

**SUPPLY AGREEMENT
FOR THE DELIVERY OF ZOLGENSMA**

This Agreement ('Agreement') is between:

Fakultní nemocnice v Motole, a State contributory organisation, Registered office: V Úvalu 84, 150 06 Prague 5 – Motol, Id. No.: 00064203, Tax Id. No.: CZ00064203 (Hospital)

and

Novartis Gene Therapies EU Limited, Block B, The Crescent Building, Northwood, Santry, Dublin 9, The Republic of Ireland ('Novartis Gene Therapies'),

hereafter referred to jointly as the 'Parties' and individually as the 'Party'.

This Agreement was concluded in conformity with Act No. 134/2016 Coll., on public procurement, as amended (hereinafter the "Public Procurement Act") and in conformity with Section 2079 *et seq.* of Act No. 89/2012 Coll., the Civil Code, as amended, and on the basis of public contract No. VZ0106713- titled "FN Motol - ONASEMNOGENUM ABEPARVOVECUM (146/20)".

Both Parties represent that they enjoy legal personality, full legal capacity and, based on mutual negotiations and agreement, they enter into this Supply Agreement.

THE PARTIES AGREE THE FOLLOWING:

1. SUBJECT OF THE AGREEMENT.

During the Term of the Agreement Novartis Gene Therapy shall sell and supply to Hospital the product Zolgensma® (hereinafter, the "Product") packaged in the form of a box containing vials corresponding to the weight of the patient in accordance with the Order Form (Annex 3) issued by the Hospital.

2. PRICE OF THE PRODUCT.

All prices shall be quoted and invoiced in Czech Krona (CZK).

Notwithstanding the dispositions of Annex 1, section 4, after Novartis Gene Therapy confirms that the price established in the RFQ issued for each patient shall be valid and maintained until such Order is completed.

Prices are designated and treated as a business secret. The Hospital shall not provide information to third parties concerning unit price of the Product, except when legally required.

3. TERM OF THE AGREEMENT

This Agreement takes effect as of the signing of this Agreement and will remain in effect for the period of two (2) years (Initial Term). At the end of the Initial Term, upon mutual written agreement, the Parties may renew this Agreement, in whole or in part, for a **Renewal Term** not to exceed the Initial Term.

4. GENERAL PROVISIONS.

4.1. Entire Agreement. This Agreement (including the documents referred to herein) constitutes the entire agreement among the Parties and supersedes any prior understandings, agreements, or representations by or among the Parties, written or oral, to the extent they related in any way to the subject matter hereof.

4.2. Hierarchy of Documents. Notwithstanding what may be established in the Annexes of this Agreement or any other documents relating to this Agreement, in the event of any conflict between the provisions of this Agreement and Annexes negotiated either prior to or subsequent to this Agreement, the order of precedence is as follows:

- i. The present Agreement;
- ii. Annex 1 - General Terms and Conditions of Sale;
- iii. Annex 2 - Novartis Gene Therapies Order Cancellation and Product Return Policy (Europe, Middle East, Africa ("EMEA") Region);
- iv. Annex 3 - Novartis Gene Therapies Order Form.

4.3. Amendments and Clarifications. The parties agree upon Annex amendments and clarifications, as follows:

4.3.1. On the subject of Annex 1:

- It is hereby clarified that for the purpose of Annex 1, the Hospital is designated as "Buyer".
- Amendment to clause 1.3 of Annex 1. Clause shall be replaced by the following: Orders as per clause 1.4 hereunder are accepted and Novartis Gene Therapies Products are supplied only on condition that the Buyer is validly authorised to administer the Novartis Gene Therapies Product, or cause the Novartis Gene Therapies Product to be administered. In this sense, in order to allow Novartis Gene Therapies to comply with its obligations as holder of a wholesale dealer license, or a manufacturer's license, or as distributor and supplier of medicinal products to statutory or public health authorities (e.g. in Ireland, the Health Service Executive ('HSE')) or to others, or to comply with its obligations as employer of employees who provide services and support to customers of Novartis Gene Therapies, or to comply with the requirements of applicable law, the Seller shall, on its own costs and with 5 days in-advance written notification, and only in serious and well-grounded cases, have the right to audit whether the Buyer complies with the provisions of this Agreement. The Buyer shall provide the Seller with necessary cooperation and allow access to relevant materials and documents or Products in accordance with

applicable laws. The Seller may appoint third person to perform the audit. The Buyer shall accept the appointment and shall provide the third person with the same cooperation as the Seller shall be entitled to under this Agreement, provided the third party shall be committed by the Seller to confidentiality with regard to Confidential Information of both Parties. In case the audit reveals the breach of this Agreement by the Buyer, the Seller is entitled to compensation of costs of the audit.

- Amendment to clause 1.8 of Annex 1: The place of delivery of the Product to the Hospital (DAP) will be hospital pharmacy of FN Motol, Department of cytostatic central preparation and this will be stated on each Order Form (Annex 3).
- It is hereby clarified that section 2.1, sixth sentence of Annex 1 is to be understood as follows: “the Buyer shall bear the entire risk of damage or loss as from the moment of delivery at the place of destination DAP”.
- Amendment to clause 2.1 of Annex 1: The sentence “Without prejudice to this, Novartis Gene Therapies reserves the right to charge the Buyer for delivery, of an amount determined by Novartis Gene Therapies at the point of processing of an order” shall not apply to this Agreement.
- Amendment to clause 2.2 of Annex 1: Title and ownership in the Novartis Gene Therapies Products shall pass to the Buyer upon delivery at the place of destination DAP.
- Amendment to clause 2.5 of Annex 1: This clause shall not apply.
- Amendment to clause 3.2. of Annex 1: The following shall be added to this section: “The Audit shall be conducted in the terms established in section 1.3.”.
- Amendment to clause 4 of Annex 1: All prices shall be quoted and invoiced in Czech Krona (CZK).
- Amendment to clause 5.1 of Annex 1: Invoices are due for payment within 60 days of the invoice date.
- Amendment to clause 6.2. of Annex 1: The Buyer must notify Novartis Gene Therapies within twenty four (24) hours after the invoice date if a partial delivery occurs, failing which no credit will be considered. No claims for non-delivery of containers (i.e. cartons, delivery cages or pallets) will be accepted if the carrier’s consignment note has been signed as complete upon or after delivery. For the avoidance of doubt, invoice will only be issued after delivery.
- It is hereby clarified that section 18.1 of Annex 1 is to be understood as follows: The notices that imply an urgent delivery can be given by e-mail to ensure a rapid response but must also be delivered by hand or by first class post, in the timelines established in each appropriate clause.

4.3.2. On the subject of Annex 2:

- It is hereby clarified that for the purpose of Annex 2, the Hospital shall be designated as a “Novartis Gene Therapies EU Authorised User”.
- It is hereby clarified that in case of a potential return of the Product under Section 2 of Annex 2 the email contact at the Hospital regarding Product quality is [REDACTED] head of control department of hospital pharmacy of FN Motol.
- Addition to clause 2.6 of Annex 2 - *Issuance of Product Credit/Refund*: In the case of an authorised Return, Novartis Gene Therapies will work with the Hospital to determine the most appropriate remedial action (replacement or credit/refund).
- Amendment to clause 2.6.2.1 of Annex 2 - *Amount of Credit/Refund*: The amount of Credit/Refund will be the actual price paid by Hospital for the Product carton returned.

4.4. Assignment. Novartis Gene Therapies may assign rights under this Agreement to its affiliated companies at any time without the consent of Hospital.

4.5. Severability. If any part of this agreement is declared unenforceable or invalid, the remainder will continue to be valid and enforceable.

5. GOVERNING LAW AND DISPUTE RESOLUTION.

The interpretation, construction and performance of this Agreement shall be governed by and construed in accordance with the laws of Czech Republic. Any claim or dispute arising (including non-contractual disputes or claims) in connection with this Agreement on its subject matter or formation shall be subject to the exclusive jurisdiction of the Czech Courts, without restricting any right of appeal. The Applicability of the CISG is excluded. Place of jurisdiction shall be Prague.

In case of inconsistency between the English language and the Czech language version of this Agreement, the English language version shall prevail.

IN WITNESS WHEREOF, the Parties have signed this Agreement in duplicate, effective from the latest date of signature below.

By Novartis Gene Therapies EU Limited:

Signature: [REDACTED]

Name: [REDACTED]

By Hospital:

Signature: [REDACTED]

Title: 

Date: _____

Signature: 

Name: 

Title: 

Date: _____

Name: _____

Title: _____

Date: _____

Signature: _____

Name: _____

Title: _____

Date: _____

Annex 1

General Terms and Conditions of Sale

Annex 2

Novartis Gene Therapies Order Cancellation and Product Return Policy (Europe, Middle East, Africa (“EMEA”) Region)

Annex 3

Novartis Gene Therapies Order Form

GENERAL CONDITIONS OF SALE effective from 15 May 2020 (“Conditions”)

1. GENERAL

- 1.1 Unless otherwise agreed in writing with a statutory director of Novartis Gene Therapies EU Limited (“**Novartis Gene Therapies**”), these Conditions shall apply with effect from 15 May 2020 to any and all requests and orders for the sale by Novartis Gene Therapies to any Buyer (as defined below) of gene therapy medicinal products offered for sale by Novartis Gene Therapies or its affiliates which are individualized to each patient and therefore cannot be sold other than for administration to such patient (“**Novartis Gene Therapies Products**”). A “**Buyer**” is any statutory or public health authority, hospital or other healthcare or health treatment center (whether established by trust or otherwise) or a person, company or other legal entity acting as an Novartis Gene Therapies wholesaler or distributor, which has been pre-authorized by Novartis Gene Therapies in accordance with the Novartis Gene Therapies Order Cancellation and Product Return Policy as an Novartis Gene Therapies Authorised User to place an electronic or other order with Novartis Gene Therapies for use of Novartis Gene Therapies Products.
- 1.2 All Novartis Gene Therapies Products marketed by Novartis Gene Therapies are sold subject to these Conditions, which (together with the Novartis Gene Therapies Order Cancellation and Product Return Policy) shall be the sole terms and conditions of any sale of Novartis Gene Therapies Products unless Novartis Gene Therapies states otherwise. These Conditions will prevail at all times over any terms and conditions on any order form, form of contract, invoice, or any other contractual terms of the Buyer, and any communication sent by the Buyer to Novartis Gene Therapies. The placing of an order for, or the acceptance of, Novartis Gene Therapies Products by the Buyer shall indicate unqualified acceptance of these Conditions. All sales of Novartis Gene Therapies Products are made pursuant to these Conditions, which together with the latest European Novartis Gene Therapies Order Cancellation and Product Return Policy and the order form a contract between Novartis Gene Therapies and the Buyer for the sale and purchase of Novartis Gene Therapies Products (“**Contract**”).
- 1.3 Orders as per clause 1.4 hereunder are accepted and Novartis Gene Therapies Products are supplied only on condition that the Buyer is validly authorised to administer the Novartis Gene Therapies Product, or cause the Novartis Gene Therapies Product to be administered, or deal and/or supply Novartis Gene Therapies Products in Europe by way of wholesale or distribution. In order to allow Novartis Gene Therapies to comply with its obligations as holder of a wholesale dealer licence, or a manufacturer’s licence, or as distributor and supplier of medicinal products to statutory or public health authorities (e.g. in Ireland, the Health Service Executive (‘HSE’)) or to others, or to comply with its obligations as employer of employees who provide services and support to customers of Novartis Gene Therapies, or to comply with the requirements of applicable law, the Buyer shall permit Novartis Gene Therapies, its representatives and any competent regulatory authority upon prior written notification to the Buyer and during regular business hours, or at a mutually convenient time agreed between the parties, the right to access, inspect and audit any site from which an order for Novartis Gene Therapies Products has been issued/sent or where Novartis Gene Therapies Products are to be stored (including any of the Buyer’s depots or sub-depots), delivered or otherwise handled, prior to considering or accepting an order that it has received from the Buyer. Such audit includes the right for Novartis Gene Therapies, its representatives and any competent regulatory authority to inspect and take copies of all records and permits, licences or other data relating to a Buyer or to the Novartis Gene Therapies Products. The Buyer shall, and shall procure that its employees, directors, staff, agents and sub-contractors shall fully cooperate with Novartis Gene Therapies and its representatives with respect to such audit. In the event of shortages or anticipated shortages of Novartis Gene Therapies Products, Novartis Gene Therapies shall be entitled at its discretion as a supplier of Novartis Gene Therapies Products, or otherwise at its discretion to be promptly provided with a copy of any information that is relevant to the order, including copy of anonymised prescriptions, licences and permits that the Buyer may hold, anonymised sales data and of any other documents or data that Novartis Gene Therapies considers necessary for Novartis Gene Therapies to determine whether any order may be considered partly or fully accepted. In providing such information and data, the Buyer must take all steps to comply with applicable laws, professional conduct obligations and with industry best practice and codes of conduct.
- 1.4 The minimum order quantity per order of Novartis Gene Therapies Products that may be placed with Novartis Gene Therapies is one (1) dose of the Novartis Gene Therapies Products. Novartis Gene Therapies Products shall, where available, be delivered with a one (1) month unexpired shelf life at the time of delivery to the Buyer, and in accordance with Novartis Gene Therapies’ standard selling unit. Novartis Gene Therapies Products must be used within fourteen (14) days of delivery to the Buyer. Orders must be placed in writing, either in electronic format to the e-mail address listed below, or if in paper format, to the address listed below.
- 1.5 Subject to availability of Novartis Gene Therapies Products, and to Novartis Gene Therapies’ right to reject or vary orders, or to cease supply of Novartis Gene Therapies Products by notice, orders processed by Novartis Gene Therapies shall be legally binding upon the Buyer and the Buyer shall be liable to pay for Novartis Gene Therapies Products as documented in Novartis Gene Therapies’ invoice to the Buyer. Any cancellation of orders is subject to the terms of, and must be carried out in accordance with, the Novartis Gene Therapies Order Cancellation and Product Return Policy, as may be amended from time to time.
- 1.6 Novartis Gene Therapies reserves the right at any time at its sole discretion to reject orders upon or after receipt, and not to process orders after receipt. Novartis Gene Therapies may also at its discretion give not less than thirty (30) days’ notice in writing to the Buyer that Novartis Gene Therapies shall no longer supply them with any Novartis Gene Therapies Products (and during such period of notice Novartis Gene Therapies may supply such Novartis Gene Therapies Products for orders which it has processed in accordance with the Conditions). Novartis Gene Therapies may vary these Conditions at any time by giving not less than thirty (30) days’ notice.
- 1.7 All materials and equipment which Novartis Gene Therapies supplies to the Buyer as part of the delivery of Novartis Gene Therapies Products, including but not limited to pallets and containers (“**Novartis Gene Therapies Equipment**”) will remain the property of Novartis Gene Therapies and are to be returned to Novartis Gene Therapies. The Buyer shall return undamaged to Novartis Gene Therapies any Novartis Gene Therapies Equipment within ten (10) days after the delivery date of Novartis Gene Therapies Products, failing which Novartis Gene Therapies shall be entitled to invoice an additional amount in respect of such pallets or containers in accordance with clause 5.
- 1.8 Novartis Gene Therapies Products shall be delivered to the address stated in the order form (noting that all Novartis Gene Therapies Products are to be delivered to inside the site of care as indicated in the order form and not to a receiving dock or similar location) and the signature at such address, of an employee or agent or other person purporting to act on behalf of the



Buyer, on Novartis Gene Therapies' or its nominees' delivery note, shall be conclusive proof of delivery of Novartis Gene Therapies Products in accordance with the Contract.

- 1.9 In these Conditions, the words and phrases "other", "including" and "in particular" shall not limit the generality of any preceding words or be construed as being limited to the same class as the preceding words where a wider construction is possible.

2. DELIVERY, TITLE AND RISK

- 2.1 Novartis Gene Therapies sells and delivers Novartis Gene Therapies Products on the basis of DAP (Delivered At Place) Incoterms 2020 ("**Incoterms**") as amended by these Conditions. In the event of any conflict between the Incoterms and these Conditions, the terms of these Conditions shall prevail. All times, dates or periods given for the delivery of Novartis Gene Therapies Products are estimates only and times shall not be of the essence. Novartis Gene Therapies will coordinate just-in-time shipment of the Novartis Gene Therapies Product for a specific patient to the Buyer after (a) completion by the Buyer of Novartis Gene Therapies' pre-authorization process and (b) receipt of an order from the Buyer for the relevant Novartis Gene Therapies Product. Novartis Gene Therapies shall use reasonable efforts to supply by agreed delivery dates, but shall not otherwise incur any liability whatsoever for any suspension or delay nor any loss or damage resulting from suspension or delay howsoever caused. The Buyer bears all risk of loss or damage at the time of delivery at the named place of destination. Novartis Gene Therapies and its nominees are responsible for carriage, transport and insurance in accordance with the Incoterms and for providing outer packaging suitable for delivery to the named place of destination. Without prejudice to this, Novartis Gene Therapies reserves the right to charge the Buyer for delivery, of an amount determined by Novartis Gene Therapies at the point of processing of an order.

- 2.2 Title and ownership in the Novartis Gene Therapies Products shall pass to the Buyer upon signature and receipt of delivery.

- 2.3 Until such time as title and ownership in Novartis Gene Therapies Products passes to the Buyer, the Buyer agrees to:

- 2.3.1 hold the Novartis Gene Therapies Products as Novartis Gene Therapies' fiduciary agent and bailee and to keep such Novartis Gene Therapies Products separate from those of the Buyer and third parties and properly stored, protected, insured and identified as Novartis Gene Therapies' property and not mix them with any other goods;
- 2.3.2 not pledge or allow any encumbrance, lien, charge or other interest to arise or be created over the Novartis Gene Therapies Products; and
- 2.3.3 not dispose of or deal with the Novartis Gene Therapies Products or any documents of title relating to them or any interest in them, except that, when the Buyer is a wholesaler or distributor, the Buyer may without prejudice to clause 2.2, on its own account, sell the Novartis Gene Therapies Products in the ordinary course of its business.

- 2.4 Novartis Gene Therapies shall have an action for the price of the Novartis Gene Therapies Products notwithstanding that title in the Novartis Gene Therapies Products has passed.

- 2.5 The Buyer irrevocably authorises and grants, and shall procure that its affiliates and sub-contractors authorise and grant to Novartis Gene Therapies its servants or agents an irrevocable licence to enter the Buyer's and its affiliates and sub-contractors premises, or any other premises over which the Buyer and its affiliates and sub-contractors has control or access in order to recover, take possession and/or to resell all Novartis Gene Therapies Products for which the Buyer has not made payments of the invoice price which may be due to Novartis Gene Therapies or of which Novartis Gene Therapies retains ownership. The Buyer and its affiliates and sub-contractors shall take all reasonable steps to help Novartis Gene Therapies recover the Novartis Gene Therapies Products. Demand for, or recovery of, the Novartis Gene Therapies Products shall not of itself discharge the Buyer's liability to pay the whole price or any other rights of Novartis Gene Therapies.

- 2.6 If any sums owing to Novartis Gene Therapies are overdue, Novartis Gene Therapies, its servants or agents shall be authorised by the licence granted by the Buyer under clause 2.5, to enter the Buyer's premises to recover, take possession and to resell all Novartis Gene Therapies Products in which title has not passed to the Buyer. The Buyer shall not purport to set off or withhold any payment claimed or due from Novartis Gene Therapies under any contract.

- 2.7 If the Buyer fails to make any payment to Novartis Gene Therapies when due, compounds with its creditors, executes an assignment for the benefit of its creditors, has a bankruptcy order made against it or being a company, enters into voluntary or compulsory liquidation or has an administrator or administrative receiver or receiver appointed over all or part of its assets or takes or suffers any similar action in consequence of debt or becomes insolvent or if Novartis Gene Therapies has reasonable cause to believe that any of these events is likely to occur:

- 2.7.1 the Buyer irrevocably authorises and grants, and shall procure that its affiliates and sub-contractors authorise and grant to Novartis Gene Therapies its servant or agents an irrevocable licence to enter without prior notice any premises where Novartis Gene Therapies Products are stored, and to re-possess and dispose of any Novartis Gene Therapies Products that are in the possession of the Buyer;
- 2.7.2 the Buyer's right to sell or otherwise dispose of Novartis Gene Therapies Products shall terminate immediately;
- 2.7.3 Novartis Gene Therapies shall have the right to withhold delivery of any Novartis Gene Therapies Products ordered; and
- 2.7.4 any and all sums unpaid in respect of Novartis Gene Therapies Products shall become immediately due and payable.

3. BUYERS' OBLIGATIONS

- 3.1. All stocks of Novartis Gene Therapies Products in possession of the Buyer shall be stored in compliance with the storage conditions as described in the product Marketing Authorisation and associated documentation including the Patient Information Leaflet. The Buyer will at all times maintain any and all licences, authorisations and registrations required by applicable law permitting it to take possession of, and/or hold and/or store and/or wholesale deal, and/or distribute and/or to administer and/or supply Novartis Gene Therapies Products in any manner (as applicable) in Europe (collectively, "**Licences**") and shall promptly

provide evidence of such Licences to Novartis Gene Therapies on request. When the Buyer is a wholesaler or distributor, the Buyer will additionally comply with all applicable laws and relevant good distribution practice legislation to ensure that the quality and integrity of Novartis Gene Therapies Products is maintained throughout the supply chain and will, for the avoidance of any doubt, only be entitled to sell or distribute the Novartis Gene Therapies Product to the specific sub-Buyer(s) in charge of




administering the Novartis Gene Therapies Product to the patient for which it has been specifically provided. For the avoidance of any doubt, when the Buyer is a statutory or public health authority, hospital or other healthcare or health treatment center, the Buyer will not be entitled to resell the Novartis Gene Therapies Product which may only be used for administration to the patient for which it has been specifically provided.

- 3.2 Without prejudice to clause 1.3, the Buyer shall permit Novartis Gene Therapies and its representatives upon prior written notification to the Buyer and during regular business hours, or at a mutually convenient time agreed between the parties, the right to access, inspect and audit any site where the Novartis Gene Therapies Products are stored (including any of the Buyer's depots or sub-depots) for the purpose of ensuring that the Buyer is complying with applicable law and the terms of the Contract. The Buyer shall, and shall procure that its employees, directors, staff, agents and sub-contractors shall fully cooperate with Novartis Gene Therapies and its representatives with respect to such audit. Such audit includes the right to inspect and take copies of all records and documents relating to the Novartis Gene Therapies Products stored at any such site.
- 3.3 In all correspondence the Buyer must quote the order number quoted by Novartis Gene Therapies and where required by Novartis Gene Therapies, must also quote the manufacturer's batch number of Novartis Gene Therapies Products.
- 3.4 In submitting orders to Novartis Gene Therapies, the Buyer warrants that in ordering Novartis Gene Therapies Products for wholesale or distribution, the Buyer will comply with the requirements contained in Article 81 (2nd paragraph) of Directive 2001/83/EC, as amended (on the Community code relating to medicinal products for human use) as same is transposed in the local law of the Buyer's jurisdiction.
- 3.5 The Buyer will, and will procure that its officers, employees and agents will:
- 3.5.1 comply with, and not breach, or commit an offence under, any laws relating to anti-bribery or corruption, including the Criminal Justice (Corruption Offences) Act 2018, the UK Bribery Act ("**UK BA**"), "The Convention against Bribery of Foreign Public Officials in International Business Transactions" of the Organization for Economic Cooperation and Development ("**OECD Convention**"), the U.S. Foreign Corrupt Practices Act ("**US FCPA**") and the French Loi n° 2016-1691 of 9 December 2016 ("**Loi Sapin 2**"), as amended, as well as similar applicable laws of the country where Buyer has its principal place of business and where it conducts activities under the Contract (collectively "**Anti-Corruption Laws**"), and to take no action that might cause itself or Novartis Gene Therapies and its affiliates to be in violation of Anti-Corruption Laws; as well as comply with any applicable Novartis Gene Therapies anti-corruption policy, as updated from time to time;
- 3.5.2 promptly notify Novartis Gene Therapies of and keep accurate records showing, all payments made and received and all other advantages given and received in connection with the Contract and the steps taken to comply with this clause 3.5, and permit Novartis Gene Therapies or its designees to inspect and take copies of those records as reasonably required; and
- 3.5.3 promptly notify Novartis Gene Therapies of any breach of this clause 3.5.
- 3.6 Before reaching final user, the Buyer will not alter the Novartis Gene Therapies Product packaging without Novartis Gene Therapies' consent. Specifically, Novartis Gene Therapies Product packaging is not to be opened and Novartis Gene Therapies Product is not to be removed from its carton. However, the carton may be removed from the shipping container so long as the Novartis Gene Therapies Product is maintained on dry ice at all times and the removal from shipping container does not alter the Novartis Gene Therapies Product labelling, except to add a prescription label to the Product, if required by applicable law.

4. PRICE

All prices for Novartis Gene Therapies Products shall be subject to alteration without prior notification, in compliance with applicable price-setting regulation, *if any*. All prices are quoted in € (Euro) and are exclusive of VAT or any other applicable tax levied on purchase of Novartis Gene Therapies Products. Novartis Gene Therapies Products will be invoiced at prices applicable as at the date of processing of an order on Novartis Gene Therapies systems. All prices shall be rounded to the nearest two (2) decimal places.

5. PAYMENT

- 5.1. Invoices are due for payment on the due date specified in the invoice issued by Novartis Gene Therapies with a delivery of Novartis Gene Therapies Products or if no due date is stated on the invoice, within thirty (30) days of the invoice date. Unless otherwise agreed in writing with a statutory director of Novartis Gene Therapies, payment must be made by electronic transfer, and reach Novartis Gene Therapies' account, as cleared funds, no later than on the due date specified in the invoice issued by Novartis Gene Therapies for Novartis Gene Therapies Products.
- 5.2. If the Buyer fails to make payment on the due date, Novartis Gene Therapies shall be entitled, without prejudice to any other rights it may have, to:
- 5.2.1 cancel the Contract or suspend any further deliveries to the Buyer;
- 5.2.2 appropriate any payment made to the Buyer to such of Novartis Gene Therapies Products as Novartis Gene Therapies may think fit; and
- 5.2.3 charge the Buyer interest on the amount unpaid until payment in full is made at the rate provided for by of five percent (5%) per annum above the European Central Bank (ECB) marginal lending facility rate from time to time calculated on a daily basis (and compounded on a monthly basis). Buyer may forward a remittance advice by email  All remittances should be sent direct to: Finance Department, Novartis Gene Therapies EU Limited, Block B, The Crescent Building, Northwood, Santry, Dublin 9, Ireland

6. DAMAGE, LOSS, SHORTAGE, OVER-DELIVERY OR NON-DELIVERY OF PRODUCTS, RECALL

- 6.1 Buyer shall inspect the Novartis Gene Therapies Product upon receipt at Buyer's facility and shall notify Novartis Gene Therapies of (i) any shortage or over-delivery of a shipment, a temperature reading that is out of range, any damage upon visual inspection of the Novartis Gene Therapies Product packaging or damage to the shipment container, in writing to Novartis Gene Therapies

within two (2) hours of receipt of the delivery, or (ii) any latent Novartis Gene Therapies Product carton defect within one (1) hour of discovery of the relevant latent defect. If the Product shipment container is damaged, the Buyer must retain the complete packaging in the state, condition and location in which they were delivered for inspection by Novartis Gene Therapies and/or



the carrier service, failing which no credit will be considered and the Buyer shall contact the carrier service customer service or local agent location to provide a back-up shipment container preconditioned. The Buyer shall furnish a description of the damage along with a photograph to Novartis Gene Therapies. All damaged Novartis Gene Therapies Product and packaging must be returned to Novartis Gene Therapies on dry ice pellets the same day following receipt of instructions and return authorisation from Novartis Gene Therapies' designated contact.

- 6.2 The Buyer must notify Novartis Gene Therapies within twenty four (24) days after the invoice date if non-delivery of a whole consignment occurs, failing which no credit will be considered. No claims for non-delivery of containers (i.e. cartons, delivery cages or pallets) will be accepted if the carrier's consignment note has been signed as complete upon or after delivery.
- 6.3 All returns of Novartis Gene Therapies Products are subject to the terms of, and must be carried out in accordance with, the Novartis Gene Therapies Order Cancellation and Product Return Policy, as may be amended from time to time. Notwithstanding the foregoing: (a) Novartis Gene Therapies will exercise the discretion afforded to it pursuant to the Novartis Gene Therapies Order Cancellation and Novartis Gene Therapies Product Return Policy in a reasonable manner, and (b) any Novartis Gene Therapies Product that is not ultimately dispensed or administered due to a reasonable determination by Novartis Gene Therapies or the Buyer that such Novartis Gene Therapies Product is unsafe for receipt, dispensing or administration shall be deemed eligible for return for purposes of the Novartis Gene Therapies Order Cancellation and Novartis Gene Therapies Product Return Policy except where the relevant Novartis Gene Therapies Product is determined to be unsafe for such purposes as a result of the Buyer's, its affiliates' or its subcontractors' negligence, willful misconduct or noncompliance with the terms of this Contract. For purposes of this provision, Novartis Gene Therapies' designated carrier service will not be considered a subcontractor of the Buyer.
- 6.4 Buyer shall use reasonable efforts to cooperate with Novartis Gene Therapies in the investigating of any Novartis Gene Therapies Product issue that resulted in the need for a recall and any reasonable, and duly documented costs involved with such investigation will be paid by Novartis Gene Therapies except that the Buyer shall pay the reasonable and duly documented costs of any such investigation to the extent arising out of or resulting from the Buyer's negligence, willful misconduct, or material breach of this Agreement.

7. INTELLECTUAL PROPERTY

- 7.1 Nothing in these Conditions shall be construed as granting or implying the grant of any licence under any intellectual property rights including patents, registered trademarks, registered designs, utility models, applications for and rights to apply for any of the foregoing; unregistered design rights, unregistered trademarks, rights to prevent passing off, database rights, topography rights and any other rights in any invention, discovery or process in each case whether registered or unregistered, held by Novartis Gene Therapies anywhere in the world and Novartis Gene Therapies shall be entitled to exercise such rights to the fullest extent legally permissible at the time of such exercise.
- 7.2 Unless this is necessary for the purpose of resale in Europe, no trademarks of which Novartis Gene Therapies (or any of its affiliates or associates) are proprietors or authorised users shall be applied to any goods originally supplied by Novartis Gene Therapies (or any such affiliate or associate) on removal from their original container. Unless this is necessary for the purpose of resale in Europe, if a trademark is affixed on Novartis Gene Therapies Products when originally supplied by Novartis Gene Therapies such trademark shall not be altered, partly removed or partly obliterated.
- 7.3 Novartis Gene Therapies gives no warranty or representation that Novartis Gene Therapies Products do not infringe any patent, trademarks, registered designs or other intellectual property rights of any third party anywhere in the world.

8. TERMINATION/SUSPENSION

- 8.1 Without affecting any other rights and remedies it might have, Novartis Gene Therapies shall be entitled to terminate the Contract and/or suspend its performance at any time without liability to the Buyer by giving written notice to the Buyer at any time if the Buyer:
- 8.1.1 is in breach of any provision of, or purports to cancel, the Contract;
- 8.1.2 has any corporate action, application, order, proceeding or appointment or other step taken or made by or in respect of it for any composition or arrangement with creditors generally, winding-up, other than for the purpose of a bona fide scheme of solvent reconstruction or amalgamation, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, or if it is unable to pay its debts as they fall due, or if it ceases to trade or if a distress, execution or other legal process is levied against any of its assets, or if any event analogous to any of the foregoing shall occur in any jurisdiction in which the Buyer is incorporated, resident or carries on business;
- 8.1.3 no longer holds any Licences necessary for it to take possession of and/or hold and/or store and/or wholesale deal and/or distribute and/or administer and/or supply Novartis Gene Therapies Products.
- 8.2 Any termination however caused shall not affect:
- 8.3.1 any right or liabilities which have accrued prior to the time of termination;
- 8.3.2 the continuance in force of any provision of the Contract which expressly or by implication is intended to come into or continue in force after termination including without limitation clauses 5, 7, 9-14 inclusive and clauses 16-17 inclusive.

9. INDEMNITY

The Buyer shall indemnify and hold Novartis Gene Therapies, its affiliates, as well as Novartis Gene Therapies' and its affiliates' officers, directors and employees harmless from and against any losses, claims, costs, expenses, damages or demands for any, direct or indirect or consequential loss, or for any loss of profit, revenue or anticipated savings and professional costs (on a full indemnity basis) arising in contract or in tort, negligence or otherwise (and whether or not the Buyer has advised Novartis Gene Therapies of the possibility of such loss or damage), arising out of or in connection with (i) any failure by a Buyer (or its servant or agents) to comply with law, with these Conditions, or with the Contract, or (ii) any negligence of the Buyer (or its servant or agents) in respect of the Novartis Gene Therapies Products including any use of the Novartis Gene Therapies

Products outside the terms and conditions of their marketing authorisations or equivalent licences and/or use outside their intended purposes, or; (iii) any use or sale of any products manufactured or otherwise used or deployed by the Buyer and incorporating or used in conjunction with Novartis Gene Therapies Products.



10. **FORCE MAJEURE**

Neither party shall be liable for any loss, damage, claim or breach due to circumstances beyond its reasonable control, including but not limited to acts of God, fire, strikes, lockouts, deliberate damage, shortage of materials or power, accidents and breakdowns of plant or machinery or prohibition or restriction by a competent authority, government imposed change (“**Event of Force Majeure**”). If an Event of Force Majeure continues for more than a period of thirty (30) days, Novartis Gene Therapies shall be entitled at its discretion and without liability to perform, suspend performance of, and/or terminate the Contract.

11. **ENFORCEABILITY, WAIVER, CUMULATIVE REMEDIES**

- 11.1 If any part of the Conditions is held to be unenforceable or illegal for whatsoever reason, such unenforceability or illegality shall not affect the validity or enforceability of any or all of the remaining conditions.
- 11.2 Any failure to exercise or delay by Novartis Gene Therapies in exercising a right or remedy arising in connection with the Contract shall not constitute a waiver of such right or remedy or of any other rights or remedies.
- 11.3 These rights and remedies are cumulative and (subject as otherwise provided) are not exclusive of any right or remedy provided by law. No exercise by Novartis Gene Therapies of any one right or remedy shall (save unless expressly provided otherwise) operate so as to hinder or prevent the exercise by it of any other right or remedy.

12. **LAW AND DISPUTES**

The interpretation, construction and performance of these Conditions shall be governed by and construed in accordance with the law of Ireland. Any claim or dispute arising (including non-contractual disputes or claims) in connection with these Conditions on their subject matter or formation shall be subject to the exclusive jurisdiction of the Irish Courts, without restricting any right of appeal.

13. **WARRANTY AND LIABILITY**

- 13.1 Novartis Gene Therapies warrants that Novartis Gene Therapies Products are manufactured with all reasonable care and skill and where applicable comply with the standard specifications set out in Novartis Gene Therapies' current published literature and that Novartis Gene Therapies Products are of satisfactory quality.
- To the extent permitted by law, all other conditions, warranties or obligations whether express or implied by statute, common law or otherwise and relating to Novartis Gene Therapies Products and/or any packaging or containers are excluded.
- 13.2 Novartis Gene Therapies shall only be liable to the Buyer in respect of claims notified to Novartis Gene Therapies in accordance with these Conditions and in particular clause 6 of these Conditions.
- 13.3 Notwithstanding any other provision of the Conditions but subject to clauses 13.4 to 13.5, Novartis Gene Therapies shall have no liability arising out of or in connection with the Contract or the products for (a) any loss of or damage to profit, revenue, anticipated savings, data, use, contract, goodwill, opportunities or business or (b) any indirect or consequential loss or damage, whether or not Novartis Gene Therapies has been informed of such loss or damage, or (c) any claim arising out of a claim against the Buyer by any third party, in each case, however arising.
- 13.4 Nothing in these Conditions shall limit or exclude any liability or any remedy arising from any fraudulent misrepresentation or any other fraudulent act or omission by or on behalf of any party to the Conditions or to the extent prohibited by law.
- 13.5 Nothing in these Conditions shall limit or exclude Novartis Gene Therapies' liability for the death or personal injury resulting from negligence or any other liability which cannot be limited or excluded by law.
- 13.6 Subject to clauses 13.3, 13.4 and 13.5, the aggregate liability of Novartis Gene Therapies for any claims arising out of or in connection with the Contract, the Novartis Gene Therapies Products or these Conditions however arising (and whether asserted by the Buyer on its behalf or on behalf of third parties) shall be limited to, and in no circumstances shall exceed, the total invoice price of the Novartis Gene Therapies Products in respect of which the claim relates and the transport costs identified in clause 2.1 less any discount given and excluding VAT.
- 13.6 The term “however arising” when used or referred to in this clause 13 shall cover all causes and actions giving rise to liability of Novartis Gene Therapies arising out of or in connection with these Conditions, the Contract or the Novartis Gene Therapies Products: (i) whether arising by reason of any misrepresentation (whether made prior to and/or in the Contract), negligence, breach of statutory duty, other tort, repudiation, renunciation or other breach of contract, restitution or otherwise; (ii) whether arising under any indemnity; (iii) whether caused by any total or partial failure or delay in supply of Novartis Gene Therapies Products or by any defect in materials; and (iv) whether deliberate (but not with malicious intent) or otherwise, however fundamental the result.



14 THIRD PARTY RIGHTS

- 14.1 All members of the Novartis Gene Therapies Group and all employees, agents and subcontractors of Novartis Gene Therapies and members of the Novartis Gene Therapies Group (each being a “**Third Party**”, together “**Third Parties**”) shall each be entitled, in its own right to enforce every defence and limitation expressed to be in favour of Novartis Gene Therapies under these Conditions and the Contract to the extent determined by Novartis Gene Therapies in its absolute discretion from time to time, as if such defences and limitations were expressed to be for the benefit of the relevant Third Party. Also, each member of the Novartis Gene Therapies Group shall be entitled in its own right to enforce, all indemnities in these Conditions and the Contract expressed to be in favour of Novartis Gene Therapies to the extent determined by Novartis Gene Therapies in its absolute discretion from time to time, as if such indemnities were expressed to be for the benefit of the relevant members of the Novartis Gene Therapies Group. The Buyer and Novartis Gene Therapies shall not be required to notify or obtain the consent of any Third Party in order to rescind or vary the Contract or any provision of it. The aggregate liability of all Third Parties and Novartis Gene Therapies collectively shall be no greater than the liability of Novartis Gene Therapies alone, as set out in the Contract. No Third Party may assign or otherwise transfer any of their rights referred to in this clause 14. For these purposes “**Novartis Gene Therapies Group**” means Novartis Gene Therapies and any group undertaking of Novartis Gene Therapies from time to time. (Group undertaking in this regard means the holding company in the Novartis Gene Therapies Group, being Novartis Pharma AG and any company or undertaking which is a subsidiary of that holding company from time to time.)
- 14.2 Without prejudice to the above, Novartis Gene Therapies reserves the right to include other members of the Novartis Gene Therapies Group as a party to the Contract via the order form.

15. ASSIGNMENT/SUBCONTRACTING

- 15.1 Novartis Gene Therapies may perform any of its obligations or exercise any of its rights under the Contract itself or through any other member of the Novartis Gene Therapies Group, provided that any act or omission of any such other member shall be deemed to be the act or omission of Novartis Gene Therapies.
- 15.2 Novartis Gene Therapies may at any time assign, transfer, charge or deal in any other manner with any of its rights hereunder and may sub-contract any or all of its obligations under the Contract.
- 15.3 The Buyer shall not assign, transfer, charge, hold on trust for another or deal in any other manner with any of its rights or obligations under the Contract, or purport to do so, or sub-contract any or all of its obligations under the Contract without the prior written consent of Novartis Gene Therapies, which consent it may exercise in its absolute discretion.

16. DATA PROTECTION

- 16.1 Each party is a Data Controller of Protected Data and shall comply with the obligations imposed on Data Controllers under Data Protection Legislation. Nothing in these Conditions shall prohibit or otherwise restrict a party from complying with such obligations.
- 16.2 The Data Recipient shall notify the Data Discloser:
- 16.2.1 without undue delay and in any event within seven (7) days upon receiving a subject access or other request from a Data Subject concerning Protected Data disclosed to the Data Recipient, or if the Data Recipient receives any other claim, complaint or allegation relating to Protected Data disclosed to the Data Recipient; and
- 16.2.2 without undue delay and in any event within forty-eight (48) hours upon becoming aware of or having reasonable cause to suspect any breach of security leading to the destruction, loss or unlawful disclosure of Protected Data disclosed to the Data Recipient, and shall provide all details of the data breach as is required under applicable Data Protection Legislation,
- and in each case the parties shall co-operate with each other in handling such an event and provide reasonable assistance to the other in the discharging of their respective duties under Data Protection Legislation.
- 16.3 Each party shall (at its own cost) assist the other in complying with its obligations as Data Controller including by providing reasonable assistance, information and cooperation as required by Data Protection Legislation to the other party and, if appropriate, to Data Subjects.
- 16.4 The Buyer shall indemnify, keep indemnified, hold harmless and keep held harmless Novartis Gene Therapies and its affiliates against all losses, claims, damages, liabilities, fines, sanctions, interest, penalties, costs, charges, expenses, compensation paid to Data Subjects, demands and legal and other professional costs (calculated on a full indemnity basis and in each case whether or not arising from any investigation by, or imposed by, a regulator) arising out of or in connection with any breach by the Buyer of its obligations under this clause 16.
- 16.5 For the purposes of this clause 16:
- 16.5.1 “**Data Controller**” has the meaning given to that term (or to the term ‘controller’) in Data Protection Legislation;
- 16.5.2 “**Data Discloser**” means the party disclosing Protected Data to the other party;
- 16.5.3 “**Data Protection Legislation**” means any applicable law that is from time to time in force relating to data protection, privacy and the processing of Personal Data, including: (i) the Data Protection Act 2018; (ii) the European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011; (iii) the General Data Protection Regulation (EU) 2016/679; and (iv) any corresponding or equivalent national laws or regulations to any of the above and any applicable laws replacing, amending, extending, re-enacting or consolidating any of the above from time to time;
- 16.5.4 “**Data Recipient**” means the party receiving Protected Data from the other party;
- 16.5.5 “**Data Subject**” has the meaning given to that term in Data Protection Legislation;
- 16.5.6 “**Personal Data**” has the meaning given to that term in Data Protection Legislation; and
- 16.5.6 “**Protected Data**” means any Personal Data received by the Data Recipient from or on behalf of the Data Discloser and processed by the Data Recipient in connection with this Agreement.



17. CONFIDENTIALITY

- 17.1 Each party will, subject to clause 17.2:
- 17.1.1 only use the other party's Confidential Information (as defined below) for the purpose of performing its obligations under the Contract;
 - 17.1.2 keep the other party's Confidential Information secret and secure; and
 - 17.1.3 not disclose the other party's Confidential Information to any other person.
- 17.2 As an exception to the above, each party may only disclose the other party's Confidential Information:
- 17.2.1 to the extent required by law; and
 - 17.2.2 to those of its directors, employees and professional advisers who need access to that Confidential Information in order to perform its obligations under the Contract provided such persons are under obligations of confidentiality equivalent to those set out in this clause 17.
- 17.3 For the purposes of this clause 17, "**Confidential Information**" means the terms of the Contract, the Novartis Gene Therapies Product and any information that relates to a party (or any of its group companies or businesses) and which is disclosed to the other party in connection with the Contract, but excluding information that:
- 17.3.1 is at the relevant time in the public domain (other than by virtue of a breach of this clause 17); or
 - 17.3.2 was received by the other party from a third party who did not acquire it in confidence.

18. NOTICE

- 18.1 Any notice given under or in connection with the Contract shall be in writing (but not email) and: (a) delivered by hand; or (b) delivered by first class post, to:
- 18.1.1 in the case of Novartis Gene Therapies, the address detailed below marked for the attention of the Finance Director; and
 - 18.1.2 in the case of the Buyer, the address detailed in the order form marked for the attention of the person listed in that order form.
- 18.2 Any notice given in accordance with this clause shall be deemed to have been served: (a) if delivered by hand, at the time of delivery; and (b) if sent by post or airmail, three (3) Working Days after the date of posting. "**Working Days**" for the purpose of these Conditions are days when Novartis Gene Therapies' offices in Dublin, Ireland are open for business.
- 18.3 This clause 18 shall not apply to the service of any proceedings or other documents in a legal action.
- 18.4. Novartis Gene Therapies reserves the right to amend these Conditions at any time. The amended conditions will be communicated to the Buyer subject to observance of a reasonable notice period prior to their effective date and shall apply to all future contracts between Novartis Gene Therapies and the Buyer.



Novartis Gene Therapies EU Limited
Registered Office: Block B, The Crescent Building, Northwood, Santry, Dublin 9, Ireland
Registered in Ireland, company number 556811



**NOVARTIS GENE THERAPIES EU LIMITED CANCELLATION AND PRODUCT RETURN POLICY
(Europe, Middle East, Africa (“EMEA”) Region)**

Novartis Gene Therapies EU Limited hereafter referred to as Novartis Gene Therapies EU reserves the right to change the Order Cancellation and Product Return Policy at any time at its sole discretion.

Unless specifically prohibited by applicable laws, Novartis Gene Therapies EU Order Cancellation and Product Return Policy (“Policy”) takes precedence in the EMEA region over all other cancellation or return of goods policies from, but not limited to, distributors, wholesalers, pharmacies, retailers, clinics, hospitals and sites of care (“Novartis Gene Therapies EU Authorised Distributor(s)”). This Policy is the current Novartis Gene Therapies EU policy for order cancellation and product return of ZOLGENSMA® (“Product”) where Novartis Gene Therapies EU is the Marketing Authorisation Holder (MAH). This policy relates to product purchased directly from Novartis Gene Therapies EU or from a Novartis Gene Therapies EU Authorised Distributor by entities qualified and authorised by Novartis Gene Therapies EU to distribute, dispense or administer Product (“Novartis Gene Therapies EU Authorised Users”). Product returns will not be accepted from any entities other than Novartis Gene Therapies EU Authorized Users, and **PRODUCT IS SOLD UNDER A POLICY OF NO ORDER CANCELLATION OR NO PRODUCT RETURN**, except as otherwise set forth herein.

In the interests of clarity i) the order cancellation policy provided in Section 1 below will apply where an Novartis Gene Therapies EU Authorised User has ordered Product from Novartis Gene Therapies EU or Novartis Gene Therapies EU Authorised Distributor but the order has not been delivered by Novartis Gene Therapies EU directly or on behalf of the Authorised Distributor to a Novartis Gene Therapies EU designated courier service for shipment; ii) the Product return policy provided in Section 2 applies after Novartis Gene Therapies EU has shipped the Product with a Novartis Gene Therapies EU designated courier service.

1 ORDER CANCELLATION


1.1 Cancellation Policy

A Product order is validly cancelled only if this cancellation is completed in accordance with the cancellation process described below. The Novartis Gene Therapies EU Authorised Distributor will not charge the Novartis Gene Therapies EU Authorized User for the cost of a Product order validly cancelled in accordance with the Policy in this Section.

1.2 Cancellation Process

Product orders may be cancelled at any time prior to the time at which the Product order is delivered by Novartis Gene Therapies EU, on behalf of the Novartis Gene Therapies EU Authorised Distributor, to Novartis Gene Therapies EU designated courier service for shipment (as determined by Novartis Gene Therapies EU). To request a cancellation, a Novartis Gene Therapies EU Authorised User must follow the procedure provided in Section 1.2.1.

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(Europe, Middle East, Africa (“EMEA”) Region)**

- 1.2.1 Promptly contact Novartis Gene Therapies EU via email at  and, if applicable, request that the Product shipment be stopped prior to the time at which the Product order is delivered by Novartis Gene Therapies EU.

2 PRODUCT RETURN

2.1 General

Product is non-returnable and not eligible for replacement or credit/refund except as set forth in this Policy. Product may be eligible for return and replacement or credit/refund, as may be applicable, if all of the following criteria are met.

- 2.1.1 Product must satisfy the requirements set forth in Section 2 of this Policy or otherwise be ineligible under this Policy.
- 2.1.2 Product must have been purchased by a Novartis Gene Therapies EU Authorised User directly with proof of purchase supplied by the returning party upon request by Novartis Gene Therapies EU or its agent or designee.
- 2.1.3 Before returning Product, Novartis Gene Therapies EU Authorised User must obtain related written confirmation directly from Novartis Gene Therapies EU as stated below in Section 2.5 (Return Process).
- 2.1.4 Product must be returned in accordance with the procedure provided in Section 2.5 below (Return Process) in the original packaging with carton label intact and fully readable, this includes bar code, lot number and expiration date.

2.2 Local Destruction

Local destruction is not generally permitted by Novartis Gene Therapies EU however with prior agreement with Novartis Gene Therapies EU and at no cost to Novartis Gene Therapies EU local destruction may be permissible under the guidance of Novartis Gene Therapies EU.


2.3 Product Eligible for Return and Replacement or Credit/Refund

Product is eligible for return and replacement or credit/refund for the reasons set forth below, as determined by Novartis Gene Therapies EU, only where the return request has been made **prior to infusion** and where the requirements of Section 2 have been satisfied, as applicable. **For the avoidance of doubt, a site of care that is qualified and authorised by Novartis Gene Therapies EU to administer the Product but does not purchase the Product (a “Non-Purchasing Site of Care”) shall not have any rights to replacement Product or credit/refund from Novartis Gene**

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Therapies EU under this Policy, but should work directly with the Novartis Gene Therapies EU Authorised User from which it obtained the Product to obtain any replacement Product or credit/refund that may be applicable. Non-Purchasing Sites of Care are not considered “Authorised Users” for purposes of this Policy.


2.3.1 Damaged Product

2.3.1.1 Damage discovered by Novartis Gene Therapies EU Authorised User: The Novartis Gene Therapies EU Authorised User should contact Novartis Gene Therapies EU at  promptly following receipt, or, in the case of concealed damage, discovery of Product damaged during shipment from Novartis Gene Therapies EU.

2.3.1.2 Damage discovered by Non-Purchasing Site of Care: Where damage is discovered by a Non-Purchasing Site of Care, the Non-Purchasing Site of Care should report the damage directly to the Novartis Gene Therapies EU Authorised User from which it obtained the Product for administration to the patient. The Novartis Gene Therapies EU Authorised User shall then notify Novartis Gene Therapies EU in accordance with the above subsection 2.3.1.1.

2.3.1.3 Follow up: Novartis Gene Therapies EU Quality Assurance team will reach out to the Authorised User to review details and may request photos to determine if the Product is fit for use or eligible for replacement or credit/refund.

2.3.2 Product Temperature Excursions

2.3.2.1 Temperature Excursion Suspected: The Novartis Gene Therapies EU Authorised User must contact Novartis Gene Therapies EU at  promptly following receipt of Product with respect to which a temperature excursion during transportation from Novartis Gene Therapies EU is suspected. As per procedure, Novartis Gene Therapies EU Quality Assurance will perform a Release for Application step before Zolgensma® is permitted to be used, this involves a documented assessment of the temperature profile throughout the distribution chain to ensure product is fit for use.

2.3.2.2 Follow up: Novartis Gene Therapies EU Quality Assurance team will contact the Authorised Distributor or User in relation to the temperature assessment as described in section 2.3.2.1 and determine if the Product is fit for use or eligible for replacement or credit/refund.

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2.3.3 Product Quality Issues

2.3.3.1 Quality Issue Suspected by Novartis Gene Therapies EU Authorised User: The Novartis Gene Therapies EU Authorised User must contact Novartis Gene Therapies EU at NovartisGeneTherapiesEU@novartis.com and provide all relevant details promptly following receipt of Product by Novartis Gene Therapies EU Authorised User that is suspected to be rendered unusable and eligible for replacement due to quality reasons related to the manufacturing of the.

2.3.3.2 Quality Issue Suspected by Non-Purchasing Site of Care: Where a suspected quality issue is discovered by a Non-Purchasing Site of Care, the Non-Purchasing Site of Care should report the suspected quality issue to the Novartis Gene Therapies EU Authorised User from which it received the Product for administration to the patient. The Novartis Gene Therapies EU Authorised User shall then notify Novartis Gene Therapies EU in accordance with the above subsection 2.3.3.1.

2.3.4 Otherwise Unusable Product

The Novartis Gene Therapies EU Authorised User must contact Novartis Gene Therapies EU at NovartisGeneTherapiesEU@novartis.com with respect to any Product that an Authorised representative of the applicable site of care—whether the site of care is an Novartis Gene Therapies EU Authorised User or a Non-Purchasing Site of Care—determines is no longer needed for any reason not described above (e.g., the prescribed patient’s health status has deteriorated to a point where Product can no longer be safely administered to the patient, Product was subsequently not infused due to patient death prior to infusion or Product was ordered in error but not cancelled in time as per Section 1 of this Policy).

2.4 Return Request

If a Product is unusable for reasons described in Section 2.3 of this Policy, the Authorised User may request to return the Product (where applicable) through the process described below, and Novartis Gene Therapies EU will determine whether to provide replacement Product or credit/refund.

2.5 Return Process

The Novartis Gene Therapies EU Authorised User must adhere to all Novartis Gene Therapies EU instructions relating to storing and handling of the product to be returned.

<p style="text-align: center;">NOVARTIS GENE THERAPIES EU LIMITED CANCELLATION AND PRODUCT RETURN POLICY (Europe, Middle East, Africa (“EMEA”) Region)</p>

2.5.1 Initial Approval and Verification

Novartis Gene Therapies EU will evaluate each request to ensure that it meets the requirements of this Policy and may require additional verification from the Novartis Gene Therapies EU Authorised User and/ or the Novartis Gene Therapies EU Authorised Distributor before approving the request.

2.5.2 Confirmation from Novartis Gene Therapies EU

If the request for Product replacement or credit/refund is approved by Novartis Gene Therapies EU in its sole discretion, the Novartis Gene Therapies EU Authorised User must return the entire Product carton, including all contents to Novartis Gene Therapies EU through Novartis Gene Therapies EU designated courier within that timeframe as a condition of receiving consideration for any replacement, credit or refund hereunder, as may be applicable.

2.5.3 Return of Product

The entire original Product carton, including all contents must be returned to Novartis Gene Therapies EU as a condition of any replacement or credit/refund hereunder. Novartis Gene Therapies EU will coordinate with the Novartis Gene Therapies EU Authorised User for the return of Product for replacement, and for the Novartis Gene Therapies EU-designated courier service to pick up items for return delivery back to Novartis Gene Therapies EU. **Only Novartis Gene Therapies EU’ designated courier is authorised to transport returned Product back to Novartis Gene Therapies EU.** It is the returning party’s responsibility to securely package all return goods to prevent breakage during transit and otherwise to comply with laws and regulations applicable to the packaging, shipping, and transport of return goods shipments. Dominion, title and risk of loss relating to returned Products shall pass from the Novartis Gene Therapies EU Authorised User to Novartis Gene Therapies EU at the time the Novartis Gene Therapies EU designated courier service accepts the package for return delivery. Novartis Gene Therapies EU designated courier service will return the Product to:

Almac Pharma Services (Ireland) Ltd.
Finnabair Industrial Estate,
Dundalk,
Co. Louth, A91 P9KD
Ireland

2.5.4 Information to Accompany Returns

Returns of Novartis Gene Therapies EU Product must include packing list containing the following information:

- Name and address of facility returning Product
- Phone Number

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- Returning pharmacy location or site of care, as applicable, name and address
- Reason for return
- Batch number and expiry date
- Additional information upon request from Novartis Gene Therapies EU.

2.5.5 Shipping Costs

Novartis Gene Therapies EU pays the designated couriers service charges related to Product returns and replacements. Any payments in connection with returned goods are limited to those set forth in this Policy, and Novartis Gene Therapies EU Authorised Users are specifically prohibited from separately charging Novartis Gene Therapies EU or deducting costs from any payment to Novartis Gene Therapies EU, if applicable, associated with the administration, shipping, or handling of returns.

2.5.6 Final Approval

Final confirmation of eligibility for return, refund, credit or replacement will be made by Novartis Gene Therapies EU after receipt of the returned Product, and any Novartis Gene Therapies EU-required documentation. Novartis Gene Therapies EU reserves the right to accept or reject the Product for credit, refund or replacement, as may be applicable.

2.6 Issuance of Product Credit/Refund

For returns accepted under this Policy for credit or refund

2.6.1 Product Not Yet Paid for by Novartis Gene Therapies EU Authorised User

Where the Novartis Gene Therapies EU Authorised User has not yet paid Novartis Gene Therapies EU or Novartis Gene Therapies EU Authorized Distributor for the Product, Novartis Gene Therapies EU will work directly or with its Authorised distributor to cancel any outstanding invoice related to the returned Product. No separate credit or refund shall be paid to the Novartis Gene Therapies EU Authorised User in connection with the return.

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2.6.2 Product Paid In Full by Novartis Gene Therapies EU Authorised User

2.6.2.1 Amount of Credit/Refund: Where the Product has been paid for in full by the Novartis Gene Therapies EU Authorised User, a credit or refund amount will be issued in accordance with Section 2.6.2.2 based on the lower of (i) the Wholesale Acquisition Cost (“WAC”) applicable at the time of purchase by the Novartis Gene Therapies EU Authorised User for the Product carton returned, less any applicable discounts, or (ii) the actual price paid by the Novartis Gene Therapies EU Authorised User for the Product carton returned. Should Novartis Gene Therapies EU be unable to verify the amount as set forth above, the amount shall be subject to valuation by Novartis Gene Therapies EU at its sole discretion. Novartis Gene Therapies EU reserves the right to determine whether a credit or refund mechanism will be used in connection with any eligible return.

2.6.2.2 Payment of Credit/Refund: A Product credit or refund, as may be applicable, will be payable by Novartis Gene Therapies EU solely to the Novartis Gene Therapies EU Authorised User as the entity that was originally invoiced by Novartis Gene Therapies EU. Novartis Gene Therapies EU will notify both Novartis Gene Therapies EU Authorised Distributor and the Novartis Gene Therapies EU Authorised User of the credit/refund approval. A Novartis Gene Therapies EU Authorised User shall work directly with the Novartis Gene Therapies EU Authorised Distributor to obtain any applicable credit or refund. Deduction from Novartis Gene Therapies EU Authorised Distributor invoices should not be taken and will not be recognized. No entity may seek a claim on its insurance or bill any patient or third party for Product for which the Novartis Gene Therapies EU Authorised User receives credit or refund hereunder.

2.6.3 Issuance of Product Replacement:

For returns accepted under this Policy for replacement Product, replacement Product will be issued in the form of a replacement Product carton for the specific patient for whom the returned Product was supplied. Replacement cartons will be delivered to the original Novartis Gene Therapies EU Authorised User only, and the Novartis Gene Therapies EU Authorised User shall ensure the replacement carton is used for that specific patient only. No entity may seek a claim on its insurance or bill any patient or third party for the returned Product for which the Novartis Gene Therapies EU Authorised User receives a replacement hereunder. Deduction from Novartis Gene Therapies EU Authorised Distributor invoices should not be taken and will not be recognized.

3. RECALLED PRODUCT

In the event of a full or partial Novartis Gene Therapies EU-initiated Product recall, Novartis Gene Therapies EU will issue instructions related to the recall, and Product shall only be returned and

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credited in accordance with such instructions, which shall supersede this Policy to the extent of a conflict.

4. INELIGIBLE RETURNS/PRODUCT NOT ELIGIBLE FOR REPLACEMENT OR CREDIT/REFUND

For the avoidance of doubt, neither replacement nor credit/refund will be extended for the Product, regardless of whether the Product otherwise satisfies the requirements of this Policy, under the following circumstances. The list below is not exhaustive of all situations disqualifying eligibility for replacement or credit/refund.

- 4.1 Product obtained illegally or that has been diverted or resold without prior written approval from Novartis Gene Therapies EU.
- 4.2 Product that Novartis Gene Therapies EU determines, at its sole discretion, is otherwise adulterated, misbranded, or counterfeit (and where such adulteration, misbranding, or counterfeiting is not caused by Novartis Gene Therapies EU).
- 4.3 Product that is repackaged or Product not in its original containers.
- 4.4 Product for which a claim may be payable under the Novartis Gene Therapies EU Authorised User’s insurance policy (e.g., for fire, smoke, heat, cold, or water damage).
- 4.5 Product distributed free of charge by Novartis Gene Therapies EU, including but not limited to Product samples or other free goods.
- 4.6 Product not purchased from Novartis Gene Therapies EU or Novartis Gene Therapies EU Authorised Distributor and shipped directly from Almac Pharma Services (Ireland).
- 4.7 Product not manufactured by or on behalf of Novartis Gene Therapies EU for distribution in the EMEA region.
- 4.8 Product that has been infused, whether in whole or in part – for the avoidance of doubt, partial cartons are not returnable for replacement or refund.
- 4.9 Product sold expressly on a non-returnable basis.
- 4.10 Product purchased or provided for research or clinical trials.
- 4.11 Product not returned via Novartis Gene Therapies EU’ designated courier in strict accordance with Novartis Gene Therapies EU’ instructions.

In addition, notwithstanding anything to the contrary in this Policy, Novartis Gene Therapies EU will not accept a Product return if the reason for such return arises from: (i) the negligence of an Novartis Gene Therapies EU Authorised User or any party to whom Novartis Gene Therapies EU ships Product or any of their agents or employees; or (ii) the failure of an Novartis Gene Therapies

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EU Authorised User to comply with any material terms of any purchase/distribution agreement with Novartis Gene Therapies EU, if and as applicable.

Novartis Gene Therapies EU reserves the right to destroy without notification, credit, exchange or return to the Novartis Gene Therapies EU Authorised User, any merchandise that does not conform to this Policy. By returning Products, the Novartis Gene Therapies EU Authorised User authorizes Novartis Gene Therapies EU as its agent to destroy, without payment, replacement or other recourse, any returned packages that are determined ineligible for credit by Novartis Gene Therapies EU.

Novartis Gene Therapies EU further reserves the right to discontinue this Policy with respect to any customer that Novartis Gene Therapies EU determines, in its sole discretion, has misused this Policy and/or misrepresented the reason for returning or cancelling Product.

5. POLICY CHANGES

Novartis Gene Therapies EU reserves the right to change this Policy at any time, in its sole discretion, without advance notice, and reserves the right to make Policy exceptions for extenuating circumstances. The version of the Policy in effect at the time an order was originally placed, shall apply and be controlling for purposes of that Product order.