SUPPLY AGREEMENT

(the "**Agreement**")

effective as of the date of signature (the "**Effective Date**"),

by and between

Novartis s.r.o.
with its registered seat at Gemini B, Na Pankráci 1724/129, 140 00 Praha 4, ID No.: 64575977, registered in the Commercial Register under File C 41352 maintained by the Municipal Court in Prague

("**Novartis**")

and

University Hospital Brno
with its registered seat at Jihlavská 20, 625 00 Brno, Czech Republic, ID No.: 65269705
represented by Roman Kraus, MD, MBA

("**Institution**")

LIST OF ANNEXES

WHEREAS:

(A) Novartis is the owner of the Marketing Authorization in the European Union of an autologous cell-based, advanced therapeutic product known as Kymriah® (tisagenlecleucel) (the "Product") and the Institution wishes to purchase the Product and administer it to eligible patients in the Territory following the terms and conditions as laid down in this Agreement.

(B) The Institution and/or Third Party healthcare institutions and Novartis Pharma AG (an Affiliate of Novartis) are parties to a technical apheresis agreement which deals with the terms and conditions for Institution's and/or Third Party healthcare institutions' collection and isolation of leukapheresis material from individual patients who have been referred by healthcare institution(s) approved by Novartis for supply to Novartis for further processing of Product ("Technical Agreement").

IT IS AGREED AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATIONS

1.1 Defined Terms

The following terms shall, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

"**Affiliate**" means any corporation or other business entity, which, directly or indirectly, is controlled by, controls, or is under common control with Novartis. For such purposes, "Control" shall mean the direct or indirect ownership of at least fifty percent (50%) of the voting interest in such corporation or other entity or the power in fact to control the management directions of such entity.

"**Applicable Standards**" means all applicable cGxP as well as all laws, regulations, guidelines, standards, permits and authorizations, including without limitation those listed in the Quality Agreement and those governing health, safety and environmental protection, applicable in the country where the Facility is located and in each country of the Territory.

"**Batch**" means a defined quantity of Product, processed in one process or series of processes, so that it could be expected to be homogeneous.

"**cGxP**" means the current good manufacturing, distribution and storage practices specified by the US Code of Federal Regulations, the EU, PIC, ICH and WHO guidelines and the corresponding national laws and regulations applicable in the country where the Facility is located and in each country of the Territory. In case of conflict, Novartis shall be required to comply with the stricter standard.

"**Delivery**" shall mean the delivery of the Product (including the corresponding appropriate documentation required by Applicable Laws and the Quality Agree-

ment) by or on behalf of Novartis to the Delivery Location DDP ("Delivery Duty Paid") (as such terms defined in Incoterms 2010).

"**Delivery Location**" shall mean the final delivery address for the Product as specified in the respective Order.

"**Facility(-ies)**" means Novartis's Manufacturing facility(-ies) as may be appointed by Novartis.

"**Intellectual Property**" means patents (whether patentable or not), trade secrets, know-how, confidential or proprietary information, technical data, trademarks, service marks, design rights, copyright or any other intellectual property right which may subsist anywhere in the world, whether capable of grant, registration or not.

"**Manufacture**" or "**Manufacturing**" means, as applicable, any and all operations, including without limitation receipt of materials, processing, testing, sterilization, quality control, releasing, storing, sample retention, serialization and packaging for shipment, carried out by or on behalf of Novartis in the preparation and supply of the Products under this Agreement and the Quality Agreement.

"**Marketing Authorization**" means, in respect of a Product, such marketing authorization, approval, license, registration or other authorizations issued by a Regulatory Authority in connection with the placing of that Product on the market in the Territory.

"**Novartis Material**" means all information, documents and materials that will be or have been generated or provided by Novartis and/or its Affiliates under this Agreement to Institution, including without limitation, Confidential Information, manufacturing and quality control instructions or requirements under any quality control agreements between the parties (including the Quality Agreement), and Specifications necessary to manufacture, label, package, store, handle, stability test, quality control test and release the Product, all in accordance with this Agreement.

"**Pick Up Location**" shall mean the final address for the pick-up of the Apheresis material as specified in the respective Order.

"**Price**" means the price per unit of Product, as further defined in **Clause 4.1** and **ANNEX 1**.

"**Quality Agreement**" means that applicable version of the quality agreement between the Parties in relation to the Product and its Manufacturing, including, without limitation by way of a master agreement between Novartis and/or its Affiliate(s) and an Institution Affiliate and the initial version of which is attached hereto as **ANNEX 5**.

"**Regulatory Authority**" means any international, national or other governmental, regulatory or administrative authority or other body competent to grant, maintain and extend approvals, registrations or other consents for the Manufacturing, importation, marketing, distribution or sale of pharmaceutical products, including without limitation the Product.

"**Specifications**" means the specifications for the Product as further defined and referenced in the Quality Agreement.

"**Territory**" means the Czech Republic.

1.2 **Currency**. Unless otherwise indicated, all monetary amounts are expressed in this Agreement in Czech crowns ("CZK").

1.3 **Interpretation**. In this agreement unless otherwise specified:

(a) the division of this Agreement into clauses, sub-clauses and Annexes and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement;

(b) any reference in this Agreement to a clause or an annex refers to the specified Clause or Annex to this Agreement;

(c) the terms "this Agreement", "hereof", "herein", "hereunder" and similar expressions refer to this Agreement;

(d) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;

(e) all references to the singular shall include the plural and vice versa;

(f) the term "including" shall mean "including without limitation"; and

(g) any reference in this Agreement to a "day" or "week" shall be references to a calendar day or week. Where express reference is made to "business day(s)" any such reference shall mean a day (with the exception of Saturday and Sunday) on which banks are open in Switzerland and the country in which the relevant Facility is located.

2. SCOPE OF THE AGREEMENT

2.1 **Manufacturing and Supply**. During the Term, Novartis shall sell, Manufacture and Deliver the Products to Institution in accordance with the terms of this Agreement.

2.2 **Supplier Warranty**. Novartis represents and warrants that it shall Manufacture, store, test release, Deliver and supply the Product in compliance with: (i) the Specifications; (ii) cGxP; (iii) the Quality Agreement; and (iv) the Manufacturing License(s), unless expressly agreed otherwise.

2.3 **Facility**. Novartis will Manufacture the Products at the Facility.

2.4 **Novartis Material**. All Novartis Material, whether or not patentable, shall be the sole and exclusive property of Novartis.

2.5 **Authorizations and Permits**. Novartis and Institution represent and warrant that on the Effective Date and throughout the Term, parties hold all licenses and any other approvals, permits, or exemptions from any Regulatory Authority which are required to perform their respective obligations under this Agreement

and have paid all fees due in relation to them and are not in material breach of any conditions under them. Without prejudice to any of parties' other rights hereunder, either party shall inform the other party promptly in writing if any such license or other approvals or permits are not obtained in a timely manner or are withdrawn or otherwise under investigation.

2.6 Institution represent and warrant that the Product shall be administered in a by Novartis qualified treatment center which has undertaken the educational training program as provided by Novartis.

2.7 The appropriate use of the Product and treatment of patients, including product ordering, receipt and storage, handling, thawing, infusion, and the follow-up of patients both short term and long-term, is entirely the responsibility of the Institution.

2.8 The Institution shall obtain each patient and/or caregiver's consent in the form set out in ANNEX 3 prior to placing any Order (as hereinafter defined).

3. ORDERS AND DELIVERY

3.1 **Orders.**

(a) Institution may place orders for Product by submitting a Product request form to Novartis using an electronic ordering system called Cell Chain Link ("Order"). Novartis shall train Institution to use the Cell Chain Link system.

(b) An overview of the Order process overview is set out in ANNEX 4 of this Agreement.

(c) Each Order shall be deemed to be a separate offer by the Institution to purchase the Product on the terms of this Agreement, which Novartis shall be free to accept or decline at its absolute discretion.

(d) Novartis can only accepts Orders when all of the following steps have been completed: (i) an Order is submitted by the Institution; (ii) a Batch ID is generated by the Cell Chain Link system; (iii) the Order is validated (with patient details checked) by a second health care professional or a pharmacists as required by Cell Chain Link and in accordance with the Institutions standard procedures; and (iv) a manufacturing date is scheduled. Each party shall use the relevant Batch ID in all subsequent correspondence relating to the Order. The Batch ID confirms the chain of identity back to the patient throughout the ordering and manufacturing process, so it is critical that the Batch ID is used in all correspondence between Novartis and the Institution.

3.2 **Terms of Delivery**. Novartis shall Deliver the Products DDP, to the Delivery Location ("Delivery Duty Paid", INCOTERMS® 2010*)*.

3.3 **Packaging**. Novartis shall ensure that the packaging of the Products, including (as applicable) any packaging for transportation complies with the requirements set forth in this Agreement and the Quality Agreement.

4. PRICE AND PAYMENT TERMS

4.1 **Price**. The Price for the Product is set forth in **ANNEX 1** and includes any and all activities or services performed in relation with this Agreement, including, without limitation, (1) the shipment of the leukapheresis material from the Pick Up Location to the Facility, (2) the shipment of the Product from the Facility to the Delivery Location, (3) the use of a dry vapor shipper for these shipments, (4) activities included in the Quality Agreement and any related activities (such as stability testing, re-testing, etc.), and (4) any packaging of the Product. The Price shall be exclusive of any VAT, which shall be payable by the Institution. "**VAT**" means within the European Union such taxation as may be levied in accordance with (but subject to derogation from) Council Directive 2006/112/EC and outside the European Union any taxation levied by reference to added value or sales.

4.2 **Payment Terms**. Novartis shall provide Institution with an invoice setting forth the Price due and payable for each Delivery of Product made under this Agreement. Each such invoice shall, to the extent applicable, identify the Order number, Batch ID number, shipping address, Price and the total amount to be remitted by Institution and the applicable VAT or other sales tax (if any) or such other information as may be required by the applicable tax laws. Institution shall pay all such invoices within 60 days counting from the delivery of the invoice was received, unless explicitly agreed otherwise between the parties.

4.3 The Institution shall not set off any amount owing by it to Novartis against any amounts owed by Institution from Novartis.

5. QUALITY ASSURANCE

5.1 **Quality Agreement**. The mutual tasks and responsibilities of the parties (or their Affiliates who are a party to the respective Quality Agreement) with regard to Quality Assurance are in particular determined in the applicable Quality Agreement as attached to this Agreement as ANNEX 5 and/or Technical Agreement entered into by the parties. A breach of the Quality Agreement shall be considered a breach of this Agreement.

6. CANCELLATION, UNUSABLE PRODUCT REPLACEMENT AND CREDIT POLICY

6.1 The Product cancellation, unusable Product replacement and credit policy as set out in ANNEX 2 will be applicable to all Orders.

7. RESPONSIBLE STANDARDS

7.1 In exercising its rights and performing its obligations under this Agreement, the Institution shall:

a) comply with all applicable laws and regulations, including those related to anti-corruption;

b) comply with industry standards where applicable;

c) comply with all policies and guidelines provided to it by Novartis in relation to the Novartis Anti-Bribery Code and any other guidelines or policies, as

amended from time to time. In the event Novartis issues additional policies in relation to Institution's activities under this Agreement, Novartis will provide Institution with a copy thereof and Institution will duly comply with such policies thereafter; and

d) perform its obligations under this Agreement with high ethical and moral business and personal integrity standards.

7.2 The Novartis anti Bribery Code, and other codes, policies and guidelines can be found at:

https://www.novartis.com/about-us/corporate-responsibility/resources-news/codes-policies-guidelines

The Institution hereby confirms that it has read and understood the Novartis policies and guidelines.

8. PRODUCT RECALLS, RETURNS AND PHARMACOVIGILANCE

8.1 **Recalls**. Upon discovery that a Product should be recalled or corrected, or may be required to be recalled or corrected, the discovering party shall give prompt notice to the QA contact of the other party, all subject to the terms of the Quality Agreement. The decision to initiate a recall or to take some other corrective action, if any, shall be made and implemented by Novartis and Institution shall fully cooperate with any such request. The recall procedure is set forth in the Quality Agreement.

9. INTELLECTUAL PROPERTY AND DATA PRIVACY

9.1 **Background IP**. Each party's background Intellectual Property, which are owned by or licensed to that party prior to the Effective Date of this Agreement or which are not invented, discovered, generated or derived under or in connection with this Agreement are and shall remain owned by or licensed to that party.

9.2 **IP Ownership**.

(a) **Novartis IP**. All Intellectual Property invented, discovered, generated or derived by or on behalf of Novartis or its Affiliates, whether solely or jointly with Institution and/or arising from or related to Novartis Material or other Confidential Information or in connection with this Agreement, shall be the exclusive property of Novartis.

(b) **Institution IP**. All Intellectual Property invented, discovered, generated or derived by Institution, which is not covered by **Clause 9.2(a)** and which is independently invented, discovered, generated or derived by or on behalf of Institution shall be the exclusive property of Institution. Novartis shall have a worldwide, perpetual, non-exclusive, royalty free, fully paid-up license under such Intellectual Property, with the right to grant sub-licenses.

(c) **Notification by Institution**. Institution shall promptly disclose in writing and make available to Novartis in electronic form, and shall cause its subcontractors to disclose in writing and make available to Novartis in

electronic form, all results, inventions and improvements (whether patentable or not) which are invented, discovered, generated or derived under or in connection with this Agreement.

(d) **IP Infringement.** Should Institution become aware of any infringement of Novartis' or its Affiliates' Intellectual Property relating to the Product or Manufacturing processes, Institution shall immediately notify Novartis thereof.

9.3 **Data Privacy.** In order to maintain the patient chain of identity during the treatment process with the Product, Novartis and certain of its Affiliates will collect the patients name, date of birth, weight, and/or country of residence in combination with the SEC (single European code) or components thereof like the Donation Identification Number or Apheresis ID, as well as information on the patient's disease indication ("Novartis Required Data") to ensure the patients safety and preserve the chain of identity.

9.4 The Institution will be the sole data controller for patient personal data processed in relation to treatment with the Product with the exception of any Novartis Required Data processed by Novartis AG and certain of its Affiliates as described in the Agreement. Novartis AG will be the data controller for Novartis Required Data.

9.5 The Institution and Novartis shall comply with all applicable laws governing the privacy and security of personal data they process, including the EU General Data Protection Regulation (the "Regulation"). The terms "process", "processed", "personal data" and "controller" shall have the meanings defined in the Regulation.

10. INDEMNIFICATION AND LIABILITIES

10.1 **Novartis Indemnification**. Novartis shall defend, indemnify and hold Institution harmless against any and all claims, demands, proceedings, losses, damages, liabilities, deficiencies and costs ("**Claims**") to the extent arising out of

(i) the breach of any representation, warranty or any other obligation of Novartis and/or its Affiliates under this Agreement;

(ii) infringement of any Intellectual Property with respect to the Product;

(iii) any damage to or defects in the Product resulting from Novartis's actions or omissions as manufacturer and supplier of the Product, except (i) to the extent that any Claim is resulting from intentional misconduct or gross negligence of Institution, its Affiliates and/or authorized subcontractors, and except (ii) to the extent that Parties have agreed on Delivery of batches that are out of specifications, in which case Parties refer to the liability as provided for in the applicable laws and regulations (including but not limited to the ATMP guidelines).

10.2 **Institution Indemnification.** Institution shall defend, indemnify and hold Novartis and its Affiliates harmless against any and all Claims to the extent arising out of

(i) the use or administration of the Products;

(ii) the breach of any representation, warranty or any other obligation of Institution or its Affiliates and/or its subcontractors under this Agreement;

(iii) non-compliance of Institution' actions or omissions as distributor and administrator of the Product with Applicable Laws, except to the extent that any Claim is resulting from intentional misconduct or gross negligence of Novartis , its Affiliates and/or authorized subcontractors.

10.3 **Indemnification Process**. The indemnification obligations of Institution and Novartis, as the case may be, shall apply only if:

(a) the party asserting its rights ("**Indemnitee**") promptly notifies the other party ("**Indemnitor**") in writing after Indemnitee receives notice of any Claims;

(b) Indemnitee has refrained and continues to refrain from making any admission of liability or any attempt to settle any such Claims without Indemnitor's consent;

(c) Indemnitor is given the opportunity to manage and control the defense or settlement of such Claims;

(d) Indemnitee reasonably co-operates with Indemnitor in the defense of any such Claims; and

(e) Indemnitee takes all such reasonable steps and action as are necessary or as the Indemnitor may reasonably require in order to mitigate any Claims.

10.4 Nothing in this Agreement shall exclude or limit any liability for (i) willful misconduct or omission; (ii) fraud; (iii) intentional breach; (iv) gross negligence; (v) personal injury or death caused by the negligence of a party; or (vi) any other liability that cannot be limited or excluded by law.

10.5 Neither party shall be liable to the other whether in contract, tort (including for negligence and breach of statutory duty), misrepresentation (whether innocent or negligent), restitution or otherwise, for any loss (whether direct or indirect) of profits, business, revenue, or goodwill; loss or corruption (whether direct or indirect) of data or information; or any special, indirect or consequential loss, costs, damages, charges or expenses however arising under this agreement.

10.6 To the extent permitted by law, all terms, conditions, warranties, undertakings, inducements or representations made by either Party (whether expressly or implied) relating in any way to this Agreement are excluded.

11. CONFIDENTIALITY

11.1 **Confidential Information**. Neither party shall disclose to any third party nor use for any purpose outside of the scope of this Agreement any information which is not in the public domain and which was disclosed in connection with this Agreement: (i) by a party or any of its Affiliates; or (ii) any unaffiliated third party at the request of such disclosing party ("**Confidential Information**"). The receiving party may only provide the disclosing party's Confidential Information to its and its Affiliates' directors, officers, employees, advisors, and consultants ("**Representatives**") who are informed of the confidential nature of the Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive than those contained herein and provided that the receiving party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by the receiving party. The obligations of confidentiality and non-use shall expire for Confidential Information which:

(a) is or becomes part of the public domain without a violation of this Agreement;

(b) was already in its possession at the time of receipt from the disclosing party, as shown by documentary evidence; or

(c) after the date of this Agreement is received from a third party whose direct or indirect source is not the disclosing party.

11.2 **Disclosure of Confidential Information**. The parties may disclose Confidential Information where reasonably required under applicable law (i) to competent Regulatory Authorities for registration or other regulatory purposes; and (ii) to competent court or governmental agencies, in which case the disclosing party (to the extent permissible under applicable law) shall inform the other party of such disclosure in writing and shall use reasonable efforts to limit the scope of such disclosure to obtain confidential treatment by the court or governmental agency. Except as expressly permitted herein, this **Clause 11.2** shall not be interpreted as relieving the receiving party of its confidentiality obligations under this **Clause 11**.

11.3 **Survival**. The obligations of confidentiality and non-use contained in this **Clause 11** shall survive the duration of this Agreement for a period of fifteen (15) years.

11.4 **Return of Confidential Information**. Upon termination or expiration of this Agreement for any reason, the receiving party will promptly return to the disclosing party all Confidential Information received from the disclosing party in connection with this Agreement. If any Confidential Information is stored in data processing machines, the Confidential Information will be deleted upon request and the deletion will be confirmed promptly in writing.

11.5 **Register of Contracts.** The Parties have agreed that **a**ny disclosure obligation under the Act No. 340/2015 Coll., on special conditions of effectiveness of specific contracts, publication of those contracts, as amended (the "Contract Register Act") shall be fulfilled by the Institution in accordance with Section 5 para. 2 of the Contract Register Act upon anonymization and obliteration of data listed Section 5 para. 8 of the Contract Register Act which are not subject to disclosure as well as personal data. For this purpose the Institution shall prepare and agree with Novartis on amended version of the Agreement with exclusion of these data (especially, Annex 1, 3 and 4 and personal data). The Institution shall fulfil the obligation of disclosure and agreement with Novartis on the version of the Agreement to be disclosed within 14 days from conclusion of the Agreement and shall immediately provide the other Party with confirmation of the contract register administrator in accordance with Section 5 para. 4 of the Contract Register Act. If the obligations of the Institution are not fulfilled on time, Novartis shall be entitled to provide the electronic copy of this Agreement and relevant metadata (after removal of information and designation of metadata excluded from publication) to the administrator of contract register.

12. TERM AND TERMINATION FOR CONVENIENCE

12.1 **Effective Date and Term**. This Agreement shall come into force on the Effective Date and continue unless terminated in accordance with the terms of this Agreement.

12.2 **Termination for Convenience**. Novartis may terminate this Agreement without cause upon written notice to Novartis at least three (3) months. Institution may terminate this Agreement without cause upon written notice to Novartis of at least six (6) months.

13. EXTRAORDINARY TERMINATION

Without prejudice to any grounds for extraordinary termination available to a party under applicable law, the parties agree that this Agreement may be terminated in accordance with the terms set forth in this **Clause 13**.

13.1 **Termination due to Material Breach**. Upon failure of any party to remedy its material breach of any of its obligations under this Agreement (where remediable) on or before sixty (60) days after receipt of written notice of said breach from the other party the party giving such notice shall have the right but not the obligation to terminate this Agreement immediately (or such longer period of time as

such party shall determine) by written notice. In respect of a material breach which is not capable of remedy, the non-defaulting party shall have the right, but not the obligation, to terminate the Agreement immediately by written notice on the defaulting party.

13.2 **Termination due to Liquidation**. Novartis or Institution at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party upon the liquidation, dissolution, winding-up, insolvency, bankruptcy, assignment for the benefit of creditors, or filing of any petition therefore, appointment of a receiver, custodian or trustee, or any other similar proceeding, by or of the other party where such petition, assignment or similar proceeding is not dismissed or vacated within sixty (60) days.

14. EFFECTS OF TERMINATION OR EXPIRATION

14.1 **Return of Novartis Material**. Upon expiration or termination of this Agreement for any reason, Institution shall promptly Deliver to Novartis or destroy at Novartis' direction all Novartis Material.

14.2 **Survival**. Except as otherwise expressly provided, termination or expiration of this Agreement will not affect any rights and obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement, nor shall it prejudice any other remedies that the parties may have under this Agreement. Upon expiration or termination of this Agreement all outstanding unpaid invoices shall become payable immediately in place of the payment terms previously agreed by the parties.

14.3 For Orders placed and accepted by Novartis in accordance with clause 3.1 of this Agreement before or upon notice of termination, but that are to be delivered after the agreement is expired and/or terminated, Institution shall pay the Price upon Delivery and the Agreement shall be deemed to survive up to the moment of such last Delivery of Product.

15. GOVERNING LAW AND JURISDICTION

15.1 **Governing Law**. This Agreement and the legal relations between the parties in connection herewith shall be governed by, and construed in accordance with, the laws of the Czech Republic, excluding the provisions of the United Nations Convention for the International Sale of Goods and any conflict of law provisions that would require application of another choice of law.

15.2 **Jurisdiction**. For the purpose of any dispute arising out of or in connection with this Agreement which cannot be resolved amicably, the parties hereby irrevocably submit to the exclusive jurisdiction of the ordinary courts of the Czech Republic.

16. MISCELLANEOUS

16.1 **Notices**. Any notices which either party may be required or shall desire to give under this Agreement shall be deemed to be duly given when in writing and delivered personally, mailed by registered mail or courier service to the party to whom notice is to be given, at the address specified below (which may be

amended upon at least seven (7) days prior written notice to the other party) or for any notices which either party may be required or shall desire to give under any Annex to this Agreement shall be given at the address specified in such Annex.

Novartis s.r.o.
Gemini B, Na Pankráci 1724/129, 140 00 Praha 4
Attn: [redacted]

University Hospital Brno
Jihlavská 20, 625 00 Brno
Attn: [redacted]

16.2 **No license**. No license or right is granted by implication or otherwise with respect to any know-how, patent application or patent owned by Novartis or any of its Affiliates or Institution, except as and if specifically set forth herein.

16.3 **Annexes**. All Annexes (and any amendments to such Annexes) and their enclosures form an integral part of this Agreement and are incorporated herein by reference.

16.4 **Order of Priority**. In the event of any conflict, inconsistency or discrepancy between this Agreement, the Annexes or the terms and conditions referenced or incorporated in this Agreement or the Appendices the following order of priority shall apply: (i) the Quality Agreement (solely in respect of Quality Assurance, quality management and compliance with the Applicable Standards), (ii) this Agreement, (iii) any Annexes, and (iv) individual Orders.

16.5 **Standard Terms**. Except as expressly otherwise agreed in writing by the parties, the provisions of this Agreement (including its Annexes) shall apply to any Order for the Product as well as any activity within the scope of this Agreement to the exclusion of any standard terms and conditions of either parties, even if reference is made to such standard terms in conditions by either party in any Order, or any other document.

16.6 **Publications.** The Institution shall not make any public announcement in relation to this Agreement, the Product, or its appointment or role as an authorised treatment center without the prior written consent of Novartis (not to be unreasonably withheld or delayed. Institution is hereby requested to sign and return the use of name and authorization form as attached to this Agreement in ANNEX 6.

16.7 **Force Majeure**. Failure of any party to perform its obligations under this Agreement (other than of the obligations to make any payments or of confidentiality) shall not subject such party to any liability or place them in breach of any term or condition of this Agreement to the other party if, and solely to the extent, such failure is caused by Force Majeure. The corresponding obligations of the other party will be suspended to the same extent. "**Force Majeure**" shall mean any unanticipated event beyond a party's (and/or its subcontractors') reasonable control that could not be avoided by due care of such non-performing party (and/or its subcontractors), including without limitation, acts of God, fire, explosion, flood, earthquake, drought, war, hostility, revolution, riot, civil disturbance, national

emergency, sabotage, embargo; provided, however, that the party affected shall promptly notify the other party of the condition constituting Force Majeure as defined herein and shall exert commercially reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed. If a condition constituting Force Majeure as defined herein prevents, or would likely prevent, a party from performing its obligations under this Agreement for more than sixty (60) days, the parties shall meet to negotiate a mutually satisfactory solution to the problem.

16.8 **Assignment**. Unless otherwise provided for herein, this Agreement and the rights and obligations hereunder may not be assigned or transferred by either party hereto without the prior written consent of the other party, provided however, that Novartis may assign this Agreement (in whole or in part) upon written notice to, but without the prior approval of Institution to: (i) an Affiliate; (ii) a third party in connection with the sale or disposal of all or part of the assets of Novartis; or (iii) if Novartis divests, out-licenses or otherwise disposes of the Product or the business or assets relating to the Product, without prejudice to its right of termination under Clause 12 and Clause 13.

16.9 **Severability**. If any provision of this Agreement is held to be invalid or unenforceable, then the offending provision (or the relevant part thereof) shall not render any other provision of this Agreement invalid or unenforceable, and the Agreement shall remain in full force and effect and shall be enforceable, and the invalid one shall be replaced by a regulation which meets the original economic intent of the invalid provision as far as legally possible.

16.10 **Waiver**. No delay or omission on the part of either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any complete or partial waiver on the part of either party of any right, power or privilege hereunder, nor shall any single or partial exercise or any right, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, power of privilege hereunder. Any provision of this Agreement may be waived if, and only if, such waiver is in writing and signed by the party against whom the waiver is to be effective.

16.11 **Survivorship**. Any of the provisions of this Agreement, including the Annexes, that are expressed or implied to survive the expiration or termination of this Agreement, shall remain in full force and effect.

16.12 **Execution**. This Agreement may be executed in two or more counterparts, each of which, when executed, shall be an original, but all counterparts shall together constitute one and the same instrument.

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Signed by the duly authorized representatives of each of the parties hereto as of the Effective Date.

University Hospital Brno

By: _____

Name: Roman Kraus, MD, MBA

Title: Director

Novartis s.r.o.

By: _____

Name: [redacted]

Title: [redacted]

By: _____

Name: [redacted]

Title: [redacted]

ANNEX 2
Kymriah Cancellation, Unusable Product and Credit Policy

Novartis s.r.o. General Terms and Condition for the Cancellation, Replacement and Credit for KYMRIAH™ (tisagenlecleucel)

Unless otherwise defined herein, capitalized terms used herein shall have the same meanings as described in the Agreement.

1. BACKGROUND

KYMRIAH is a genetically modified autologous immunocellular therapy manufactured for a specific patient. KYMRIAH is prepared from autologous blood of the patient collected by leukapheresis. The patient leukapheresis material may be used only to manufacture an end product for that specific patient. Should the patient become permanently ineligible to receive the therapy once the manufacturing process has started, the manufactured product cannot be used with any other patient.

Infusion of KYMRIAH must begin prior to the expiration date indicated on the label affixed to the infusion bag. KYMRIAH cannot be infused after the expiration date on the label has passed, even if a temporarily ineligible patient were to become eligible to receive a KYMRIAH infusion after the expiration date.

KYMRIAH is provided as a one-time treatment for the specific patient in one or more sealed, patient-specific infusion bags.

Cancellations of an order results in significant manufacturing resource utilization and could have an adverse impact on other patients' ability to receive KYMRIAH. Appropriate patient selection is important.

2. CANCELLATION

If KYMRIAH is not Delivered, the following terms on cancellation apply.

2.1 Cancellation Policy –A treatment center may file a cancellation request for KYMRIAH that has been ordered by it or on its behalf to Novartis prior to receipt of KYMRIAH in accordance with the process set forth below. Novartis will not charge for the cost of a validly cancelled KYMRIAH order.

2.2 Cancellation Process –To request a cancellation, a treatment center must:

1) Complete a KYMRIAH Product Cancellation Form prior to the treatment center's receipt of KYMRIAH. The completed product cancellation form must be signed by the prescribing physician and must be submitted to the Novartis Service Center. The form can be obtained by contacting the Novartis Customer Service Center or by contacting the Novartis, Ing. Petr Jursa, Finance Head Oncology.
2) Upon review and approval of the completed KYMRIAH Product Cancellation Form, the Novartis Customer Service Center will notify the treatment center that the cancellation request is complete.

3. PRODUCT REPLACEMENT OR CREDIT

After Delivery of KYMRIAH, the treatment center can request replacement or a credit in accordance with the terms as defined below.

3.1 KYMRIAH Replacement or Credit –If the specific circumstances set forth below in Section 3.3 render KYMRIAH unusable, the treatment center may request replacement product or a credit. Novartis will determine, in its sole discretion, whether replacement product can be provided (if replacement product is available) or issue a credit; except that in the case of unusable product replacement or credit requests that result from the deterioration of the patient's performance status or patient death (set forth in Section 3.3(7) and (8) below), Novartis will provide a credit. In order for a treatment center to request replacement product or a credit for unusable KYMRIAH:

1) The treatment center must follow the Novartis-approved unusable KYMRIAH replacement or credit request process.
2) The reason for the replacement or credit request must meet the requirements as defined herein.

3.2 Product not Eligible for Credit – Credit is not available for Product that:

1) Was received free of charge; or
2) Novartis determines, in its sole discretion, is adulterated, misbranded, or counterfeit.

3.3 Unusable KYMRIAH replacement or credit request requirements – Subject to the process outlined below, Novartis, in its sole discretion, will provide replacement product of Kymriah (if replacement product is available) or issue a credit for unusable product under the following circumstances:

1) Treatment center human error renders KYMRIAH unsuitable for infusion, provided that the treatment center has used best efforts to comply with the Prescribing Information approved as approved by the applicable regulatory authority and any other requirements for the handling and administration of KYMRIAH.
2) KYMRIAH temperature excursions at the treatment center, provided that the treatment center has used best efforts to comply with the Prescribing Information approved as approved by the applicable regulatory authority and any other requirements for the handling and administration of the Product.
3) KYMRIAH is damaged during shipment but not recognized until after Delivery to the treatment center. The treatment center must, in addition to the QA process as detailed in the Annex 5 of the Agreement regarding Quality, also call the Novartis Customer Service Center to complete a Product Quality Complaint.
4) KYMRIAH temperature excursion during transportation but not recognized until after receipt at the treatment center. The treatment center must, in addition to the QA process as detailed in the Annex 5 of the Agreement regarding Quality, also call the Novartis Customer Service Center to complete a Product Quality Complaint.
5) Product quality issue identified at any point after receipt, but prior to infusion. The treatment center must, in addition to the QA process as detailed in the Annex 5 of the Agreement regarding Quality, also call the Novartis Customer Service Center to complete a Product Quality Complaint.

Subject to the process outlined below, Novartis will issue a credit for unusable product under the following circumstances:

6) KYMRIAH has expired before KYMRIAH can be administered to the patient in accordance with the approved Prescribing Information and any Novartis instructions for product use. Credit request **must** be submitted within thirty (30) days of product expiration. Note, Novartis may, in its sole discretion, reject credit requests where delays in administering the product are due solely to treatment center protocols that differ from the approved Prescribing Information or other Novartis instructions for product use.
7) If after Delivery of KYMRIAH to the treatment center, but before infusion, a physician determines and certifies that, in his/her independent clinical judgement, the prescribed patient's performance status has deteriorated to a point where KYMRIAH can no longer be safely administered to the patient.
8) Patient death prior to infusion.

3.4 KYMRIAH Replacement or Credit Request Process – To request replacement product or credit, a treatment center must:

1) If the prescribing physician is requesting replacement of KYMRIAH, the physician must first contact the Novartis Customer Service Center. Novartis will determine in its sole discretion whether the option to provide replacement product is available, and if so, the treatment center may select this option on the Unusable Product Replacement and Credit Form.
2) Complete the KYMRIAH Unusable Product Replacement and Credit Request Form and submit the form to the Novartis Customer Service Center. This form must be filled out completely, must include the reason for the request, and must be signed by the prescribing physician and the treatment center or storage site representative. This form can be obtained by calling the Novartis Customer Service Center or by contacting the Novartis, Ing. Petr Jursa, Finance Head Oncology.
3) Novartis will evaluate the request to ensure that it meets the requirements as set out herein and may require additional verification from the treatment center before approving the request.
4) The credit issue and replacement product processes are set forth below.

3.5 Credit Issue Process – If a credit request is approved, the Novartis Customer Service Center will notify the treatment center of the approval. Novartis will issue the credit to the treatment center. The credit issued to the treatment center is equal to the treatment center's acquisition cost at time of original invoice. A treatment center may not seek a claim on its insurance for product for which it receives credit or replacement.

3.6 Replacement Product Process – If a request for replacement product is approved, Novartis will issue a credit for the initial purchase order, in accordance with the Credit Issue Process described in Section 3.5, and will instruct the treatment center to submit a new purchase order for the replacement product.

3.7 Product Disposal –After Delivery of Kymriah to the treatment center, the treatment center shall dispose of the unusable product at its own expense and in accordance with applicable laws and regulations and institutional processes and procedures and evidence of disposal is given to Novartis, regardless of the reason for the unusable product replacement or credit request, or whether the request is approved or denied. .

4. FREQUENT CANCELLATION AND UNUSABLE PRODUCT CREDIT POLICY

Cancellations of pending KYMRIAH orders and requests for unusable product credit occur for a variety of reasons and may impact other patients' ability to receive KYMRIAH. Appropriate patient selection is important to ensure timely supply for patients in need of KYMRIAH. For that reason, Novartis has put

in place the following terms for frequent cancellation and unusable product credit:

1) If, during a 6-month period, a treatment center makes unusable product credit requests or cancellations after Novartis has started manufacturing KYMRIAH on two (2) orders or more, the treatment center must complete Novartis training on appropriate patient selection before placing any further KYMRIAH orders. For the avoidance of doubt, each 6-month period shall be calculated separately per product, starting with the first order of that product.
2) If, during a 6-month period, a treatment center makes unusable product credit requests or cancellations after Novartis has started manufacturing KYMRIAH on three (3) or more orders, Novartis in its sole discretion may require the treatment center to place a nonrefundable product order deposit with Novartis s.r.o. toward the purchase of KYMRIAH on future product orders.
    a) The nonrefundable product order deposit will be [redacted] and will be due upon acceptance of the product order by Novartis.
    b) Upon receipt of KYMRIAH, Novartis will credit the nonrefundable product order deposit toward the final purchase acquisition cost for that product order.
    c) If the product order is canceled after Novartis has started manufacturing or an unusable product credit request is made for the order, the nonrefundable product order deposit will be forfeited by the treatment center.
    d) The nonrefundable product order deposit requirement will stay in place until two (2) consecutive orders have been placed that did not result in an unusable credit request or cancellation after Novartis had started manufacturing KYMRIAH.
3) Unusable product replacement or credit requests for product quality reasons (set forth in Section 3.3above) will not be counted for purposes of determining whether the frequent cancellation/unusable product credit request policy applies.

Novartis reserves the right to discontinue KYMRIAH ordering privileges for any treatment center with frequent cancellation/unusable product credit requests, until a co-signed training plan has been executed. The policy described herein does not limit Novartis' ability to suspend treatment center certification and ordering privileges in its sole discretion.

5. CHANGES TO THESE GENERAL TERMS & CONDITIONS

These General Terms & Conditions can be revised at any time, upon approval of both parties, not to be unreasonably withheld. The version of these General Terms & Conditions in effect at the time a Product Request Form is submitted shall apply and be controlling for purposes of that product order.

ANNEX 5
QUALITY AGREEMENT

(As attached, immediately following this page, and the remainder of this page is left blank intentionally.)

QUALITY AGREEMENT

In addition to Article 2 Good Distribution Practice and Article 3 Purchase of Products, Novartis s.r.o. (Novartis) and the Institution agree:

1. Background

Kymriah is Advanced Therapy Medicinal Product (ATMP) manufactured from patient T-cells collected by apheresis. The special properties of the Product make special demands on the processes. Due to the special storage and logistical requirements (below -120 C), Product is delivered straight from the European warehouse (Boenen) to the Institution, under the Wholesale and Distribution license of Novartis s.r.o.. Each batch is certified in accordance with European GMP requirements by the responsible Qualified Person of Novartis before Delivery. Each Batch is patient specific.

The purpose of this Agreement is to clearly distribute between the Parties the duties arising from applicable laws governing handling of human medicinal products, in particular Act no. 378/2007 Coll., on Pharmaceuticals and on changes of various related acts (Act on Pharmaceuticals), as amended, hereinafter referred to as "AOP", its implementing regulations governing good manufacturing practice and good distribution practice, i.e. the order no. 229/2008 Coll., as amended.

2. Scope

The process in the scope of this Quality Agreement is incoming inspection to ensure the proper product quality before the usage of Product. The steps to be followed are described in the Risk Management Plan (RMP) material (Pharmacy/Cell Lab/Infusion Center Training Material) provided to the Institution via Institution Pharmacy, and Good Receipt Form provided within each delivery (as more detailed in Annex F to the Supply Agreement). In addition, this Quality Agreement defines the procedure of complaints, recalls and the destruction of unused Product. The contact persons for quality assurance issues and the generic e-mail address for the exchange of documents are listed under clause 9 of this Quality Agreement.

3. Responsibilities

According to Novartis procedures and principle GDP requirements, Novartis is responsible to qualify and approve Hana Adlerová as trained personnel to be able to supply Product.

Institution Director (Roman Kraus) and Head of Department of Internal Medicine, Hematology and Oncology [redacted] are responsible to define the internal roles and responsibilities of Institution to fulfill the requirements of this Quality Amendment. Head Physician of Institution CAR-T Program [redacted], Head of Institution Pharmacy [redacted] and Head of Institution Cell Lab [redacted] can delegate their duties by internal Institution procedures. Institution shall

ensure that at a minimum the activities, roles and responsibilities that are outlined in Schedule 1 attached to this Quality Agreement between Institution, Institution's Pharmacy and Cell Therapy facility are agreed upon, implemented and adhered to described in this Schedule 1.
Novartis is obliged to be a holder of Distribution License and is obliged to keep the Authorization valid and in force during the term of this Agreement. Institution is obliged to be a holder of authorization to provide healthcare services, dispense medicinal products to patients (pharmacy care), and is obliged to keep the Authorization valid and in force during the term of this Agreement.

4. Incoming check by Institution

The Product shall only be used by the Institution after a completed incoming check and evaluation of the possible transport deviation and confirmation of release for application by Novartis. The following process shall be followed by the Institution and Novartis:

4.1. Upon receipt of Product, the qualified and trained personnel of Institution will check the integrity of the Batch and transport in accordance with the RMP material (training material) and "Goods Receipt Form FRM-8028223" (provided with the delivery), read out the transportation temperature data and document it on the Good Receipt Form without delay, and send the completed Goods Receipt Form FRM-8028223 and Temperature data with supportive photos or other documents (if applicable) by e-mail to [redacted]. Up-to-date list of personnel eligible to sign Goods Receipt Form in the name of institution is maintained in section 9 of this QUALITY ANNEX 5.
4.2. Novartis and Institution have agreed that in the event of changes in the contact details of personnel in section 9 of this QUALITY ANNEX, the Party concerned shall notify without delay the other Party of the change in writing to [redacted] (in case of change of contact details of Institution) and [redacted] (in case of change of contact details of Novartis).
4.3. For the avoidance of doubt, administration of the Product shall only take place, after Novartis' confirmed the Good Receipt Form.
4.4. Institution is becoming Product owner and responsible for risk of damage after takeover of Product from transportation company.
4.5. Institution is responsible to learn about requirements of storage of Product supplied by Novartis and is obliged to respect them to ensure that its original quality is maintained.

5. Procedure for return / destruction of Product

5.1. After transferring Product to the Institution, Product cannot be physically returned due to the special requirements of the Product.
5.2. Following the ANNEX 2 Kymriah Cancellation, Replacement and Credit for KYMRIAH™ (tisagenlecleucel), the Institution is responsible for proper destruction of Product in line with all applicable regulatory requirements.

6. Procedure for technical complaints

6.1. Definition of technical complaints:
Any written or verbal report of dissatisfaction with the Product identity, quality, stability, reliability, safety, effectiveness, performance or use of a Novartis Product.
6.2. If a technical complaint arises, the Institute informs Novartis immediately (within 24 hours) to the following contacts: [redacted], [redacted] (Novartis reception)
6.3. Novartis shall without delay initiate the subsequent steps and clarifies with the Institute, among other things, the possibility of replacement delivery.
6.4. Further details are set out in ANNEX 2, Kymriah Cancellation, Replacement and Credit for KYMRIAH™ (tisagenlecleucel).

7. Recall procedure

7.1. In case of a recall, Novartis will inform the Institute by phone and in writing without any delay to the contact specified in section 9..
7.2. The Institution shall take appropriate and immediate measures to put the Product in quarantine until the final clarification of the background and further instructions of Novartis.
7.3. Novartis informs the Institution about the final decision regarding the recall.
7.4. In case of a recall the Institution shall fully cooperate and take appropriate measures promptly and as requested by Novartis.

8. Changes

Adjustments to this Quality Agreement may be made with the consent of the persons responsible for Quality Assurance of both parties.

9. Contact details

Novartis Quality Assurance

[redacted]	[redacted]
[redacted]	[redacted]

University Hospital Brno

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]

10. Signatures

NOVARTIS

By: _____

(Signature)

Name: [redacted]

Title: [redacted]

Date: _____

Institution

By: _____

(signature)

Name: Roman Kraus, MD, MBA

Title: Director

Date: _____

NOVARTIS

By: _____

(Signature)

Name: [redacted]

Title: [redacted]

Date: _____

Institution Pharmacy

By: _____

(signature)

Name: [redacted]

Title: [redacted]

Date: _____

Schedule 1 to the Quality Agreement

Roles and Responsibilities

Activities	Cell Lab	Physician	Pharmacy	Novartis
Ordering				
Submit a product request		x		
Ensure accuracy of data in CCL by reviewing and verifying the patient details in the product request, and approving the product request		x		
In case of cancellation, submit Product Cancellation Form to the Customer Service Center		x		
Reception				
Access Cryoport Live View from shipping notification email to check temperature excursions	x		x	
Check transport deviations in the dry shipper (configuration, shipper certificate, outside labelling, etc.)	x		x	
Unloading Kymriah cryobags from the dry shipper, inspect the cryobags and document any product issue	x		x	
Store final product in local cryo tank / freezer below -120 °C in a cassette maintaining Batch ID traceability	x			
Prepare empty dry shipper for pick up	x			
Confirm patient identity and receipt of Kymriah in CellChain Closing the Chain of Identity (retyping DIN number)	x			
Fill in Part A of the Good Receipt Form and send to Novartis	x		x	
Completion of Part B and C of Good Receipt Form and send to Cell Lab and Pharmacy				x
Confirm receipt of completed Goods Receipt Forms to Novartis			x	
Ensure accuracy of data in Product Replacement / Credit Request Form by reviewing and verifying the patient details			x	
In case of unusable product, submit Product Replacement / Credit Request Form to the Customer Service Center of Novartis		x		
Product destructions, recalls and complaints				
Decision on product destruction as per the Kymriah Cancellation, Replacement and Credit Policy and send conformation to the Cell Lab	x		x	
Physical destruction of the product and notification to Novartis	x			
Identification of any product technical complaint from reception to infusion, and notification with supporting documentation to the Pharmacy	x	x		
Notification by email of product technical complaints			x	
Clarification and decision on product technical complaints from Novartis				x
Recall decision and inform pharmacy				x
Notification of all suspected serious or unexpected adverse reactions concerning Kymriah in accordance with its legal		x		

Activities	Cell Lab	Physician	Pharmacy	Novartis
obligation set out in Sec 93b of AOP, to the State Institute for Drug Control or simultaneously to Novartis by e-mail at [redacted] or by telephone on the number [redacted]				

ANNEX 6
USE OF NAME AND LOGO
AUTHORIZATION FORM

Authorization to Use Name and Logo

We, University Hospital Brno ("Site") hereby acknowledge that Novartis Pharma AG and / or any of its affiliated companies (collectively comprising "Novartis") is working with our site located at Jihlavska 20, 625 00 Brno, Czech Republic to become a certified treatment center for the purposes of administration of CTL019 tisagenlecleucel-T therapy for as long as our site retains the status of a certified treatment center for the above-mentioned therapy.
We hereby authorize Novartis to use our name, address, phone number, email and/or logo and a link to our website www.fnbrno.cz of our organization on the Novartis website[s] and public-facing documents, both in print and electronic medium, whenever referring to our organization as a treatment center, including in a map based location finder. Novartis agrees to use the institution name and/or logo as depicted below.

University Hospital Brno, Jihlavská 20, 625 00 Brno, Czech Republic, ID No.: 65269705

University Hospital Brno
By: _____
Name: Roman Kraus, MD, MBA
Title: Director
Date: _____