

2. **Processes for Regularly Testing, Assessing, and Evaluating the Effectiveness of Technical and Organizational Measures:**

   - Lixte performs periodic security assessments and audits.
   - Lixte uses penetration testing and vulnerability assessments to identify and mitigate risks.

3. **Measures for User Identification and Authorization:**

   - Lixte has Implemented stringent user identification and authorization procedures.
   - Lixte uses unique user IDs and robust authentication methods to prevent unauthorized access.

4. **Measures for the Protection of Data During Transmission:**

   - Lixte utilizes encryption technologies (e.g., SSL/TLS) to secure data during transmission.
   - Lixte ensures secure communication channels for data transfer. Lixte employees are not allowed to use e-mail for data transfer of data that is protected under GDPR.

5. **Measures for the Protection of Data During Storage:**

   - Lixte encrypts sensitive data at rest using strong encryption standards.
   - Lixte has Implemented access controls to restrict data access to authorized personnel only.

6. **Measures for Ensuring Physical Security of Locations at Which Personal Data Are Processed:**

   - Lixte has secured its physical location in Pasadena with access control systems and surveillance.
   - Lixte has implemented policies to manage visitor access and ensure data confidentiality.

7. **Measures for Ensuring Events Logging:**

   - Lixte maintains detailed logs of data access, modification, and transfer events.
   - Lixte regularly reviews and analyze logs to detect and respond to potential security incidents.

8. **Measures for Ensuring System Configuration, Including Default Configuration:**

   - Lixte has implement baseline security configurations for systems and applications.
   - Lixte regularly updates and patches systems to address vulnerabilities.

9. **Measures for Internal IT and IT Security Governance and Management:**

   - Lixte has outsourced IT security for implementing and monitoring security measures.
   - Lixte has developed and enforced IT security policies and procedures including cybersecurity

10. **Measures for Certification/Assurance of Processes and Products:**

    - Lixte might seek certifications in the future to validate the effectiveness of security measures.
    - Lixte conduct regular audits to ensure compliance with security standards.

11. **Measures for Ensuring Data Minimization:**

    - Lixte collects and processes only the minimum amount of data necessary for the specified purpose.

- Lixte regularly reviews data collection practices to ensure compliance with data minimization principles.

12. **Measures for Ensuring Data Quality:**

    - Lixte and its Clinical Research Organizations have implemented procedures for data validation and accuracy checks.
    - Lixte has no means to allow data subjects to review and correct their data as Lixte does not have this level of data.

13. **Measures for Ensuring Limited Data Retention:**

    - Lixte has defined and will enforce data retention policies to limit the duration of data storage.
    - Lixte regularly reviews and securely deletes data that is no longer needed in line with regulatory requirements.

14. **Measures for Ensuring Accountability:**

    - Lixte has established clear roles and responsibilities for data protection within the organization. Ultimate accountability for data protection lies with the head of IT which is our Chief Operating Officer.

    - Lixte maintains records of processing activities and demonstrate compliance with GDPR requirements.

15. **Measures for Allowing Data Portability and Ensuring Erasure:**

    - Lixte does not have procedures to facilitate data portability requests from data subjects. Lixte does not have this level of data.

16. **Measures for Handling and Responding to Data Subject Rights' Requests:**

    - Lixte has not established dedicated channels for receiving and addressing data subject rights' requests as Lixte does not have this type of data
    - Lixte ensures timely and transparent responses to requests for data access, rectification, erasure, and other rights under GDPR but this will be limited to the response as Lixte does not have this type of data.