THIRD PARTY SPONSORED / INVESTIGATOR INITIATED INTERVENTIONNAL TRIAL AGREEMENT

BY AND BETWEEN

NOVARTIS GENE THERAPIES SWITZERLAND GMBH

AND

FUNDACIÓN PÚBLICA ANDALUZA PARA LA GESTIÓN DE LA INVESTIGACIÓN EN SALUD DE SEVILLA

[redacted]

THIRD PARTY SPONSORED / INVESTIGATOR INITIATED TRIAL AGREEMENT

This Third Party Sponsored/**I**nvestigator **I**nitiated Trial Agreement ("**Agreement**") is entered into as of 09th of October 2020("**Effective Date**") between

Novartis Gene Therapies Switzerland GmbH located at [redacted] ("**Novartis Gene Therapies**") and

Fundación Pública Andaluza para la Gestión de la Investigación en Salud de Sevilla, located at [redacted] ("**Sponsor**")

and

Dr Olaf W. Neth located at [redacted] ("**Principal Investigator**").

WHEREAS, the Sponsor has proposed and is willing to undertake a clinical study known as "NEONATAL SCREENING TO THE EARLY DETECTION OF PATIENTS WITH SPINAL MUSCULAR ATROPHY AND INMUNODEFICIENCIES" (the "**Study**"), such Study to be carried out at the Participating Sites;

WHEREAS, the Sponsor has assumed responsibility for the initiation, management and financing of the Study and will be the sponsor of the Study for the purpose of the International Conference on Harmonisation (**I**CH) Guideline for Good Clinical Practice ("**ICH GCP**") and the European Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (the "**EU Clinical Trials Directive**");

WHEREAS, Novartis Gene Therapies is interested in the scientific outcome of the Study; and

WHEREAS, at the Sponsor's request, Novartis Gene Therapies has agreed to provide funding for the Study and provide such information, advice and assistance as may be required during the course of the Study and agreed between the parties on the terms and conditions set out in this Agreement; and

WHEREAS, the Principal Investigator and the Sponsor have agreed to conduct the Study on the terms and conditions set out in this Agreement.

NOW, THEREFORE, the parties have agreed as follows:

1. DEFINITIONS

The following definitions shall apply:

"**Affiliate**" means, with respect to a party, any corporation or other business entity controlled by, controlling or under common control with that party. "**Control**" for the

purposes of this definition shall mean direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in an entity, or such other relationship as, in fact, constitutes actual control.

"**Applicable Laws**" means all laws, regulations, orders and guidelines applicable to the conduct of the Study and the processing of Personal Data, including, *without limitation*, EU Clinical Trials Directive (as defined in the preamble above), General Data Protection Regulation 2016/679, ICH GCP (as defined in the preamble above), and the applicable version of the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.

"**Intellectual Property**" means all patents, design rights (whether registered or unregistered), trademarks, service marks, domain names, trade and business names, publicly available and registered applications for any of the foregoing, copyrights, inventions, Information, trade secrets, know-how and registered database rights including all applications for the same, all extensions and renewals to any of them and publicly available and registered applications for any of them and any right or form of protection of a similar nature and having equivalent or similar effect to any of them which may subsist anywhere in the world.

"**Invention**" means all discoveries, improvements, inventions, new concepts and ideas arising from the Study together with all related results and information.

"**Novartis Gene Therapies Information**" means technical knowledge, know-how, experience, data and business background of a confidential nature provided by Novartis Gene Therapies under this Agreement.

"**Participating Sites**" means any clinical site which is participating in the performance of the Study.

"**Personal Data**" means any information that identifies or can identify a specific individual, that is collected, accessed, received, transmitted, maintained or used directly or indirectly, in connection with the Study.

"**Principal Investigator**" means the individual identified in the header of this Agreement who will be responsible for the direction of the Study in accordance with applicable Sponsor policies.

"**Protocol**" means the Study protocol, a signed copy of which shall be attached at Annex 1, and any amendments thereto.

"**Sponsor**" means an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.

"**Sponsor Intellectual Property**" has the meaning set forth in Section 10.1.

"**Study Data**" means the information that is collected as part of the Study.

"**Subcontractor**" means any party who has been contracted by the Sponsor to perform part of the Study or provide goods or services in support thereof.

"**Third Party**" means a party who agrees to contribute financial or other in-kind support to the sponsor for the study.

2. TERM OF THE AGREEMENT

This Agreement becomes effective on the Effective Date and will remain in effect until the Study has been completed and the Sponsor has provided Novartis Gene Therapies

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with a copy of the final study report, unless terminated earlier pursuant to the provisions of this Agreement.

3. RESPONSIBILITY OF THE SPONSOR

3.1 The Sponsor shall be the sole sponsor of the Study. Prior to initiating the Study, the Agreement shall be fully executed and shall include the final Protocol in Annex 1, which has been previously submitted by the Sponsor in English, to Novartis Gene Therapies for Novartis Gene Therapies' review for the purpose of confirming its scientific soundness. If the Protocol is not in English, the Protocol synopsis in English shall be attached to the Agreement in addition to the Protocol.

3.2 For purposes of the Study, Sponsor shall be the data controller (as defined in GDPR) and is solely responsible for adherence to all data protection laws, as they relate to the Study.

3.3 The Sponsor through the Principal Investigator shall:

(a) Ensure that the Study is conducted in compliance with this Agreement, the Protocol and with all Applicable Laws, including ICH GCP;

(b) Obtain all necessary approvals from an appropriate ethics committee and competent regulatory authorities prior to starting the Study and maintain such approvals for the duration of the Study;

(c) Procure that Participating Sites obtain the written informed consent of each subject or patient enrolled in the Study;

(d) Control the scientific and technical conduct of the Study;

(e) Retain all records resulting from the Study ("**Records**") for the duration required by ICH GCP and other Applicable Laws; and

(f) Be responsible for the management and payment of all Participating Sites and any Subcontractors engaged by the Sponsor.

3.4 Throughout the term of this Agreement, the Sponsor through the Principal Investigator shall allow Novartis Gene Therapies and its agents to visit the facilities where the Study is performed, including third party sites, to audit the facilities and Records, to review documents and to interview relevant personnel, to assure Novartis Gene Therapies that the Study is being and has been conducted in compliance with this Agreement, the Protocol and with all Applicable Laws. Such audit shall take place during normal business hours and upon reasonable advance notice to Sponsor. Novartis Gene Therapies shall notify Sponsor in writing of any observations or findings of non-compliance and the Parties shall agree on corrective action to be implemented, which action shall be implemented at Sponsor's expense. The Sponsor agrees to inform Novartis Gene Therapies through the Principal Investigator immediately in case of an inspection of the Study announced by national or foreign health authorities and to allow any such health authorities to inspect the Records. Auditing by Novartis Gene Therapies or its agents shall be performed in accordance with Applicable Laws.

3.5 The Study shall be carried out under the supervision of the Principal Investigator. In the event that the Principal Investigator ceases to be involved in the Study for whatever reason, the Sponsor agrees to notify Novartis Gene Therapies immediately. Within thirty (30) days after such notification the Sponsor and Novartis Gene Therapies shall agree a successor who has similar clinical expertise and similar experience, and who is acceptable to both parties. The new Principal Investigator shall sign an amendment

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to the Agreement to ensure he or she complies with the terms of the Agreement. The key contacts of Novartis Gene Therapies and the Sponsor for matters related to the Study shall be as specified in **Annex 2** (Key Contacts).

3.6 The Sponsor shall be responsible for the management and payment of all Participating Sites and Subcontractors engaged by the Sponsor. It is the responsibility of the Sponsor to ensure that all work performed by Subcontractors is done in compliance with this Agreement and to provide Subcontractors with all necessary documentation to allow the proper performance of the Study. The Sponsor undertakes to impose on all Subcontractors terms and conditions not less strict than those set out in this Agreement, including, but not limited to provisions contained in Section 3.4 (concerning auditing rights), Section 6 (Publication), Section 8 (Confidentiality), Section 9 (Ownership of Data) including Section 9.3 (concerning Novartis Gene Therapies' access right to the Study Data), Section 10 (Intellectual Property) and Section 27.1(Sponsor's Indemnity Obligations). The Sponsor agrees that to the extent the terms of any current or future executed contract between the Sponsor and any Subcontractor and the terms of this Agreement conflict, the terms of this Agreement shall govern. The Sponsor shall be liable to Novartis Gene Therapies for any breach of those obligations by any Subcontractor.

3.7 The Sponsor shall keep designated Novartis Gene Therapies personnel fully informed of the progress of the Study. In particular, the Sponsor will provide Novartis Gene Therapies half-yearly and at any other time upon Novartis Gene Therapies' written request with progress reports, which will include the following information and any other information that Novartis Gene Therapies may reasonably request:

- general study progress, milestones and overall enrollment/recruitment status in total and per Participating Sites

3.8 The Sponsor through the Principal Investigator shall notify Novartis Gene Therapies of any significant amendment made to the Protocol prior or during the conduct of the Study, and of any non-routine communications with any ethics committee or health authority prior to or during the conduct of the Study. A significant amendment to the Protocol (hereinafter a "**Significant Amendment**") shall be defined as any modification to the Protocol which may impact the conduct of the study, the scientific value of the Study, the potential benefit of the patient or patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects requiring a formal amendment to the Protocol. If, in the Principal Investigator's opinion, it is necessary to make a Significant Amendment to the Protocol during the Study, the Sponsor will immediately inform Novartis Gene Therapies prior to submission to any ethics committee or health authority. If the amendments made to the Protocol substantially change or alter the original proposal approved by Novartis Gene Therapies, Novartis Gene Therapies reserves the right to terminate the Agreement early according to Section 12.2.

3.9 The Sponsor through the Principal Investigator shall provide Novartis Gene Therapies promptly with copies of all interim reports produced during the performance of the Study and shall also provide Novartis Gene Therapies with a copy of the final third party study report ("**TPSR**") produced at the end of the Study which includes a full summary of safety and efficacy information from the Study as soon as the report is finalized preferably within four (4) months from the last visit by the last patient ("**LPLV**") but no later than seven (7) months after completion of the Study. The final study report shall comply with the established principles and standards for the corresponding format according to ICH GCP and shall be in English.

3.10 The Sponsor shall independently prepare and submit publication(s) reporting study results to scientific congress and/or journal. Sponsor shall provide Novartis Gene

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Therapies the publication draft prior to submission/presentation, and the final presented or published version as outlined in Section 6. The final publication shall be provided within twenty-four (24) months from LPLV.

4. RESPONSIBILITY OF NOVARTIS GENE THERAPIES

4.1 Novartis Gene Therapies has agreed to provide financial support for the Study in the maximum amount of **82.570 € (EIGHTY TWO THOUSAND FIVE HUNDRED AND SEVENTY EUROS).** Payment shall be made by Novartis Gene Therapies according to the Payment Plan set forth in Annex 3.

4.2 Payment will be made by Novartis Gene Therapies within sixty (60) days of receipt of invoices from the Sponsor, according to the Payment Plan detailed in Annex 3. Such invoices shall reflect the amounts stated in Section 4.1 and shall bear the reference code: PTR NOVARTIS GENE THERAPIES NETH 2020

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[redacted] No payments other than those explicitly foreseen under Section 4.1 shall be made by Novartis Gene Therapies to the Sponsor with respect to the Study unless agreed in writing (excluding writings exchanged by e-mail). Such agreement must be executed by authorized personnel, must include a specific statement of any fees or costs to be paid and the reasons for payment, and must be attached as an Annex to this Agreement.

5. PUBLIC STATEMENTS

5.1 Each party shall have the right to make public disclosure of its involvement in the Study and any disclosures required by Applicable Laws. The disclosing party will provide the other party with any proposed public statement or press release regarding the Study within a reasonable time prior to the planned disclosure.

5.2 The non-disclosing party shall have the right to give comments and suggestions for modification of such public statements or press releases, and the disclosing party agrees to consider and discuss such comments and suggestions with the other party in good faith. The disclosing party agrees to accept such comments and suggestions to the extent based on confidentiality of information or patent protection concerns. The non-disclosing party will not request more than one (1) month for such review.

5.3 The Sponsor through the Principal Investigator shall register the Study and post Study results on clinicaltrialsregister.eu and/or one or more other online clinical trial registries in accordance and compliance with all Applicable Laws and the requirements and guidelines of each online clinical trial registry on which the Clinical Trial will be posted. Each such posting shall comply with all applicable requirements of this Agreement including, but not limited to, Sections 5 and 8; however, to the extent that Section 5.2 is deemed to require Novartis Gene Therapies' consent for any such posting, such consent is hereby given. Novartis Gene Therapies will not register the Study, nor post Study results on clinicaltrialsregister.eu and/or any other online clinical trial registry.

6. PUBLICATION

6.1 The Sponsor shall independently prepare and submit the study-related publications to scientific congresses and/or journals. Novartis Gene Therapies shall have the right to review a draft of each publication and presentation (including, but not limited to, full manuscripts, abstracts, poster presentations and oral presentations) of results of the Study prior to its submission or disclosure to anyone not affiliated with Novartis Gene Therapies or the Sponsor. A copy of each proposed publication and presentation shall be submitted to Novartis Gene Therapies for review at least thirty (30) business days for manuscripts, and fifteen (15) business days for abstracts, posters and oral presentations prior to such submission or disclosure. If publication is in a language other than English, the Sponsor shall provide Novartis Gene Therapies the abstract in English for Novartis Gene Therapies' review prior to submission and/ or presentation. The Sponsor and the Principal Investigator acknowledge that such right is for the purpose of enabling Novartis Gene Therapies to provide peer input regarding the scientific accuracy of data, verify that proprietary information is not being inadvertently divulged, to secure intellectual property rights (as needed), and to provide any relevant supplementary information prior to submission to congress or journal. In no circumstances will the review be undertaken with the purpose of influencing or amending the reported outcomes and the authors' interpretation of data in the publication.

6.2 At the request of Novartis Gene Therapies, any Novartis Gene Therapies Information contained therein shall be excised from the proposed publication or presentation.

6.3 Novartis Gene Therapies may require any proposed publication or presentation to be delayed for up to four (4) months to enable a patent application to be prepared and filed. The four (4) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis Gene Therapies, whichever is later.

6.4 Novartis Gene Therapies' support must be disclosed in the acknowledgement section of the publication(s).

6.5 In addition, Sponsor shall share with Novartis Gene Therapies a copy of the final publication upon presentation (abstract, poster, oral presentation) and/or a copy of the final journal manuscript.

7. USE OF THE SPONSOR'S OR NOVARTIS GENE THERAPIES' NAME

The Sponsor, the Principal Investigator and Novartis Gene Therapies will, and will cause their Subcontractors and agents to, obtain prior written permission from the relevant party before using the name, symbols and/or marks of the other party in any form of publicity in connection with the Study, according to Section 5. This shall not include documents or legally required disclosure by the Sponsor or Novartis Gene Therapies that identifies the existence of the Agreement.

8. CONFIDENTIALITY

8.1 Novartis Gene Therapies may disclose to the Sponsor certain confidential and proprietary information and materials relating to its business and the Sponsor may disclose to Novartis Gene Therapies certain confidential and proprietary information relating to the Study solely for the purpose of facilitating, supporting and/or conducting such Study. All confidential and proprietary information exchanged by Novartis Gene Therapies and the Sponsor shall constitute "**Information**."

8.2 In consideration of Novartis Gene Therapies' and the Sponsor's disclosure of Information to each other, each recipient agrees that, during the term of this Agreement and for a period of five (5) years from the termination or expiry of this Agreement, it shall retain in confidence the Information belonging to the other, and will prevent disclosure of such Information to third parties and will not use the Information provided by the other party or any of its Affiliates for any purpose other than as provided in this Agreement, without the prior written consent of the disclosing party. These restrictions shall not apply to Information which:

(a) May be communicated to the Sponsor's scientific and/or (institutional) review committee(s) under a similar, appropriate understanding of the confidential nature of the proprietary information supplied and under a similar obligation of confidentiality and non-use as set forth herein;

(b) Is required, but only to the extent necessary to be disclosed, to obtain informed consent from those patients or subjects who are eligible and choose to participate in the Study. Notwithstanding the foregoing, such Information will not be provided in response to unsolicited inquiries by telephone or to individuals who are interested in information about the Study, but not potential Study patients;

(c) At the time of disclosure is or thereafter becomes available to the public through no fault of the receiving party;

(d) As shown by written records, was known to, or was otherwise in the possession of the receiving party or its Affiliate prior to the receipt of such Information from the other party;

(e) As shown by written records, is obtained by the receiving party from a source other than the other party and other than one who would be breaching a commitment of confidentiality to that other party by disclosing the Information to the receiving party; or

(f) As shown by written records, is developed by or on behalf the receiving party or its Affiliates independently of any disclosure made hereunder.

8.3 The Sponsor and Novartis Gene Therapies shall ensure that their employees, Subcontractors, Third Parties and agents and any other persons assisting in the conduct of the Study to whom Information is disclosed are informed of the obligations of confidentiality and non-use under this Agreement and are made subject to the same obligations of confidentiality and non-use as set out herein.

8.4 Notwithstanding anything else in this Section 9, each party shall be permitted to disclose the other party's Information if obliged to do so by the order of a court or Applicable Law, provided that the receiving party notifies the disclosing party of such obligation prior to said disclosure insofar as possible to enable the disclosing party to take reasonable actions to avoid or minimize the degree of such disclosure and such Information is disclosed only to the extent necessary.

8.5 Notwithstanding anything else in this Section 9, Novartis Gene Therapies shall be allowed under conditions not less strict than the conditions set forth under this Agreement to disclose Information belonging to the Sponsor to Novartis Gene Therapies' Affiliates for the purposes of improving the knowledge of the Study subject within Novartis Gene Therapies and its Affiliates.

8.6 Notwithstanding anything else in this Section 9, the Sponsor will not be bound by any obligations of confidentiality where maintaining confidentiality could prejudice patient safety or welfare, or where it is obliged by law to disclose information.

8.7 The obligations set forth in this Section 9 shall survive discontinuation or completion of the Study.

9. OWNERSHIP OF DATA

9.1 The Study Data and all copyrights therein shall be the property of the Sponsor, subject to the rights of Novartis Gene Therapies as specified in Section 11.

9.2 The Sponsor through the Principal Investigator shall ensure that the Study Data are kept in orderly, safe and secure storage in accordance with regulatory requirements for document retention following the local archiving regulations for such data.

9.3 The Sponsor through the Principal Investigator shall grant Novartis Gene Therapies access to all Study Data generated in the course of the Study at no additional cost. Novartis Gene Therapies shall have the right to make copies of the Study Data. Notwithstanding any other provision of this Agreement, Novartis Gene Therapies and its Affiliates and their licensees or sublicensees shall have the right to use the Study Data for all purposes, including, but not limited to, regulatory purposes (including filing), patent purposes, and publication referencing purposes at no additional costs.

9.4 Sponsor through the Principal Investigator shall ensure that patient informed consent identifies all anticipated purposes for use of Study Data and shall ensure patient informed consent permits the sharing of Study Data with Novartis Gene Therapies, its Affiliates and any successors and assigns of either party, including those located outside the European Economic Area. In obtaining and documenting the patient informed consent, Sponsor shall comply with the applicable regulatory requirement(s), and shall adhere to ICH GCP and to the ethical principles as laid out in the Declaration of Helsinki.

10. INTELLECTUAL PROPERTY

10.1 Copyright in the Study Data and any Invention, whether patentable or not, made by the Sponsor, its employees and agents and any other persons assisting with the conduct of the Study arising from the performance of the Study shall be the property of the Sponsor ("**Sponsor Intellectual Property**"). Further uses of the Sponsor Intellectual Property shall be considered in a Separate Agreement with the Servicio Andaluz de Salud.

10.2 Sponsor agrees to, and to cause its employees, agents and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis Gene Therapies to permit Novartis Gene Therapies to obtain the benefit of its rights under this Agreement.

10.3 Sponsor shall ensure that the Principal Investigator and the Sponsor's employees, agents and collaborators involved in the Study will comply with its obligations under this Agreement.

11. STATUS OF THE PARTIES

Each party is acting hereunder as an independent contractor. No provision of this Agreement shall be deemed to constitute any party as the agent, employee, partner, joint venture, or legal representative of any other party for any purpose whatsoever. No party is granted any express or implied right or authority to assume, or to create, any

obligation or responsibility, or to execute any agreements or to make any commitments verbally or in writing for or on behalf of, or in the name of, any other party in any manner or thing whatsoever without that other party's express written consent.

12. TERMINATION

12.1 This Agreement may be terminated by either party for any reason upon not less than thirty (30) days' written notice as long as permitted under applicable law; otherwise, this Agreement may be unilaterally terminated by either party upon written notice to the other party for serious medical, scientific or safety reasons.

12.2 Either party may also terminate this Agreement with immediate effect in the event that (a) the other party commits a material breach and fails to remedy such breach within thirty (30) days from the receipt of a notice informing the breaching party of its failure to comply with its obligations under this Agreement or any of the Annexes, or (b) as per Section 3.8.

13. CONSEQUENCES OF TERMINATION

13.1 Upon termination of Novartis Gene Therapies' involvement in this Agreement for whatever reason all Novartis Gene Therapies Information shall be returned to Novartis Gene Therapies, subject to any regulatory and ethical requirements.

13.2 In case of termination by the Sponsor according to Section 12.1or 12.2, the Sponsor will provide Novartis Gene Therapies with access to all Study Data including computer data files as well as any relevant software and source codes to enable Novartis Gene Therapies to retrieve and satisfactorily access all computerized data. For purposes of this clause, Personal Data is excluded from the obligation of disclosure. In addition, as long as permitted under applicable law, the Sponsor shall provide Novartis Gene Therapies with an abbreviated TPSR or abbreviated final report. Furthermore, Sponsor shall submit the study-related publications based on Study Data obtained before termination to scientific congresses and/or journals and Novartis Gene Therapies shall have the right to review the draft(s) in accordance to the section 6 of the Agreement. Finally, pursuant to Section 17 of the Agreement, termination by the Sponsor will not affect all the rights and obligations which are intended to survive termination of this Agreement.

13.3 Upon the effective date of termination according to Sections 12.1 or 12.2, the Sponsor shall conduct an accounting report, subject to verification and approval by Novartis Gene Therapies. Within thirty (30) days after receipt of adequate documentation setting forth the results of such accounting, Novartis Gene Therapies will make payment to the Sponsor (in no event exceeding the difference between the maximum amount specified in Section 4.1 and the total amount paid previously by Novartis Gene Therapies to the Sponsor under or in connection with this Agreement) for:

(a) All Study activities properly rendered and costs properly incurred by the Sponsor according to the terms of this Agreement up to the effective date of termination and not yet paid for; and

(b) Reasonable non-cancelable commitments properly incurred by the Sponsor for the conduct of the Study prior to receipt of notice of termination.

13.4 In case of termination by Novartis Gene Therapies due to Sponsor's material breach, Novartis Gene Therapies shall owe no further payment to the Sponsor.

13.5 The Sponsor will refund to Novartis Gene Therapies within thirty (30) days following the termination date any funds advanced to it but not expended or irrevocably committed by the Sponsor prior to the date of termination.

14. WARRANTIES

14.1 The Sponsor represents and warrants to Novartis Gene Therapies that it is not a party to any agreement which would prevent it from fulfilling its obligations under this Agreement and that during the term of this Agreement the Sponsor will not enter into an agreement to undertake studies which would in any way restrict its ability to undertake the Study or fulfill its obligations under this Agreement.

14.2 The Sponsor warrants and represents to Novartis Gene Therapies that it has the full right and authority to enter into this agreement, and that it is not aware of any impediment which would inhibit its ability to perform the terms and conditions imposed on it by such agreement.

14.3 The Sponsor warrants and represents to Novartis Gene Therapies that the Sponsor's policies applicable to the performance of the Study are consistent with the terms of this Agreement and Protocol.

14.4 For the purpose of transparency, and to ensure Novartis Gene Therapies is providing adequate funding, Sponsor shall disclose to Novartis Gene Therapies any other funding received from a Third Party to undertake the Study, and as the case may be, Sponsor shall disclose the amounts received from the other supporting party. Sponsor shall disclose this information to Novartis Gene Therapies along with the request for support.

15. DISCLAIMER

Any advice furnished by Novartis Gene Therapies and/or its Affiliates is given free of charge and Novartis Gene Therapies and/or its Affiliates assumes no obligation or liability for the advice given or the results obtained and any such advice shall not constitute a warranty as to any matter, all such advice being given and accepted at the recipient's risk.

16. NOTICE

Any notice required or permitted hereinunder shall be in writing and shall be deemed given as of the date it is (a) delivered by hand or (b) sent by registered or certified mail, postage prepaid, return receipt request, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

If to Novartis Gene Therapies:

Medical Matter:

Contract Matters:

If to Sponsor:

Medical Matters:

Administrative Matters:

17. SURVIVAL

Except where explicitly provided elsewhere herein, termination of this Agreement for any reason, or expiration of this Agreement, will not affect: (a) obligations, including the payment of any sums which have accrued as of the date of termination or expiration, and (b) rights and obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement.

18. ENTIRE AGREEMENT

This Agreement (together with any documents referred to herein) constitutes the entire and only agreement and understanding between the parties with respect to its subject matter and supersedes any previous agreements, understandings, or arrangements between the parties in respect of the Study (whether oral or written). Any claimed representation, promise or condition in connection with the subject matter of the Agreement that is not incorporated herein shall not be binding upon any party. No modification, extension, waiver, or other variance of any provision hereof, or any release of any right hereunder, shall be valid or binding unless the same is in writing and signed by all parties. In the event of any conflict between the operative provisions of this Agreement and the Annexes hereto, the operative provisions of this Agreement shall govern.

19. AMENDMENT

This Agreement and the Protocol may be extended, renewed or otherwise amended at any time by the mutual written consent of parties hereto.

20. FORCE MAJEURE

Neither the Sponsor nor Novartis Gene Therapies shall incur any liability to any other party in the event of non-performance or delay in the performance of its obligations hereunder if caused directly or indirectly by strikes, lockouts, riots, sabotage, act of war or piracy, destruction of essential equipment by fire, explosion, storm, flood, earthquake, failure of power supplies or transport facilities, failure of agents, or sub-contractors or any other event or circumstances whatsoever beyond the reasonable control of the party liable to perform for a period equal to any such non-performance or delay. However, the party affected shall use all reasonable endeavours to limit the amount of non-performance or delay in performance of its obligations hereunder.

21. WAIVER

The failure of a party at any time to require full or partial performance of any provisions of this Agreement will not affect in any way the full right of that party to require that performance subsequently. Any waiver of a breach of this Agreement must be in writing signed by the party granting the waiver.

22. SEVERABILITY

Any provision of this Agreement which is declared void or unenforceable by any competent authority or court shall to the extent of invalidity or enforceability be deemed severable and not affect the provisions of this Agreement which shall continue unaffected.

23. ASSIGNMENT

Neither party may assign its rights and obligations under this Agreement without the other party's prior written consent, except that Novartis Gene Therapies may (a) assign

its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the parties and their respective successors and permitted assigns.

24. NO TRANSFER OF PROPRIETARY RIGHTS NOT SPECIFIED

It is agreed that neither Novartis Gene Therapies nor the Sponsor transfers to the other by operation of this Agreement any patent right, copyright, or other proprietary right of either party, except as specifically set forth herein.

25. LIABILITY

Subject to the provisions of Section 27.2, the Sponsor as the Sponsor of the Study shall be liable for all damages incurred by a patient arising out of the performance of the Study.

26. INSURANCE

26.1 The Sponsor as the sponsor of the Study agrees to take out adequate clinical trial insurance or make alternative arrangements as is necessary and required by applicable regulatory requirements to cover its obligations as Sponsor of the Study including, but not limited to, providing full compensation (including indirect losses) to participants in the Study suffering injury or death or loss caused by the administration of drugs or any clinical intervention or procedure in accordance with the relevant Protocol and all legal requirements laid down by local regulations.

26.2 Upon Novartis Gene Therapies' request the Sponsor shall provide evidence of such insurance or alternative arrangement.

27. INDEMNIFICATION

27.1 The Sponsor agrees to indemnify and hold harmless Novartis Gene Therapies, its Affiliates and their respective employees, directors, officers, representatives, sub-contractors, and agents from and against any loss, damages, liabilities, reasonable costs and expenses (including reasonable attorney's fee and expenses), incurred in connection with any claim, proceeding, or investigation arising out of this Agreement and of this Study, except to the extent as provided under Section 27.2.

27.2 Novartis Gene Therapies agrees to indemnify and hold harmless the Sponsor and its employees, directors, officers, representatives, sub-contractors and agents from and against any loss, damages, liabilities, reasonable costs and expenses (including reasonable attorney's fee and expenses) incurred in connection with any claim, proceeding, or investigation arising out of this Agreement (hereinafter referred to as "**Claims**") to the extent that such Claims arise from the willful wrongful act or omission or the negligence of Novartis Gene Therapies.

28. LAW AND JURISDICTION

This Agreement shall be governed by, and construed in accordance with, the substantive laws of Spain without regard to the conflict of law provisions thereof. For the purpose of any dispute which cannot be resolved amicably, the parties submit to the exclusive jurisdiction of the ordinary courts of Madrid, Spain.

[redacted]

IN WITNESS WHEREOF, the parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

Novartis Gene Therapies Switzerland GmbH

[redacted]

Name: Micheline Wille

Title: Head EMEA Medical Affairs

[redacted]

Title: EMEA Head SME, Gene Therapy

[redacted]

FISEVI

[redacted]

Name: José Cañón Campos

Title: Managing Director

[redacted]

Acknowledged and agreed:

[redacted]

Olaf W. Neth

Principal Investigator

[redacted]