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Certificate Issued Date	:	11-Jul-2022 11:43 AM
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CLINICAL TRIAL AGREEMENT

Please write or type below this line

This **Clinical Trial Agreement** ("Agreement"), effective as of the date of last signature ("Effective Date"), is entered into between **Parexel International Clinical Research Private Limited,** having an address at **CoWrks, RMZ Eco World, Ground floor, Bay Area-Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village Bangalore - 560103, India,** acting on behalf of **Regeneron Pharmaceuticals, Inc.,** having an address at **777 Old Saw Mill River Road, Tarrytown, NY 10591 United States** ("Sponsor"), **Manipal**

Center for Clinical Research, having an address at **Mezzannine floor of KMC, old library building, Manipal University, Manipal-576104, Karnataka, India** ("Institution") and **Dr. Arvind N. Prabhu**, having an address at **Kasturba Medical College and Hospital, Tiger Circle Road, Madhav Nagar, Manipal - 576104, Karnataka, India.** ("Principal Investigator")

The Institution and the Principal Investigator are hereinafter called "Institution/Principal Investigator" when it is intended that they be referred to jointly.

WHEREAS, the Sponsor desires to conduct a clinical study ("Study") of **Pozelimab and Cemdisiran** (each individually and collectively being the "Investigational Drug") as part of a multi-center study under a protocol **R3918-MG-2018** entitled **"Efficacy And Safety of Pozelimab and Cemdisiran Combination Therapy In Patients With Symptomatic Generalized Myasthenia Gravis"** (as the same may be amended from time to time, the "Protocol"), a copy of which is incorporated herein by reference as Exhibit A;

WHEREAS, the Institution has the facilities and expertise to conduct the Study and has agreed to perform the Study on the terms and conditions as hereinafter set forth;

WHEREAS, Sponsor has engaged, pursuant to a separate contract, **Parexel International Clinical Research Private Limited** together with its clinical Affiliates, as defined below, ("CRO"), having an address at **CoWrks, RMZ Eco World, Ground floor, Bay Area- Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, Bangalore -560103, India**, to act as Sponsor's agent and contract research organization in managing, coordinating and carrying out Sponsor's responsibilities in connection with the Study contemplated by this Agreement. The parties hereto acknowledge and agree that Sponsor shall have the right to delegate any of its rights and obligations hereunder to CRO, including those relating to payments, regulatory submissions, and communications but shall remain the liable party under this Agreement.

NOW, THEREFORE, in consideration of the mutual promises set forth in this Agreement, the parties hereby agree as follows:

1. SCOPE OF WORK.

1.1 Principal Investigator. The Institution shall conduct and supervise the Study through Principal Investigator. The Institution shall notify the Sponsor promptly if the Principal Investigator is unable or unwilling to continue the Study or if the Principal Investigator's affiliation with the Institution ceases, whereupon the Sponsor will have a right of approval with respect to the designation of a new Principal Investigator.

1.2 Conduct of the Study. The Institution and Principal Investigator shall conduct the Study in accordance with this Agreement, the Protocol, all reasonable written instructions of the Sponsor, and all applicable laws and regulations, including, without limitation, any applicable requirements of the India Drugs and Cosmetics Act, 1940; New Drug and Clinical Trial Rules, 2019; the Indian Council for Medical Research Guidelines for Biomedical and Health Research Involving Human Participants, 2017; Guidelines on Good Clinical Practice in India issued by the Central Drugs Standard Control Organisation; the United States Food and Drug Administration ("FDA"); the International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines; and the applicable requirements of Declaration of Helsinki ("Applicable Law"). The Institution/Principal Investigator shall refrain from, and shall cause any other employee, contractor, or agent performing or assisting with the Study on behalf of the Institution/Principal Investigator ("Study Staff") to refrain from using the Investigational Drug in any manner that is contrary to the provisions of, or outside the scope of, the Protocol or that is contrary to Sponsor's written instructions.

1.3 Approvals. The Institution/Principal Investigator shall seek approval of the Study, the Protocol, and a written form of Informed Consent (as defined in Section 1.4) mutually acceptable to the Institution/Principal Investigator and the Sponsor, from the appropriate ethics committee (the "EC"), and shall seek any other approvals required for the Study from applicable internal safety or review boards.

1.4 Informed Consent. The Principal Investigator shall obtain from each person participating in the Study ("Study Subject") a valid informed consent ("Informed Consent"), signed by the Study Subject (unless such signature is waived by the EC) and appropriately documented. The Institution/Principal Investigator shall conduct the Study in a manner consistent with the Informed Consents.

1.5 Amendment of the Protocol. The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institution/Principal Investigator.

1.6 Supervision. The Institution/Principal Investigator shall supervise the Study Staff and shall ensure that all Study Staff are appropriately trained, qualified, and certified, and are informed of and abide by the applicable terms of this Agreement. Institution/Principal Investigator shall use its reasonable best efforts to maintain consistency of Study Staff throughout the duration of the Study.

1.7 Enrollment. The enrollment for the Study shall be competitive. The Institution/Principal Investigator shall use its reasonable best efforts to enroll a minimum of 3-4 subjects to the Study. The Institution/Principal Investigator may enroll more than 4 subjects by informing Sponsor and upon Sponsor discretion without a contract amendment.

Sponsor may increase or decrease the Institution's/Principal Investigator's enrollment of Study Subjects based upon enrollment patterns at other Study centers.

2. RECORDS, REPORTING, AND AUDITS.

2.1 Study Materials. The Institution/Principal Investigator shall keep and maintain, diligently and in sufficient detail to satisfy the requirements of all Applicable Laws, such Study data and records as are required by the Protocol and Applicable Law, including, without limitation any completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institution for the Sponsor ("Study Materials").

2.2 Record Retention. The Institution must, and must ensure that Principal Investigator will, retain all essential study documents, including Study Materials, source documents, and Study Subject medical records for at least fifteen (15) years following the completion or discontinuation of the Study, or longer, if a longer period is required by relevant regulatory authorities. After the required retention period has expired, the Institution shall provide the Sponsor sixty (60) days' written notice before destroying any Study Materials. If the Institution or Principal Investigator's situation is ever such that archiving can no longer be ensured, the Institution must inform the Sponsor and the relevant records will be transferred to a mutually agreed-upon destination.

2.3 Study Subject Medical Information. The Sponsor may access the Study Materials during regular business hours, upon reasonable advance notice to the Institution/Principal Investigator. The Sponsor shall comply with Applicable Law regarding the confidentiality of Study Subjects' medical records and other health information, shall hold the Study Subjects' personal identifying information in confidence, and shall act in accordance with the Informed Consents. Subject to the foregoing, the Sponsor may copy Institution/Principal Investigator records containing such information to the extent permitted by Applicable Law and the express authorization of Informed Consents from relevant Study Subjects. Institution/Principal Investigator acknowledges that Sponsor may disclose Study Materials to its drug development partners, other clinical investigators in the Study, the FDA and foreign regulatory agencies. If in connection with the performance of the Agreement, Sponsor comes in contact with individually identifiable information of patients at the Institution who are not Study Subjects, Sponsor will use commercially reasonable efforts to maintain the confidentiality of such information and not use it for any purpose. Institution certifies that it has implemented reasonable and appropriate security controls that would allow Sponsor to remotely access patient data in its electronic medical record system in compliance with applicable data protection laws.

2.4 Periodic Reporting. The Principal Investigator shall provide Sponsor with the data called for in the Protocol on properly completed case report forms within two (2)

business days of collection or as otherwise specified in the Protocol.

2.5 Adverse Experience Reporting. The Principal Investigator shall notify Sponsor of serious adverse experiences, adverse experiences or drug reactions of any Study Subject in accordance with the requirements of the Protocol. The Principal Investigator shall also comply with all Applicable Law with regards to adverse experience reporting.

2.6 Audits by the Sponsor. The Institution/Principal Investigator shall make available to the Sponsor (or its agent) the Study site, the Study Staff, and, subject to Applicable Law relating to patient confidentiality, all Study Materials for purposes of review and audit upon reasonable advance notice during regular business hours. Upon receipt of written notice from the Sponsor of any violations of the Protocol, this Agreement, or Applicable Law found in such audit, the Principal Investigator and the Institution shall promptly take action to correct such violations and shall provide confirmation to Sponsor of such corrective action.

2.7 Audits by Regulatory Authorities. Institution shall make available to regulatory authorities, the Study site, the Study Staff, and, subject to Applicable Law relating to patient confidentiality, all Study Materials for purposes of review and audit. Institution recognizes that the Study and the Institution is subject to inspection by regulatory agencies worldwide, including the FDA. The Institution/Principal Investigator shall provide the Sponsor prompt, advance notification of any audit by a regulatory authority, which audit is directly related to the Study (or, when advance notification is impracticable, prompt notification of any completed audit). To the extent possible, the Institution/Principal Investigator shall permit the Sponsor to review and comment in advance on any written communication from the Institution/Principal Investigator to the regulatory authority in connection with such an audit; provided, however, that such review does not have a material adverse impact on the timeliness of the Institution/Principal Investigator's response to the regulatory authority. The Institution/Principal Investigator shall promptly provide the Sponsor with copies of all communications between the Institution/Principal Investigator and the regulatory authority related to such audit unless prohibited from so doing by the regulatory authority, and shall promptly take action to correct any deficiencies found by the regulatory authority during the audit. With respect to a pending audit directly related to the Study by the FDA or by any comparable foreign regulatory authority with jurisdiction over drug approval, the Institution/Principal Investigator shall permit the Sponsor's representatives to be present at such audit unless prohibited from so doing by Applicable Law. With respect to any audit by any regulatory authority, which audit is not directly related to the Study, the Institution/Principal Investigator shall promptly notify the Sponsor of any findings of such an audit that may have an adverse effect on the Institution/Principal Investigator's ability to conduct the Study in accordance with the Protocol or Applicable Law.

3. SPONSOR OBLIGATIONS.

3.1 Compliance with Law. The Sponsor shall comply with Applicable Law in the performance of its activities relating to the Study, and shall obtain all approvals and consents required in connection with such activities.

3.2 Supply of Investigational Drug. The Sponsor and/or its Affiliate shall supply the Institution/Principal Investigator with quantities of the Investigational Drug adequate for the Institution/Principal Investigator to conduct the Study in accordance with the Protocol. The Investigational Drug shall remain the sole property of the Sponsor and/or its Affiliate. The Institution/Principal Investigator shall take reasonable steps to ensure that it has adequate supplies of the Investigational Drug, shall store, use, handle, and return or dispose of the Investigational Drug in accordance with the Protocol, and shall not use any Investigational Drug after its labeled expiration date.

3.3 Payments. The Sponsor shall make payments to Institution according to the payment schedule attached hereto as Exhibit B ("Budget and Payment Terms"). In no event shall the payments hereunder exceed the amount set forth in Exhibit B without the prior written consent of the Sponsor.

3.4 Subject Injury. The Sponsor shall reimburse the Institution for the reasonable and necessary medical expenses incurred in treating any injury or illness to a Study Subject that are directly related to the administration of the Investigational Drug or the proper performance of any other Study procedure, each in accordance with the Protocol and the Sponsor's written instructions to the Institution/Principal Investigator. The Sponsor is not required to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a private third party, (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any agent or employee of the Institution (including the Study Staff), or (d) medical expenses for injury or illness unrelated to the Investigational Drug and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institution/Principal Investigator, including, without limitation, medical expenses associated with a pre-existing medical condition or the progression of the underlying disease.

3.5 Registration of Study. To the extent required by Applicable Law, it shall be the responsibility of the Sponsor to register the Study at (i) www.clinicaltrials.gov; (ii) any other registry the requirements of which are consistent with the guidelines of the International Committee of Medical Journal Editors ("ICMJE") on trial registrations, in each case to the extent required by the ICMJE guidelines (as in effect at the time the Study begins) in order for the Study results to be eligible for publication in an ICMJE journal; or (iii) any other registry as might be required by Applicable Law, including the Clinical Trial Registry

of India.

3.6 Communication of Findings. The Sponsor will use reasonable efforts to promptly report to Principal Investigator any findings discovered that could affect the safety of participants or their willingness to continue their participation in the Study.

4. OWNERSHIP OF DATA, RECORDS, AND INTELLECTUAL PROPERTY.

4.1 Ownership of Data and Records. All rights, title, and interest in (i) the Study Materials, (ii) the Protocol, and (iii) any other scientific, technical, business, or other data or information relating to the Investigational Drug or this Agreement that is disclosed to the Institution/Principal Investigator by the Sponsor shall be the sole and exclusive property of the Sponsor.

4.2 Ownership of Inventions. The Institution/Principal Investigator shall promptly disclose, and shall cause the Study Staff to promptly disclose to the Sponsor in writing any inventions or discoveries made in the performance of the Study by or on behalf of the Institution/Principal Investigator that relate to the administration or use of the Investigational Drug ("Inventions"). The Sponsor hereby owns all right, title, and interest in and to any Inventions and Institution/Principal Investigator agrees to execute any documents or undertake any further actions if requested by Sponsor to evidence transfer of title thereto or to facilitate the prosecution, allowance, maintenance, correction, or extension of any patent or patent application relating to Inventions (including, but not limited to assignments, declarations, affidavits, and the like), at Sponsor's reasonable expense. The Institution represents and certifies that all Study Staff are required to assign all rights, title and interest in and to the Inventions to Institution.

5. CONFIDENTIALITY.

5.1 Obligations. For purposes of this Agreement, the following is "Confidential Information": (a) Study Materials; (b) any information related to the Study that is disclosed by or on behalf of the Sponsor to the Institution/Principal Investigator orally or in electronic or written form; and (c) Inventions. During the term of this Agreement and for a period of five (5) years after the expiration or termination of this Agreement ("Confidentiality Period"), the Institution/Principal Investigator shall maintain the confidentiality of the Confidential Information, and may not transfer or disclose Confidential Information to any third party other than the EC and other applicable internal safety and review boards, except as provided in Section 5.3 or the Protocol. During the Confidentiality Period, the Institution/Principal Investigator may use Confidential Information in performing the Study, for the provision of related patient care, or for other non-commercial internal clinical or educational uses, but shall not use any Confidential Information for any other purpose.

5.2 Exceptions. Notwithstanding Section 5.1, information shall be deemed not to be Confidential Information to the extent that it:

(a) is or later becomes publicly known other than through a breach of this Agreement by the Institution, its employees, or its agents (including the Principal Investigator);

(b) is lawfully made available to the Institution, its employees, or its agents (including the Principal Investigator) by a third party that the Institution reasonably believes owes no obligation of confidentiality to the Sponsor; or

(c) was already known to or is independently developed by the Institution, its employees, or its agents (including the Principal Investigator), as evidenced by written records.

5.3 Permitted Disclosures. Notwithstanding Section 5.1, Confidential Information may be disclosed to the extent that it:

(a) is disclosed to Study Staff, but only to the extent required in connection with the performance of the Study, and only if such Study Staff are subject to obligations of confidentiality and non-use at least as restrictive as those in this Article 5;

(b) is disclosed to Study Subjects or prospective Study Subjects as reasonably necessary or appropriate in the course of discussions regarding the Informed Consent, or the performance of the Study;

(c) is disclosed to a physician or a Study Subject as reasonably necessary or appropriate in connection with the medical treatment of the Study Subject;

(d) is required to be disclosed by the Institution by law or by order of any governmental authority; provided, however, that, except with respect to disclosures made pursuant to Section 2.7, the Institution/Principal Investigator shall use reasonable efforts to disclose the minimum Confidential Information necessary to comply with such requirement, and the Institution/Principal Investigator shall give the Sponsor advance notice of the disclosure when practicable, and prompt notice of the disclosure otherwise, to permit the Sponsor to seek a protective order to limit the disclosure.

5.4 Confidentiality of Terms. Institution/Principal Investigator shall maintain the confidentiality of the terms of this Agreement, subject to Section 7.5 and the exceptions set forth in Sections 5.2 and 5.3.

6. BIOLOGICAL SAMPLES.

6.1 Definition. "Biological Sample" means (i) any material collected from a Study Subject, including, without limitation, any blood, serum, urine, saliva, bone marrow or tissue sample, and (ii) any tangible material isolated therefrom, including but not limited to DNA, RNA and other biological substances.

6.2 Collection, Storage and Use Under Protocol. If the Protocol requires the collection of Biological Samples, then Institution/Principal Investigator shall collect and use such Biological Samples in accordance with the Protocol, the Informed Consent, and in compliance with Applicable Law. At the request of Sponsor, or if otherwise required by the Protocol, Institution/Principal Investigator shall deliver the Biological Samples to Sponsor or Sponsor's designee. Sponsor shall use such Biological Samples in accordance with the Protocol, the Informed Consent, and in compliance with Applicable Law.

6.3 Retention and Destruction. Institution and Sponsor, as applicable, shall maintain all Biological Samples for as long as required by the Protocol and Applicable Law. Neither Institution nor Principal Investigator shall destroy or permit the destruction of any Biological Samples in their possession without the prior written consent of Sponsor. At the request of Sponsor, Institution shall either deliver Biological Samples in Institution's possession to Sponsor or continue to store Biological Samples for any period that the Sponsor may request at Sponsor's expense.

6.4 Secondary Research. Institution/Principal Investigator may not (i) use the Biological Samples collected under the Protocol, (ii) collect additional quantities of Biological Samples (i.e. exceeding quantities which the Protocol specifies to be collected), and/or (iii) retain any quantities of Biological Samples not used for purposes of conducting the research specified by the Protocol, for purposes of testing or use in research that is not described in the Protocol, including pharmacokinetic, pharmacogenomics, and biomarker testing and research.

7. PUBLICATION AND DISCLOSURE.

7.1 Right of Publication. Notwithstanding Section 5.1, upon completion or termination of the Study and subject to this Article 7, the Institution/Principal Investigator may publish, otherwise publicly disclose or submit for publication an article, manuscript, abstract, report, poster, presentation, or other material, in written or electronic form, that includes: (i) an analysis of the results of the Study generated by the Institution and/or Principal Investigator at the Institution; (ii) a summary of the Protocol; and (iii) supporting data generated by the Institution and/or Principal Investigator at the Institution in connection with the Study and identifying information regarding the Investigational Drug, in each case as would be reasonably required for purposes of publication in a peer-reviewed scientific journal (any such article, manuscript, abstract, report, poster, presentation, or

other material, a "Manuscript").

7.2 Multi-Center Publication. The parties, recognizing the importance of communicating clinical trial results to the public and to the medical and scientific communities in an accurate and complete manner, intend for the first publication of the Study to include the results from all of the Study centers and to appear in a peer-reviewed scientific journal, in accordance with the Protocol. Without the prior written agreement of the Sponsor, the Institution/Principal Investigator shall not publish, submit or otherwise present for publication, directly or indirectly, any Manuscript prior to the publication of an article in a peer-reviewed scientific journal summarizing the data generated by all of the Study centers, unless no such article is so published before the first anniversary of the finalization of the clinical study report, in which case the Institution/Principal Investigator may publish or submit for publication a Manuscript without further delay (subject to the other Sections of this Article 7).

7.3 Review Period. Not less than forty-five (45) days prior to submission for publication or presentation of any Manuscript, the Institution/Principal Investigator shall provide the Sponsor with a copy of the Manuscript. The Institution/Principal Investigator shall consider in good faith any comments submitted by the Sponsor regarding the content thereof, and shall delete any Confidential Information that the Sponsor requests in writing be deleted. At the Sponsor's request, the Institution/Principal Investigator shall delay publication for an additional sixty (60) days to allow patent applications to be filed.

7.4 Use of Name. No party may use the name, logo, or trademark of any other party or its employees or Affiliates in any press release, publicity, or advertising without the prior written approval of the other party, except as required by Applicable Law or expressly permitted by this Agreement.

7.5 Disclosure by Institution/Principal Investigator. The Institution/Principal Investigator shall have the right to include the Study title and any other information publicly available on any registry in which the Study is listed pursuant to Section 3.5, in any list of active or past clinical trials conducted by the Institution/Principal Investigator published on the Institution/Principal Investigator's website or in an Institution/Principal Investigator print publication; provided, however, that no additional information, whether about the Study, the Investigational Drug, or the Sponsor, may be included.

7.6 Disclosure by Sponsor. The Institution and Principal Investigator acknowledge that the Sponsor is required by applicable laws and pharmaceutical industry codes of conduct to document and publicly disclose certain transfers of value made to healthcare professionals and healthcare organizations, and such disclosures may include information about the payments or other transfers of value provided to Institution and/or the Principal Investigator and Study Staff under this Agreement. The Sponsor may store and

use information relating to the Institution, Principal Investigator and/or Study Staff and arising out of this Agreement for the purpose of its business and may publicly disclose in its discretion such information (including, but not limited to, the name and professional address of the Institution and/or the Principal Investigator and Study Staff, any financial and in-kind payments received under this Agreement, the nature of the engagement and any other payment or service-related information) as may be deemed appropriate by Sponsor for the fulfillment of its transparency obligations or as may otherwise be dictated by Applicable Law or any pharmaceutical industry codes of conduct to which the Sponsor or any of its Affiliates is subject. For such purposes, the Sponsor may transfer such information to its Affiliates and/or third party service providers, who may be established in a different jurisdiction to the Institution and Principal Investigator, which jurisdiction may not offer the same level of protection for personal information. Payments to the Institution for work done by specified individuals may reference both the Institution and the individual. In accordance with applicable data protection laws, the Principal Investigator and Study Staff may contact the Sponsor at any time to correct any mistakes or request deletion of their personal information held by Sponsor.

7.7 Acknowledgment. The Institution/Principal Investigator shall publicly acknowledge in any Manuscript the Sponsor's financial or editorial contribution to the research, and the Institution/Principal Investigator may use the Sponsor's name for that purpose.

8. INDEMNITIES AND INSURANCE.

8.1 Indemnification. The Sponsor shall indemnify, defend, and hold harmless the Institution and its officers, directors, employees, and agents (including the Principal Investigator) from any loss, liability, damage, or expense (including reasonable attorneys' fees and costs until such time as the Sponsor assumes the defense) from any claim of bodily injury that may arise directly from the administration of the Investigational Drug or the proper performance of any procedure required by the Protocol or the Sponsor's written instructions; provided, however, that to the extent that the claim is a result of (a) the failure of the Institution or one of its officers, employees, or agents (including the Principal Investigator) to comply with the terms of this Agreement or to follow the Protocol or the Sponsor's written instructions, accepted medical practice, or Applicable Law, or (b) any act of negligence or willful misconduct of the Institution or one of its officers, employees, or agents (including the Principal Investigator) (claims arising from (a) and (b) being referred to as "Institution Error Claims"), the Sponsor shall have no such obligation, and the Institution shall indemnify, defend, and hold harmless the Sponsor (and its officers, directors, employees, and agents, as applicable) from any loss, liability, damage or expense, but only to the extent arising from any such Institution Error Claim.

8.2 Limitation of Liability. Except for the parties' indemnification obligations above or as otherwise determined by a final adjudicated court order, no party hereto shall have any liability to any other for any special, indirect or consequential losses or damages suffered by the other.

8.3 Indemnification Procedure. The party seeking indemnification (the "Indemnitee") shall promptly notify the other party (the "Indemnitor") of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material related information. If such notice is not prompt, the Indemnitor's obligation under this Article 8 will be reduced to the extent that such delay prejudices the Indemnitor's defense of the claim. The Indemnitor shall have the right to manage the defense and settlement of any claim, except that the Indemnitor may not enter into any settlement admitting fault on behalf of the Indemnitee without the Indemnitee's prior written approval. The Indemnitee may not enter into any settlement of any such claim without the written permission of Indemnitor. The Indemnitee shall reasonably cooperate with the Indemnitor in the defense of the claim. The Indemnitee may hire its own counsel, at its own expense, to monitor the defense. In addition, the Indemnitee may elect to assume control of the defense of such claim, in which case the Indemnitor shall have no obligation to indemnify or further defend the Indemnitee with respect to such claim.

8.4 Insurance. During the term of this Agreement and for three (3) years thereafter, the Institution/Principal Investigator and the Sponsor each shall carry liability insurance in the type appropriate and customary for the conduct and sponsorship of clinical trials (or maintain a comparable program of self-insurance). Upon request, each party shall provide to the other party a certificate of such insurance or evidence of such a self-insurance plan.

9. REPRESENTATIONS AND COVENANTS.

9.1 Regulatory Approvals. Each party represents and warrants that it has and will maintain during the term of this Agreement all regulatory approvals required for the conduct of its respective activities in connection with the Study, and that all persons who perform activities under this Agreement on its behalf (including, in the case of the Institution/Principal Investigator, the Study Staff) have and will have the necessary expertise, qualifications, certifications and training, including, without limitation, training related to current Good Clinical Practices ("cGCP").

9.2 Debarment. The Institution certifies that it is not (a) debarred by the FDA under 21 U.S.C. § 335a or any foreign equivalent or to the Institution's knowledge is not threatened with debarment by a pending proceeding, action, or investigation, (b) excluded from participation in any federal health care program under 42 C.F.R. Part 1001 et seq. and is not the subject of an exclusion proceeding, and (c) otherwise disqualified under federal or

state law, or to the Institution's knowledge is not threatened with such disqualification by a pending proceeding, action, or investigation, from participating in the Study. The Institution certifies that it will not engage, directly or indirectly, any person (including the Principal Investigator) to perform services under this Agreement if (a) that person is debarred by the FDA under 21 U.S.C. § 335a or any foreign equivalent or to the Institution's knowledge is threatened with debarment by a pending proceeding, action, or investigation, (b) that person is excluded from participation in any federal health care program under 42 C.F.R. Part 1001 et seq. or is the subject of an exclusion proceeding, or (c) that person is otherwise disqualified under federal or state law, or to the Institution's knowledge is threatened with such disqualification by a pending proceeding, action, or investigation, from participating in the Study. The Principal Investigator certifies that he/she has never been debarred by any regulatory authority nor threatened with debarment by a pending proceeding, action, or investigation or otherwise disqualified under local law. The Institution/Principal Investigator certifies that it/he/she will immediately notify the Sponsor in writing if any such debarment, exclusion, or disqualification occurs, or if any such debarment, exclusion, or disqualification proceeding, action, or investigation is commenced or, to the Institution/Principal Investigator's knowledge, is threatened, with respect to any such person or to the Principal Investigator him/herself. The Sponsor certifies that it is neither debarred by the FDA under 21 U.S.C. § 335a or otherwise disqualified under federal or state law and that it will not use any persons that are either debarred by the FDA under 21 U.S.C. § 335a or otherwise disqualified under federal or state law to assist the Sponsor in conducting the Study.

9.3 Fair Market Value. Each party represents that the compensation provided under this Agreement represents the fair market value of the activities performed by the Institution, has been negotiated in an arm's-length transaction, and has not been determined in any manner with regard to any implicit or explicit agreement to provide favorable procurement decisions with regard to the Sponsor's products, or to the value or volume of any business or referrals generated between the parties.

9.4 No Charge. The Institution/Principal Investigator covenants that it will not charge any Study Subject or any third party for (i) the Investigational Drug, or (ii) any items or services that are funded by the Sponsor under this Agreement or that are provided without charge by the Sponsor for Study purposes.

9.5 Power and Authority. The Institution/Principal Investigator represents that it has the requisite power and authority to cause all Study Staff to comply with the Institution/Principal Investigator's obligations under this Agreement.

9.6 Institution/Principal Investigator Disclosures. The Institution/Principal Investigator (a) shall provide to the Sponsor a completed and signed Site Information Form and a *curriculum vitae* or other statement of qualifications showing the education, training,

and experience that qualifies the Principal Investigator as an expert in the clinical investigation of the Investigational Drug for the use under investigation; (b) shall cause, before the commencement of the Study, during the course of the Study, and for up to one year after the completion or termination of the Study, at the Sponsor's reasonable request, the Principal Investigator and any sub-investigator to disclose to the Sponsor (and afterwards to notify the Sponsor of any relevant changes to) any financial arrangement between the Sponsor and any investigator (whether Principal Investigator or sub-investigator, and including any spouse or dependent child thereof) as to which the value of the compensation could be influenced by the outcome of the Study, any significant payments of other sorts from the Sponsor, any proprietary interest in the Investigational Drug, or any significant equity interest in the Sponsor held by the Principal Investigator or sub-investigator, and including any spouse or dependent child thereof; and (c) shall comply, and shall ensure that the Principal Investigator and any sub-investigator comply, with all applicable disclosure requirements related to conflict of interest that are imposed by the FDA or other regulatory or governmental authorities.

9.7 Inside Information. Institution and Principal Investigator understand that the information provided by Sponsor in connection with the Study may be considered to be material, nonpublic information that could affect the market price of the common stock of Sponsor or possibly other companies when and if it is made public. Institution and/or Principal Investigator and others associated with either or both of them in the conduct of the Study may be viewed as "insiders" who have gained this material nonpublic information as a result of participation in the Study. Therefore, the Principal Investigator agrees that neither he/she nor any member of his/her immediate family (or other people sharing their household) will buy or sell, or advise others to buy or sell, the common stock of Sponsor during the pendency of the Study or as a result of the Study, at any time until the results of the Study are publicly available. The Principal Investigator agrees that he/she will inform all appropriate persons associated with the Study of this agreement and the terms and conditions of this Section 9.7.

9.8 Anti-bribery.

(a) The parties acknowledge that the Sponsor and its representatives and agents are bound by all applicable anti-corruption and anti-bribery laws and regulations, including but not limited to, the United States Foreign Corrupt Practices Act (FCPA) and United Kingdom Bribery Act. Institution and Principal Investigator represent, warrant, and covenant that they will not cause, and will direct Study Staff not to cause, Sponsor or its representatives or agents to be in breach of their responsibilities through any act as described in this Section.

(b) In performing the Study and/or services under this Agreement the Institution, and Principal Investigator, (i) agree that it has not and shall not, and will direct

their Study Staff not to, directly or indirectly, offer to make, promise, authorize or accept any payment or anything of value, including bribes, gifts and/or donations to or from any public official, regulatory authorities or anyone else for the improper purpose of influencing, inducing or rewarding any act, omission or decision in order to secure an improper advantage, including to obtain or retain business, and (ii) shall comply with all applicable anti-corruption and anti-bribery laws and regulations, including but not limited to, the India Prevention of Corruption Act, 1988. The Institution or Principal Investigator shall notify the Sponsor or its representatives or agents immediately upon becoming aware of any breach under this Section.

(c) For the purpose of ensuring compliance with applicable anti-bribery laws and regulations, Institution agrees that Sponsor or its representatives or agents shall have the right to conduct an investigation or audit of the Institution during the term of this Agreement to monitor compliance with the terms of this Section. The Institution shall cooperate fully with such investigation or audit, the timing of which shall be at the sole discretion of the Sponsor.

9.9 Data Protection. In providing the services, Institution shall comply, (and shall cause Principal Investigator and Study Staff to comply,) with all applicable data protection laws related to information that identifies or can be used to identify, contact or precisely locate the individual person to whom such information pertains from which identification of or contact information for an individual person can be derived ("Personal Information") including by:

(a) processing and using Personal Information solely for the purpose of complying with their obligations or exercising their rights under this Agreement or applicable data protection laws;

(b) taking all reasonable steps to ensure that Personal Information is protected from unauthorized or unlawful processing or accidental destruction; and

(c) ensuring that Personal Information is not transferred outside the country where the Personal Information originated without the other party's prior written consent or without complying with the applicable data protection laws with respect to any such transfer.

10. TERM AND TERMINATION.

10.1 Term. This Agreement shall take effect on the Effective Date and shall continue until six (6) months after the earlier of (a) the date on which the Study is completed and final clinical research data are provided by the Institution/Principal Investigator to Sponsor; or (b) the date on which the Study is terminated as provided for herein.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

Parexel International Clinical Research Private Limited
on behalf of
Regeneron Pharmaceuticals, Inc

By: _____

Name: Jahanara Rahuldev

Title : Vice President, FSP Biometrics, India

Date: 6-Dec-2022.

Manipal Center for Clinical Research

By: _____

Name: Dr. Satish Rao, B. S.

Title : Director

Date: _____

Principal Investigator

_____

Name: Dr. Arvind N. Prabhu, Associate Professor and Unit Head, Neurology Department

Date: 03-JAN-2023

Exhibit A

Protocol

(Provided under separate cover)

- CRO address listed above
- Date of Supply
- Appropriate supporting documentation (i.e. third-party invoices, receipts).

Invoices and associated documentation should be de-identified of patient personal information (e.g. name, date of birth, initials, etc.) prior to being submitted to CRO.

Where the payee is GST registered then payment will not be made by CRO without receipt of a valid GST invoice. In addition to the above invoice requirements, GST registered payees must also include the following information:

- GST registration number of the supplier (payee), prefixed with their country code (if applicable); and
- Name, address and GST registration number of the customer (CRO);and
- GST, Net & Gross Amount (if applicable); and
- GST Rate (if applicable)

Invoices, which exclude any of the designated information above, may result in delayed payments.

Final Invoices: Payee must provide the final invoice to Sponsor within sixty (60) days of Study site closure. Sponsor is not liable for payment of invoices sent after such time.

K. **PROTOCOL VIOLATIONS:** Sponsor retains the absolute right to deny payment or offset against sums due hereunder for a payment previously due for a Study Subject when a Protocol Violation has occurred.

L. **PAYMENTS:** The following Payee is legally eligible and capable to receive compensation related to his/her performance under this Agreement.

All payments will be made to the Payee listed in the table below.

PAYEE INFORMATION	
Payable To	Manipal Academy of Higher Education
Payee Mailing Address	Manipal Academy of Higher Education, Manipal.edu, Madhav Nagar, Manipal-576104, Karnataka, India.
Attention	Dr. Arvind N. Prabhu
Phone	08202922050
Email	Uss.research@manipal.edu
Bank Name	State Bank of India

Bank Branch Name	Manipal branch
Bank Branch Address	State Bank of India, Madhuvan Serai, Ground Floor, Near Smrithi Bhavan, Tiger Circle, Manipal, Karnataka-576104, India.
Bank Type	S B account
Bank ABA Routing Number	N/A
Bank Account Name	State Bank of India
Bank Account Number	37983533287
IFSC/ Swift Code	SBIN0004426
Tax ID (GST Registration)	29AAETM8695B1Z4
NPI	N/A
Company Email Contact for Credit Remittance Advice	Sbi.04426@sbi.co.in

In the event that payee details are modified during the course of the study, the parties agree that no amendments to this Agreement shall be required, provided that Institution provides written notification to CRO with revised payee details to the following e-mail address *InvestigatorPaymentHelpDesk@PAREXEL.com*. CRO will attempt to independently verify banking information changes to ensure they are valid. If Institution does not respond to these verification attempts, CRO will modify the banking information as per the email but accepts no liability for incorrect payee details provided by the Institution, its representative or any other third party. Any payments that are fraudulently misdirected will not be re-paid.

Exhibit B- Attachment B-1

Standard	Conditional	Overall
Rs 1,267,455.80	Rs 742,361.00	Rs 2,009,816.80

Overhead Percent: 30%

Location: India

Currency: Rupees

Procedure	Sponsor Qty	OH	Selected Cost	SV1	SV2	SV3	V4	V5	V6	V7	V8	V9	V10	V11n
Week				Up to -5	-1	0	1	2	4	6	12	16	20	24
Demographics/Inclusion/Exclusion criteria	3	✔	1,496.00	1,496.00	1,496.00	1,496.00								
Informed consent	1	✔	1,465.00	1,465.00										
Initial Visit with Medical and Surgical History, MG crises and MG-related hospitalizations, Phys & Vitals (including duration of MGFA classification, Demographics, Risk assessment for Neisseria Gonorrhea and Counseling, TB History, Prior Medication, Height, Weight, and Schedule of MG procedures, where indicated)	1	✔	4,094.00	4,094.00										
Study Drug Administration: Administer Pozelimab/Placebo/Cemdisiran SC Dose Q4W (Includes 30 minutes post-injection observation on Days 1 and 169)	14	✔	1,732.00			2,598.00			1,732.00	1,732.00	1,732.00	1,732.00	1,732.00	
Patient Safety Card for Neisseria meningitidis	1	✔	10,025.00		10,025.00									
MG Activities of Daily Living Scale(MG-ADL)	20	✔	237.00	237.00	237.00	237.00		237.00	237.00	237.00	237.00	237.00	237.00	237.00
Quantitative MG Score (QMG)	16	✔	1,418.00		1,418.00	1,418.00		1,418.00	1,418.00	1,418.00	1,418.00	1,418.00	1,418.00	1,418.00
Myasthenia Gravis Composite (MGC)	15	✔	363.00		363.00	363.00		363.00	363.00	363.00	363.00	363.00	363.00	363.00
CGIC (4 scales: MG body function, MG disease, ocular/bulbar weakness, and generalized weakness)	4	✔	3,567.00								3,567.00			3,567.00
CGIS (4 scales: MG body function, MG disease, ocular/bulbar weakness, and generalized weakness)	5	✔	1,524.00			1,524.00					1,524.00			1,524.00
MGFA-PIS	3	✔	363.00											363.00
Myasthenia Gravis QoL, MG-QoL 15r	15	✔	330.00			330.00		330.00	330.00	330.00	330.00	330.00	330.00	330.00
Neuro-QOL-Fatigue	15	✔	1,566.00			1,566.00		1,566.00	1,566.00	1,566.00	1,566.00	1,566.00	1,566.00	1,566.00
EQ-5D-5L	7	✔	621.00			621.00					621.00			621.00
PGIC (2 scales: MG functioning and MG disease)	4	✔	3,567.00								3,567.00			3,567.00
PGIS (2 scales: MG functioning and MG disease)	4	✔	1,524.00			1,524.00					1,524.00			1,524.00
ECG w/ Interpret. & Report	5	✔	2,011.00		2,011.00			2,011.00						2,011.00
Brief Visit w/ Vitals	22	✔	1,295.00		1,295.00	1,295.00	1,295.00	1,295.00	1,295.00		1,295.00	1,295.00	1,295.00	
Physical Exam with Vitals (including Weight and Risk assessment for Neisseria gonorrhea at Screening Visit 2, where indicated)	5	✔	2,269.00							2,269.00				2,269.00
Concomitant Meds/Treatments	29	✔	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Adverse Events Assessment	29	✔	801.00	801.00	801.00	801.00	801.00	801.00	801.00	801.00	801.00	801.00	801.00	801.00
MG crises and MG-related hospitalizations	24	✔	3,033.00		3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00
Columbia Suicide Severity Rating Scale (C-SSRS)	31	✔	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00
Venipuncture - enipuncture - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG), where indicated	27	✔	179.00	179.00	179.00	179.00		179.00	179.00	179.00	179.00	179.00	179.00	179.00
Special Handling - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG), where indicated	27	✔	590.00	590.00	590.00	590.00		590.00	590.00	590.00	590.00	590.00	590.00	590.00
Single PK/ADA - Drug Conc. Samples for Pozelimab	20	✔	1,060.00			1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00
Spec Handling - Drug Conc. Samples for Pozelimab	20	✔	590.00			590.00	590.00	590.00	590.00	590.00	590.00	590.00	590.00	590.00
Single PK - Plasma cemdisiran and metabolites conc.sample (pre-dose and post-dose), Plasma total C5 sample, and Serum pozelimab and cemdisiran ADA sample for immunogenicity, where indicated.	33	✔	1,060.00	1060.00		3,180.00	1,060.00	1,060.00	1,060.00	1,060.00	3,180.00	1,060.00	1,060.00	3,180.00
Spec Handling - Plasma cemdisiran and metabolites conc.sample (pre-dose and post-dose), Plasma total C5 sample, and Serum pozelimab and cemdisiran ADA sample for immunogenicity, where indicated.	22	✔	590.00	590.00		590.00	590.00	590.00	590.00	590.00	590.00	590.00	590.00	590.00
Biomarker Collection:Complement hemolytic assay (serum CH50 & AH50), CCP Wieslab, CAP Wieslab, and Anti-LRP4 (ELISA), where indicated	13	✔	1,060.00	1,060.00		1,060.00	1,060.00	1,060.00	1,060.00		1,060.00			1,060.00
Biomarkers: Complement hemolytic assay (serum CH50 & AH50), CCP Wieslab, CAP Wieslab, and Anti-LRP4 (ELISA), where indicated	13	✔	591.00	591.00		591.00	591.00	591.00	591.00		591.00			591.00
Procedures Sub Total (Rs)				Rs 15,649.00	Rs 24,934.00	Rs 28,132.00	Rs 13,366.00	Rs 20,280.00	Rs 19,981.00	Rs 19,304.00	Rs 32,804.00	Rs 18,330.00	Rs 18,330.00	Rs 34,520.00

Procedure	Sponsor Qty	OH	Selected Cost	V11b	V12	V13	V14	V15	V16	V17	V18a	V18b	V19	V20	V21	V22	V23	V24	V25
Week				24	28	32	36	40	44	48	52	52	60	72	84	96	108	116	120
Demographics/Inclusion/Exclusion criteria	3	✔	1,494.00																
Informed consent	1	✔	1,495.00																
Initial Visit with Medical and Surgical History, MG crises and MG-related hospitalizations, Phys & Vitals (including duration of MFGA classification, Demographics, Risk assessment for Neisseria Gonorrhea and Counseling, TB History, Prior Medication, Height, Weight, and Schedule of MG procedures, where indicated)	1	✔	4,084.00																
Study Drug Administration: Administer Pozelimab/Placebo/Cemdisiran SC Dose Q4W (Includes 30 minutes post-injection observation on Days 1 and 169)	14	✔	1,732.00	2,598.00	1,732.00	1,732.00	1,732.00	1,732.00	1,732.00	1,732.00									
Patient Safety Card for Neisseria meningitidis	1	✔	10,025.00																
MG Activities of Daily Living Scale(MG-ADL)	20	✔	237.00		237.00	237.00	237.00			237.00			237.00		237.00		237.00		237.00
Quantitative MG Score (QMG)	16	✔	1,418.00			1,418.00	1,418.00			1,418.00			1,418.00		1,418.00		1,418.00		1,418.00
Myasthenia Gravis Composite (MGC)	15	✔	363.00				363.00			363.00			363.00		363.00		363.00		363.00
CGIC (4 scales: MG body function, MG disease, ocular/bulbar weakness, and generalized weakness)	4	✔	3,567.00							3,567.00									3,567.00
CGIS (4 scales: MG body function, MG disease, ocular/bulbar weakness, and generalized weakness)	5	✔	1,524.00							1,524.00									1,524.00
MGFA-PIS	3	✔	363.00							363.00									363.00
Myasthenia Gravis QoL, MG-QoL 15r	15	✔	330.00		330.00		330.00			330.00			330.00		330.00		330.00		330.00
Neuro-QOL-Fatigue	15	✔	1,566.00		1,566.00		1,566.00			1,566.00			1,566.00		1,566.00		1,566.00		1,566.00
EQ-5D-5L	7	✔	621.00				621.00			621.00			621.00						621.00
PGIC (2 scales: MG functioning and MG disease)	4	✔	3,567.00							3,567.00									3,567.00
PGIS (2 scales: MG functioning and MG disease)	4	✔	1,524.00							1,524.00									
ECG w/ Interpret. & Report	5	✔	2,011.00								2,011.00								2,011.00
Brief Visit w/ Vitals	22	✔	1,295.00			1,295.00	1,295.00	1,295.00	1,295.00	1,295.00			1,295.00	1,295.00	1,295.00	1,295.00	1,295.00	1,295.00	
Physical Exam with Vitals (including Weight and Risk assessment for Neisseria gonorrhea at Screening Visit 2, where indicated)	5	✔	2,269.00								2,269.00								2,269.00
Concomitant Meds/Treatments	29	✔	600.00		600.00	600.00	600.00	600.00	600.00	600.00	600.00		600.00	600.00	600.00	600.00	600.00	600.00	600.00
Adverse Events Assessment	29	✔	801.00		801.00	801.00	801.00	801.00	801.00	801.00	801.00		801.00	801.00	801.00	801.00	801.00	801.00	801.00
MG crises and MG-related hospitalizations	24	✔	3,033.00		3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00		3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00	3,033.00
Columbia Suicide Severity Rating Scale (C-SSRS)	31	✔	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00
Venipuncture - enipuncture - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG), where indicated	27	✔	179.00			179.00	179.00	179.00	179.00	179.00	179.00		179.00	179.00	179.00	179.00	179.00	179.00	179.00
Special Handling - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG), where indicated	27	✔	590.00			590.00	590.00	590.00	590.00	590.00	590.00		590.00	590.00	590.00	590.00	590.00	590.00	590.00
Single PK/ADA - Drug Conc. Samples for Pozelimab	20	✔	1,060.00		1,060.00		1,060.00			1,060.00			1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00
Spec Handling - Drug Conc. Samples for Pozelimab	20	✔	590.00		590.00		590.00			590.00			590.00	590.00	590.00	590.00	590.00	590.00	590.00
Single PK - Plasma cemdisiran and metabolites conc.sample (pre-dose and post-dose), Plasma total CS sample, and Serum pozelimab and cemdisiran ADA sample for immunogenicity, where indicated.	33	✔	1,060.00	2,120.00	1,060.00		3,180.00			3,180.00			1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00	1,060.00
Spec Handling - Plasma cemdisiran and metabolites conc.sample (pre-dose and post-dose), Plasma total CS sample, and Serum pozelimab and cemdisiran ADA sample for immunogenicity, where indicated.	22	✔	590.00	590.00	590.00		590.00			590.00			590.00	590.00	590.00	590.00	590.00	590.00	590.00
Biomarker Collection:Complement hemolytic assay (serum CH50 & AH50), CCP Wieslab, CAP Wieslab, and Anti-LRP4 (ELISA), where indicated	13	✔	1,060.00		1,060.00		1,060.00			1,060.00					1,060.00			1,060.00	1,060.00
Biomarkers: Complement hemolytic assay (serum CH50 & AH50), CCP Wieslab, CAP Wieslab, and Anti-LRP4 (ELISA), where indicated	13	✔	591.00		591.00		591.00			591.00					591.00			591.00	591.00
Procedures Sub Total (Rs)				Rs 8,194.00	Rs 16,136.00	Rs 12,771.00	Rs 23,722.00	Rs 11,116.00	Rs 11,116.00	Rs 33,267.00	Rs 12,369.00	Rs 2,886.00	Rs 17,219.00	Rs 12,684.00	Rs 16,349.00	Rs 12,684.00	Rs 16,898.00	Rs 14,335.00	Rs 30,876.00

Procedure	Sponsor Qty	OH	Selected Cost	FU-0	FU-1	FU-2	FU-3
Week				4	8	16	26
Demographics/Inclusion/Exclusion criteria	3	✔	1,496.00				
Informed consent	1	✔	1,465.00				
Initial Visit with Medical and Surgical History, MG crises and MG-related hospitalizations, Phys & Vitals (including duration of MFGA classification, Demographics, Risk assessment for Neisseria Gonorrhea and Counseling, TB History, Prior Medication, Height, Weight, and Schedule of MG procedures, where indicated)	1	✔	4,094.00				
Study Drug Administration: Administer Pozelimab/Placebo/Cemdisiran SC Dose Q4W (includes 30 minutes post-injection observation on Days 1 and 169)	14	✔	1,732.00				
Patient Safety Card for Neisseria meningitidis	1	✔	10,025.00				
MG Activities of Daily Living Scale(MG-ADL)	20	✔	237.00		237.00		237.00
Quantitative MG Score (QMG)	16	✔	1,418.00				
Myasthenia Gravis Composite (MGC)	15	✔	363.00				
CGIC (4 scales: MG body function, MG disease, ocular/bulbar weakness, and generalized weakness)	4	✔	3,567.00				
CGIS (4 scales: MG body function, MG disease, ocular/bulbar weakness, and generalized weakness)	5	✔	1,524.00				
MGFA-PIS	3	✔	363.00				
Myasthenia Gravis QoL, MG-QoL 15r	15	✔	330.00				
Neuro-QOL-Fatigue	15	✔	1,566.00				
EQ-5D-5L	7	✔	621.00				
PGIC (2 scales: MG functioning and MG disease)	4	✔	3,567.00				
PGIS (2 scales: MG functioning and MG disease)	4	✔	1,524.00				
ECG w/ Interpret. & Report	5	✔	2,011.00				
Brief Visit w/ Vitals	22	✔	1,295.00	1,295.00	1,295.00	1,295.00	
Physical Exam with Vitals (including Weight and Risk assessment for Neisseria gonorrhea at Screening Visit 2, where indicated)	5	✔	2,269.00				2,269.00
Concomitant Meds/Treatments	29	✔	600.00	600.00	600.00	600.00	600.00
Adverse Events Assessment	29	✔	801.00	801.00	801.00	801.00	801.00
MG crises and MG-related hospitalizations	24	✔	3,033.00				
Columbia Suicide Severity Rating Scale (C-SSRS)	31	✔	2,886.00	2,886.00	2,886.00	2,886.00	2,886.00
Venipuncture - enipuncture - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG), where indicated	27	✔	179.00	179.00	179.00	179.00	179.00
Special Handling - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG), where indicated	27	✔	590.00	590.00	590.00	590.00	590.00
Single PK/ADA - Drug Conc. Samples for Pozelimab	20	✔	1,060.00				1,060.00
Spec Handling - Drug Conc. Samples for Pozelimab	20	✔	590.00				590.00
Single PK - Plasma cemdisiran and metabolites conc.sample (pre-dose and post-dose), Plasma total C5 sample, and Serum pozelimab and cemdisiran ADA sample for immunogenicity, where inidicated.	33	✔	1,060.00				1,060.00
Spec Handling - Plasma cemdisiran and metabolites conc.sample (pre-dose and post-dose), Plasma total C5 sample, and Serum pozelimab and cemdisiran ADA sample for immunogenicity, where inidicated.	22	✔	590.00				590.00
Biomarker Collection:Complement hemolytic assay (serum CH50 & AH50), CCP Wieslab, CAP Wieslab, and Anti-LRP4 (ELISA), where indicated	13	✔	1,060.00				
Biomarkers: Complement hemolytic assay (serum CH50 & AH50), CCP Wieslab, CAP Wieslab, and Anti-LRP4 (ELISA), where indicated	13	✔	591.00				
Procedures Sub Total (Rs)				**Rs 6,351.00**	**Rs 6,588.00**	**Rs 6,351.00**	**Rs 10,862.00**

Non Procedures	Sponsor Qty	OH	Selected Cost	SV1	SV2	SV3	V4	V5	V6	V7	V8	V9	V10	V11a
IRT (dispense for dosing)	21	✔	1,339.00			1,339.00			1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	
Physician's Fees without Exam Costs - Per Visit	31	✔	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00
Study Coordinator/Data Entry Fee - Per Visit	31	✔	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00
Patient Diary Collection, Monitoring, Review, and Dispense - Per Visit	7	✔	1,494.00											
Patient Diary Instruction - Per Visit	1	✔	935.00											
Pharmacy, Complex (e.g. SC Q4W, DBTP,DBEP) - Per Preparation (formerly Per Visit); dispense drug	13	✔	3,421.00			3,421.00			3,421.00	3,421.00	3,421.00	3,421.00	3,421.00	
Randomization (through IRT)	2	✔	1,529.00			1,529.00								
Non Procedures Sub Total (Rs)				Rs 11,569.00	Rs 11,569.00	Rs 17,858.00	Rs 11,569.00	Rs 11,569.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 11,569.00
Overhead (selected costs) 30%				Rs 8,165.40	Rs 10,950.90	Rs 13,797.00	Rs 7,540.50	Rs 9,546.70	Rs 10,893.00	Rs 10,689.90	Rs 14,769.90	Rs 10,397.70	Rs 10,397.70	Rs 13,826.70
Total Cost Per Visit with Overhead(Rs)				Rs 35,383.40	Rs 47,453.90	Rs 59,787.00	Rs 32,675.50	Rs 41,377.70	Rs 47,203.00	Rs 46,322.90	Rs 64,002.90	Rs 45,056.70	Rs 45,056.70	Rs 59,915.70
Total Cost Per Patient (Rs)				Rs 1,267,455.80										

Non Procedures	Sponsor Qty	OH	Selected Cost	V11b	V12	V13	V14	V15	V16	V17	V18a	V18b	V19	V20	V21	V22	V23	V24	V25
IRT (dispense for dosing)	21	✔	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00		1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00	1,339.00
Physician's Fees without Exam Costs - Per Visit	31	✔	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00
Study Coordinator/Data Entry Fee - Per Visit	31	✔	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00
Patient Diary Collection, Monitoring, Review, and Dispense - Per Visit	7	✔	1,494.00									1,494.00	1,494.00	1,494.00	1,494.00	1,494.00	1,494.00	1,494.00	
Patient Diary Instruction - Per Visit	1	✔	935.00									935.00							
Pharmacy, Complex (e.g. SC Q4W, DBTP,DBEP) - Per Preparation (formerly Per Visit); dispense drug	13	✔	3,421.00	3,421.00	3,421.00	3,421.00	3,421.00	3,421.00	3,421.00	3,421.00									
Randomization (through IRT)	2	✔	1,529.00	1,529.00															
Non Procedures Sub Total (Rs)				Rs 17,888.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 16,329.00	Rs 11,569.00	Rs 18,337.00	Rs 14,402.00	Rs 14,402.00	Rs 14,402.00	Rs 14,402.00	Rs 14,402.00	Rs 14,402.00	Rs 12,908.00
Overhead (selected costs) 30%				Rs 7,815.00	Rs 9,738.30	Rs 8,736.00	Rs 11,718.30	Rs 8,233.50	Rs 8,233.50	Rs 14,878.80	Rs 7,181.40	Rs 5,466.90	Rs 9,486.30	Rs 8,125.80	Rs 9,798.30	Rs 8,125.80	Rs 9,360.60	Rs 8,821.10	Rs 13,135.20
Total Cost Per Visit with Overhead(Rs)				Rs 33,807.60	Rs 42,204.30	Rs 37,830.00	Rs 56,766.30	Rs 35,678.50	Rs 38,678.50	Rs 64,474.80	Rs 31,119.40	Rs 23,689.90	Rs 41,107.30	Rs 36,211.80	Rs 42,446.30	Rs 36,211.80	Rs 40,360.60	Rs 37,358.10	Rs 36,919.20

Non Procedures	Sponsor Qty	OH	Selected Cost	FU-0	FU-1	FU-2	FU-3
IRT (dispense for dosing)	21	✔	1,339.00				
Physician's Fees without Exam Costs - Per Visit	31	✔	5,995.00	5,995.00	5,995.00	5,995.00	5,995.00
Study Coordinator/Data Entry Fee - Per Visit	31	✔	5,574.00	5,574.00	5,574.00	5,574.00	5,574.00
Patient Diary Collection, Monitoring, Review, and Dispense - Per Visit	7	✔	1,494.00				
Patient Diary Instruction - Per Visit	1	✔	935.00				
Pharmacy, Complex (e.g. SC Q4W, DBTP,DBEP) - Per Preparation (formerly Per Visit); dispense drug	13	✔	3,421.00				
Randomization (through IRT)	2	✔	1,529.00				
Non Procedures Sub Total (Rs)				**Rs 11,569.00**	**Rs 11,569.00**	**Rs 11,569.00**	**Rs 11,569.00**
Overhead (selected costs) 30%				**Rs 5,376.00**	**Rs 5,447.10**	**Rs 5,376.00**	**Rs 6,729.30**
Total Cost Per Visit with Overhead(Rs)				**Rs 23,296.00**	**Rs 23,604.10**	**Rs 23,296.00**	**Rs 29,160.30**

Invoiceable Items Per Patient

Conditional Procedure	Sponsor Qty	Total	OH	Selected Cost w/o OH	Selected Cost w/OH	Notes/Comments
Genomics consent; DNA consent; Genetics	1	1,306.50	✔	1,005.00	1,306.50	For participation into optional genomics study
Informed Consent for Serum and Plasma for FBR Optional Studies	1	1,904.50	✔	1,465.00	1,904.50	For participation in the serum and plasma, and wearables optiional sub-studies
Skin test, tuberculosis (TB); intradermal, Mantoux screening test, Tuberculin Sensitivity Test, Pirquet test, PPD test for Purified Protein Derivative	1	985.40	✔	758.00	985.40	Optional screening by tuberculin skin test
Venipuncture - Central labs (T-cell interferon gamma and serology (Anti-AChR, anti-LRP4, and Anti-MusK Antibodies) may be performed by central lab, as needed)	1	232.70	✔	179.00	232.70	Performed as needed
Spec Handling - Central labs (T-cell interferon gamma and serology (Anti-AChR, anti-LRP4, and Anti-MusK Antibodies) may be performed by central lab, as needed)	1	767.00	✔	590.00	767.00	Performed as needed
Hepatitis B Surface Antigen (HBsAg)	1	1,270.10	✔	977.00	1,270.10	As needed, per protocol
Hepatitis C antibody (HCV RNA PCR)	1	6,498.70	✔	4,999.00	6,498.70	As needed, per protocol
HIV Test	1	9,436.70	✔	7,259.00	9,436.70	As needed, per protocol
Follicle stimulating hormone (FSH)	1	4,123.60	✔	3,172.00	4,123.60	(If needed for post-menopausal status), as needed
Vaccination/revaccinate for meningococcal infection and against Streptococcus pneumoniae and Haemophilus influenza type B, if needed	3	28,052.70	✔	7,193.00	9,350.90	If needed, per protocol

Conditional Procedure	Sponsor Qty	Total	OH	Selected Cost w/o OH	Selected Cost w/OH	Notes/Comments
Patient Safety Card for Neisseria meningitidis (Replacement Cards)	6	78,195.00	✔	10,025.00	13,032.50	As needed, per protocol
SC Injection Training (as needed)	4	2,303.60	✔	443.00	575.90	As needed, per protocol
Concomitant meds/Treatment	3	2,340.00	✔	600.00	780.00	To be used for follow- up Phone call and unscheduled visits, per protocol
Adverse Events Assessment	3	3,123.90	✔	801.00	1,041.30	To be used for follow- up Phone call and unscheduled visits, per protocol
Physical Exam with Vitals (including Weight, where indicated)	1	2,949.70	✔	2,269.00	2,949.70	To be used for Unscheduled Visit
Venipuncture - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG)	1	232.70	✔	179.00	232.70	To be used for Unscheduled Visit
Special Handling - Central labs for Blood Chemistry, Hematology, INR, Serum Pregnancy, Urinalysis, Immunoglobulin G (IgG)	1	767.00	✔	590.00	767.00	To be used for Unscheduled Visit
Venipuncture - Whole Blood for DNA and RNA Isolation (optional), where indicated	3	698.10	✔	179.00	232.70	For partcipation in optional sub study
Spec Handling - Whole Blood for DNA Isolation (optional) and RNA Isolation (optional), where indicated	3	2,301.00	✔	590.00	767.00	For partcipation in optional sub study
Daily Antibiotics Prophylaxis	31	52,551.20	✔	1,304.00	1,695.20	Daily oral antibiotic prophylaxis recommendation mitigate risk of infection, per protocol

Conditional Procedure	Sponsor Qty	Total	OH	Selected Cost w/o OH	Selected Cost w/OH	Notes/Comments
Drug Administration - Oral	31	42,718.00	✔	1,060.00	1,378.00	Daily oral antibiotic prophylaxis recommendation mitigate risk of infection, per protocol
Pharmacy, Simple (Daily antibiotics prophylaxis) - Per Preparation (formerly Per Visit); dispense drug	31	35,504.30	✔	881.00	1,145.30	Dispense of the daily oral antibiotic
Venipuncture (simple) - Future Research Serum and Plasma (optional)	11	2,559.70	✔	179.00	232.70	For partcipation in optional sub study
Spec Handling - Future Research Serum and Plasma (optional)	11	8,437.00	✔	590.00	767.00	For partcipation in optional sub study
Venipuncture for collection of specimen(s): Serum Pregnancy to confirm a positive urine pregnancy test	25	5,817.50	✔	179.00	232.70	As needed, per protocol.
Lab handling and/or shipping of specimen(s):Serum Pregnancy to confirm a positive urine pregnancy test	25	19,175.00	✔	590.00	767.00	As needed, per protocol
Collection of specimen; urine collection - Central Lab	25	22,392.50	✔	689.00	895.70	As needed, per protocol
Special Lab handling and/or shipping	25	19,175.00	✔	590.00	767.00	As needed, per protocol
Physician's Fees without Exam Costs - Per Visit	2	15,587.00	✔	5,995.00	7,793.50	To be used for Unscheduled and Follow-Up Phone Call Visits, per protocol
Study Coordinator/Data Entry Fees - Per Visit	2	14,492.40	✔	5,574.00	7,246.20	To be used for Unscheduled and Follow-Up Phone Call Visits, per protocol

Conditional Procedure	Sponsor Qty	Total	OH	Selected Cost w/o OH	Selected Cost w/OH	Notes/Comments
Patient Reimbursement - Per Visit (as per the ICF)	31	134,044.00		4,324.00	4,324.00	To be used for scheduled Visit, per protocol
Patient Reimbursement - Per Visit (for unscheduled visits)	1	4,324.00		4,324.00	4,324.00	To be used for Unscheduled Visit, per protocol
Simple Telephone Reminder - To withhold cholinesterase inhibitors for approximately 10 hours prior to their visit, to be resumed after visit assessments are complete	20	27,300.00	✔	1,050.00	1,365.00	Reminder To withhold cholinesterase inhibitors for approximately 10 hours prior to their visit, to be resumed after visit assessments are complete, per prototcol
Simple Telephone Consult/Visit	2	4,469.40	✔	1,719.00	2,234.70	To be used for follow- up Phone call visits, per protocol
Pregnancy reporting	6	15,701.40	✔	2,013.00	2,616.90	Post Safety Follow-up and Follow-up phone call visits , per protocol
Ultrasound, abdomen, abdominal (echography) (uls), real time and image documentation complete: For Interpretation and Report use code R6700.	1	13,893.10	✔	10,687.00	13,893.10	If clinically indicated according to Guidance on Abnormalities in Transaminases and Other Liver Function Tests
Interpretation and Report; Ultrasound, abdomen, abdominal (echography) (uls)	1	3,762.20	✔	2,894.00	3,762.20	If clinically indicated according to Guidance on Abnormalities in Transaminases and Other Liver Function Tests
(INR)	1	1,431.30	✔	1,101.00	1,431.30	If clinically indicated according to Guidance on Abnormalities in Transaminases and Other Liver Function Tests
Viral Serology: Hepatitis B, HBsAG, Hepatitis C,HCV, Human immunodeficiency virus, HIV	1	4,161.30	✔	3,201.00	4,161.30	If clinically indicated according to Guidance on Abnormalities in Transaminases and Other Liver Function Tests
Administer open-label pozelimab and cemdisiran SC Q4W (In OLTP, patients in combination therapy (Q4W) will receive seventeen (17) IP administrations)	17	38,277.20	✔	1,732.00	2,251.60	For patients assigned to combination treatment
Pharmacy, Complex (e.g. SC Q4W, In OLTP, patients in combination therapy (Q4W) will receive seventeen (17) dispensing) - Per Preparation (formerly Per Visit); dispense drug	17	75,604.10	✔	3,421.00	4,447.30	For patients assigned to combination treatment
Administer Open-label cemdisiran 600 mg SC Q12W (patients assigned to cemdisiran monotherapy treatment)	5	11,258.00	✔	1,732.00	2,251.60	For patients assigned to cemdisiran monotherapy treatment
Pharmacy, Complex (e.g. SC Q12W) - Per Preparation (formerly Per Visit); dispense drug	5	22,236.50	✔	3,421.00	4,447.30	For patients assigned to cemdisiran monotherapy treatment

Site Level Other Direct Costs

Site Costs	Sponsor Qty	Total	Selected Cost w/o OH	Selected Cost w/OH	Notes/Comments
Study Start-Up Fee/Site Set-Up Fee	1	55,000.00	55,000.00	55,000.00	One time site payment
Log and File Serious Adverse Event (SAE) Reports/Forms: per Incident	1	5,000.00	5,000.00	5,000.00	One time site payment per each case
Reconsent, Informed consent performed again with the same patient	1	1,465.00	1,465.00	1,465.00	One time site payment
Pharmacy: Set-Up Fee	1	20,000.00	20,000.00	20,000.00	one time site payment
Document Storage, Archiving Total Cost	1	75,000.00	75,000.00	75,000.00	One time site payment

1.Maximum quantity payable per site is the total quantity multiplied by the number of subjects actually enrolled.

2.The parties agree that they will discuss any units that exceed the cap in good faith, leveraging the EDC data. All agreed upon changes must be included in a contract amendment.

3. For time points where only Study Coordinator time is referenced - it is expected that the Study Coordinator will complete all needed data entry.

4. In OLTP, patients in monotherapy (Q12W) will receive five (5) IP administrations.

5. In OLTP, patients in combination therapy (Q4W) will receive seventeen (17)IP administrations.