



POST TRIAL ACCESS AGREEMENT

This Post Trial Access Agreement is made between:

Provider: CSL Innovation GmbH f/k/a CSL Behring GmbH having its principal place of business at Emil-von-Behring-Str. 76, 35041 Marburg, Germany (hereinafter referred to as “CSL”),


and

Institution: Motol University Hospital, having its principal place of business at V Úvalu 84, 150 06 Prague 5 – Motol, Czech Republic, ID No. 00064203 (hereinafter referred to as “Institution”).

Whenever the context requires, the singular terms shall be considered plural, and plural terms shall be considered singular.

This Agreement is effective upon the date of last signature by a party. However, the product cannot be administered until regulatory approval for Post Trial Access has been issued.

WHEREAS:

1. CSL has conducted a clinical trial CSL312_3002 titled An Open-label Study to Evaluate the Long-term Safety and Efficacy of CSL312 (Garadacimab) in the Prophylactic Treatment of Hereditary Angioedema, EUDRA/CT number 2020-003918-12 (hereinafter referred to as “Trial”) at the Institution with  an employee of Institution as “Requesting Physician” in the Trial, and hereinafter referred to as “Requesting Physician”.
2. CSL and Institution wish to ensure that participants (hereinafter “Participant” or “Participants”) who have completed the Trial continue to have access to the investigational product Garadacimab (hereinafter referred to as “Product”) post-trial (hereinafter “Post-Trial Access (PTA)”) due to participants’ continuing need based on Requesting Physician’s medical judgment and as per the protocol’s Inclusion/Exclusion criteria.
3. Institution warrants that Requesting Physician is Institution’s employee.

NOW, THEREFORE, the parties agree as follows:

1. **Provision of Product:**
 - a. CSL agrees to provide free of charge and at its own expense the Product to the Institution for the continued treatment of Participants who have completed the Trial and are deemed by the Requesting Physician to benefit from continued access to the Product. CSL undertakes to use reasonable efforts to supply the Product to the Institution through Institution’s pharmacy in a timely manner to ensure the continuous treatment of Participants with the Product.



- b. The request for Post-Trial Access has been made in writing by the Requesting Physician to CSL's designated representative. If the request is made to CSL designated representative, approval must still be received by CSL.
- c. Institution is responsible for seeking Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") review, if necessary and in accordance with institutional IRB/IEC policies, obtaining and maintaining any required regulatory filing/approval/clearance for Post-Trial Access and approval for the treatment prior to drug shipment for each eligible patient and each shipment.
- d. The above-referenced request has been approved by the appropriate ethics committee, if necessary and received any other regulatory approvals as required by local law.
- e. Confirmation of Participant's consent must be provided to CSL prior to drug shipment.
- f. The investigational Product is not approved/authorized or not available by other means in Czech Republic.

2. Duration:

- a. The provision of Product will continue for a period of maximum 3 years or until the stopping criteria listed below, whichever comes first:
 - 1. Product is deemed unsafe or ineffective for the study or the participant;
 - 2. CSL is no longer manufacturing or producing or developing the Product;
 - 3. Requesting Physician is no longer prescribing the Product;
 - 4. Participant no longer wants to take Product;
 - 5. Alternative products available to treat underlying disease;
 - 6. Product is commercially available in Czech Republic for the indication noted in the protocol and has been approved for reimbursement from public health insurance for the indication noted in the protocol; or
 - 7. The regulatory approval for Post Trial Access has expired.

3. Post-Trial Access:

- a. Institution on behalf of itself and the Requesting Physician, certifies the following is true:



1. The participant has completed the above-referenced trial, in which the Product was administered;
2. The benefit of the Product to the participant outweighs its risks in the opinion of the Requesting Physician;
3. The participant specifically consents to his inclusion into the post-trial access program that is being proposed, including the criteria about re-evaluation of benefit-risk. Institution and/or Requesting Physician must document the participant's consent. Confirmation of participant's consent must be provided to CSL prior to drug shipment;
4. The administration of the Product resulted in a clinical benefit to the Participant and outweighs its risks based on the Requesting Physician's benefit/risk assessment of the Participant's response to the intervention, and what is known about the Product at the time of the decision in consultation with CSL;
5. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; and
6. The Participant has a serious or life-threatening condition.

4. **Responsibilities of the Institution and/or Requesting Physician:**

- a. The Institution shall ensure Requesting Physician administers the Product in accordance with the regulatory approval for Post-Trial Access, the protocol or written instructions [including amendments] used during the Trial, and any additional written guidelines provided by CSL.
- b. The Institution and/or Requesting Physician will monitor the participants and report any adverse events or any serious adverse events to CSL in a timely manner as per the regulatory approval for Post-Trial Access, the protocol or any other written guidance or instructions provided by CSL.
- c. The Product supplied by CSL shall only be used for the treatment of participants as outlined in the request for Post Trial Access, and will not be exchanged for money, property, or services, and will not be transferred to any other entity without CSL's written consent.
- d. Institution and/or Requesting Physician is solely accountable for the treatment decisions on the appropriateness of the Product for the participant, and the risks associated with the use of the Product under Post Trial Access as set forth by generally binding law and regulations.
- e. To the extent permissible by law, Institution and/or Requesting Physician agree and acknowledge that CSL accepts no liability arising from the use of the Product under Post Trial Access.



- f. Institution will allow site visits upon written request by CSL.
5. **Informed Consent**
- a. The Institution and Requesting Physician shall obtain written informed consent from the participant and/or legal guardian (if applicable) and shall ensure that:
1. Participant(s) reads, understands, and signs a current Informed Consent Form (ICF) prior to the commencement of treatment with the Product under this Agreement;
 2. Participant(s) will receive a copy of their signed ICF; and the original ICF will be filed at the Institution;
 3. All relevant and applicable local legal, regulatory and Data privacy legislation shall be complied with;
 4. All relevant Product information shall be provided to the participants, and shall ensure that the Participant/parent/legal guardian understand and are aware that the affected packages of the investigational Product are yet to receive approval for marketing and commercial use in Czech Republic, and are being provided to treat the Participant under regulations permitting access to unapproved drugs outside of a clinical trial based on medical judgement of Requesting Physician that Participant qualifies under said regulations,
6. **Compliance with Laws:**
- a. Both parties agree to comply with all applicable laws and regulations governing the provision of post-trial access to investigational products.
7. **Confidentiality:**
- a. The Institution agrees on behalf of the Requesting Physician, Research Personnel, its agents and employees to maintain the confidentiality of all information including information related to the Product and the Trial, except as required by law or by an enforceable decision of a court or competent public authority or as necessary to provide care to the participants. CSL acknowledges that Institution is obliged to publish this Agreement in the publicly accessible Registry of Contracts.
8. **Liability:**
- a. Institution and/or Requesting Physician shall indemnify to the extent set out by generally binding provisions of applicable law and hold harmless CSL from and against all actual and alleged losses including but not limited to , negligence, or intentional torts , resulting from or arising out



of any third-party claims, actions or proceedings that is related to the breach of this Agreement by Institution and/or Requesting Physician .

- b. Furthermore, CSL, its affiliated entities, and their respective agents, contractors, and personnel shall be released and discharged from all liabilities, claims, or expenses relating to the use of the Product to treat Participants enrolled in the Post Trial Access program, except to extent caused by manufacturing defect of the Product.
- c. CSL represents and warrants that the manufacture, packaging and labeling of the Product provided pursuant to this Agreement shall be in compliance with good manufacturing procedures.

9. **Insurance:**

- a. Institution and/or Requesting Physician shall maintain in full force and effect throughout the performance of the Post Trial Access program a normal and customary insurance program including but not limited to general liability, medical malpractice, and errors and omissions with limits appropriate to cover its liability for any bodily injury which may be caused as a result of fault, malpractice, or negligence of any Institution professional during the pendency of the Post Access Trial period. Institution shall provide CSL proof of insurance upon request.
- b. Institution acknowledges that CSL does not carry medical malpractice insurance, nor will it accept responsibility for such.
- c. CSL shall maintain in full force and effect throughout the performance of the Study sufficient insurance to cover liability of the CSL. CSL is permitted to self-insure. Proof of insurance or a statement of self-insurance shall be provided upon request.

10. **No Rights in the Product, Pre-Existing Intellectual Property, and Confidential Information of CSL:**

- a. It is expressly agreed and understood that neither Institution nor Requesting Physician, including any of their affiliates, employees, contractors, or agents, shall acquire any rights of any kind whatsoever with respect to the Product, CSL's Pre-Existing Intellectual Property, or any CSL Confidential Information as a result of performance of the Study, under this Agreement, or otherwise. Nothing in this Agreement shall restrict CSL in the use, manufacture, or sale of Product.

11. **Intellectual Property:**

- a. All Intellectual Property created or derived as a result of Post Trial Access or modified from the underlying clinical trial will vest automatically upon its creation in CSL.



12. **Rights in Data:**

- a. Any data that originates from the Post Trial Access or is modified from the underlying clinical trial belongs to CSL.

13. **The costs of treatment:**

- a. Including but not limited to administration costs, costs associated with laboratory or other monitoring, physician and hospital fees, and costs for treatment related to any adverse events, will be the responsibility of the Institution, insurer, health care system, and/or participant.

14. **Publication Rights:**

- a. Institution and/or Requesting Physician shall have no rights regarding publication that arise under this Agreement.

15. **Audit:**

- a. CSL shall have the right, upon reasonable prior written notice and during normal business hours, to audit, inspect, and review the records, facilities, and processes of the Institution relating to the conduct of the Post Trial Access. Such audits may include, but are not limited to, records, documents, and facilities related to Post Trial Access, so that CSL may comply with its regulatory requirements. CSL acknowledges that the records and facilities will be made available to it only to the extent permitted by applicable legal regulations.

16. **Return of Product:**

- a. Upon termination or completion of the Post Trial Access under this Agreement Institution shall return or destroy all Product according to CSL's direction, at CSL's reasonable expense.

17. **Miscellaneous:**

- a. All notices under this Agreement shall be in writing and shall be sent by registered or certified mail (deemed delivered upon receipt).
- b. This agreement cannot be assigned without written consent, except CSL may assign this Agreement to its affiliates without consent.
- c. This Agreement shall be governed by and construed in accordance with the laws of the Czech Republic, with any disputes relating to this Agreement to be resolved exclusively in courts located in Czech Republic with local jurisdiction according to the registered seat of the Institution, .
- d. This Agreement can be signed in counterparts, each considered an original. This Agreement may be signed by electronic signature, which shall have the same force and effect as an original signature.



- e. This Agreement comprises the entire agreement with respect to the Post Trial Access Program, superseding prior agreements between the Parties regarding the Post Trial Access Program.
- f. If any part of this Agreement is unenforceable, the rest remains in effect. No Party waives their rights by not enforcing them.
- g. CSL may terminate or suspend this Agreement, with or without cause at any time, effective immediately upon written notice. Termination is contingent upon safe withdrawal of the Participants from the Product.
- h. Paragraphs 2-17 shall survive the expiration or termination of the Agreement.

Annexes: Schedule A – Affirmation of Requesting Physician

SIGNATURE PAGE TO FOLLOW

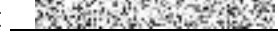
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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

(1) CSL INNOVATION GmbH

By: 

Name: 

Title: Global Clinical Scientist Lead

Date: 08. Oktober 2025 | 22:27:46 PDT

(1) CSL INNOVATION GmbH

By: 

Name: 

Title: VP Immunoglobulin TA

Date: 13 October 2025 | 09:29:25 CEST

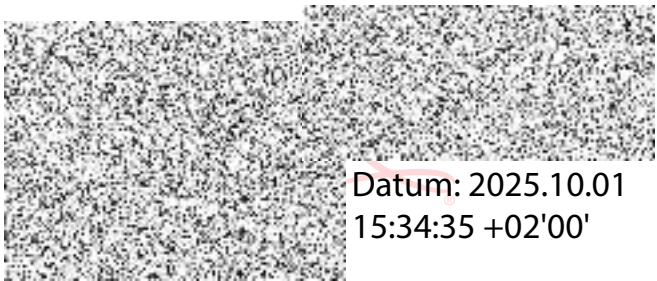
(2) Institution

By: _____

Name: MUDr. Petr Polouček, MBA

Title: Director of Motol University Hospital

Date: _____


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Read and Acknowledged:

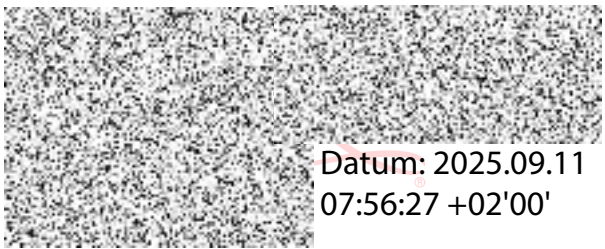
(3) Requesting Physician

By: _____

Name: 

Title: Requesting Physician

Date: _____


Datum: 2025.09.11
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SCHEDULE A
AFFIRMATION OF REQUESTING PHYSICIAN

I, Prof. Dr. Anna Šedivé, DSc. (hereinafter "Requesting Physician"), affirm and aver the following information is true and correct:

1. I am currently employed by Motol University Hospital, which is located at V Úvalu 84, 150 06 Prague 5 – Motol, Czech Republic.

2. I was the Principal Investigator for CSL312_3002 titled An Open-label Study to Evaluate the Long-term Safety and Efficacy of CSL312 (Garadacimab) in the Prophylactic Treatment of Hereditary Angioedema, EUDRA/CT number 2020-003918-12 ("Trial").

3. I have made a formal request to CSL Behring, LLC, the sponsor of the above-referenced Trial for post-trial access (hereinafter "Post-Trial Access") of CSL312 (hereinafter "Product") to be provided to 3 participants that were enrolled in the above-referenced Trial (hereinafter "Participants"; individually "Participant").

4. Each Participant has a serious or immediately life-threatening disease or condition.

5. I have assessed each Participant and determined that each individual Participant has received a benefit from the Product that is outweighed by any risks from the Product.

a. The Participant responded to Product with no or very limited number of HAE attacks; and

b. The Participant experienced no clinically meaningful adverse effects from the Product.

6. In my independent medical judgement, there is no comparable or satisfactory alternative therapy to treat the Participant's condition.

7. This request for Post-Trial Access is made based solely on my medical knowledge and judgement.

IN WITNESS WHEREOF, Requesting Physician has executed this Affirmation as of the date written below:

Requesting Physician

By: _____

Name: 

Title: 

Date: _____



Datum: 2025.09.12
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