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EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT ("**APA**")[1] for the production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States

NUMBER — **SANTE/2020/C3/054 - SI2.838958**

1. The European Commission (the '**Commission**'), acting on behalf and in the name of the Member States listed in Annex I (hereinafter referred to as "**Participating Member States**") being represented for the purposes of signature of this APA by Ms Stella Kyriakides, Commissioner for Health and Food Safety:

on the one part and

2. Moderna Switzerland GmbH

a limited liability company ("Gesellschaft mit beschränkter Haftung") organized and existing under the laws of Switzerland

Company Number CHE-344.522.989

Aeschenvorstadt 48 (c/o Katja Schott, Walder Wyss), 4051 Basel, Switzerland

CHE-344.522.989 MWST

(the '**contractor**'), represented for the purposes of the signature of this APA which has the form of a framework contract by Stéphane Bancel, Managing Director,

on the other part,

The Commission, acting on behalf and in the name of the Participating Member States, and the contractor are together referred to as the "**Parties**" and each individually as a "**Party**"

HAVE AGREED

to the **special conditions and** the **general conditions of this APA** and the following annexes:

Annex I – List of Participating Member States

Annex II – Model for Vaccine Order Form

Annex III – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

[1] This APA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

Annex IV – Description of the contractor's intended utilization of the Down Payment

Annex V – List of confirmed and planned manufacturing network partners including the location(s) of manufacturing

Annex VI – Preliminary Specifications of the Product

which form an integral part of this APA.

RECITALS

A. The world is experiencing an emergency healthcare crisis due to the SARS-CoV-2 ("***COVID-19***") pandemic (the "***COVID-19* pandemic**") and the global demand for vaccines to prevent *COVID-19* virus infection is expected to be in order of magnitude of billions of doses.

B. The *contractor* and its *affiliates* are currently working to develop and manufacture an mRNA-based vaccine to help protect against *COVID-19* virus infection in humans.

C. The *contractor* is currently conducting a Phase 3 study of the Product in the United States (the "**COVE Study**"). As of 23 November 2020, the independent, NIH-appointed Data Safety Monitoring Board (DSMB) has informed the contractor that the COVE Study has met the statistical criteria pre-specified in the study protocol for efficacy. Furthermore, the *contractor* is currently establishing its manufacturing capacities in Europe through partnerships with experienced contract manufacturing organisations ("**CMOs**") in order to meaningfully contribute to controlling the *COVID-19 pandemic*. While the *contractor* has prioritised and accelerated its efforts to develop and manufacture the *Product* in light of the current *COVID-19 pandemic*, there is nonetheless substantial uncertainty around these efforts.

D. The *Commission* intends to create the environment required to support a secure manufacturing network and optimisation for the production of vaccines against *COVID-19*. To this effect the *Commission* has concluded an agreement with all Member States of the European Union to conclude, on behalf and in the name of the Member States, Advance Purchase Agreements with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the *COVID-19 pandemic* at Union level.

E. The *Commission* wishes to secure supply of the *Product* for human use for the *Participating Member States* during the *COVID-19 pandemic* as promptly as possible.

F. The intention of the *Commission*, on behalf of the *Member States*, is to ensure that the population in the European Union will be able to access a vaccine in sufficient quantities and at a fair price, but also in safe conditions. The vaccine should only be available to the population once its safety and efficacy will have been cleared by the competent regulatory bodies.

G. According to the Agreement between the *Commission* and the Member States[2] and in particular Article 4 thereof, the *Commission* can conclude an Advance Purchase Agreement that contains a right and an obligation for Participating Member States to acquire vaccine doses. Where the *Commission* intends to enter into such an agreement, it shall inform the Member States of such intention and the detailed terms. In case a Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the *Commission*. All *Participating Member States* not having opted out in accordance with the Agreement between the *Commission* and the Member States are deemed to have authorised the *Commission* to negotiate and conclude an Advance Purchase Agreement with the vaccine manufacturer in their name and on their behalf.

H. This *APA* is such an agreement which the *Commission* enters into on behalf and in the name of the Participating Member States which have not opted out of the agreement. These *Participating Member States* will then have an obligation to acquire the *Product* and a right to be supplied with the respective *Product* doses. While the *APA* is legally binding upon those *Participating Member States*, it will be further implemented by means of the conclusion of contracts between the *Participating Member States* and the *contractor*. The present APA will be complemented by a *Vaccine Order Form* ("**Vaccine Order Form**") between each of the *Participating Member States* and the *contractor*. A model *Vaccine Order Form* for the agreement between each of the *Participating Member States* and the *contractor* is attached in Annex II.

I. The production, advance sale and supply of the *Product* as per this *APA* require significant investments by the *contractor* to increase the speed of the preparation of the at-scale production capacity along the entire production value chain in the EU required for a rapid deployment of the millions of *doses* of the *Product*. The *Commission* as well as the *Participating Member States* are willing to contribute to financing of those investments in the form of up-front payments.

J. Pursuant to these terms and conditions, access to *Product doses* will be allocated to Participating Member States according to a population distribution key, unless a different allocation would be communicated by the *Commission* to the *contractor*. The up-front payments, paid by the *Commission*, should be taken into account in equal terms per *dose* ordered by the Member States.

K. The *Parties* recognise that the accelerated timelines to develop, produce, sell and supply the *Product* means that the *contractor* under no circumstance can warrant, or assume any liability, at the time of entry into force of this *APA* that the *Product* will be ultimately available or will produce the desired results, i.e. shows sufficient efficacy to prevent a *COVID-19* infection, or be without unacceptable side effects. The *Participating Member States* are willing to share those risks, which includes an obligation of the *Participating Member States* to indemnify the *contractor* and its CMOs in case of liability incurred, settlements paid and certain costs relating to

[2] Such agreement is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak, OJ L 117, 15.4.2020, p. 3. The agreement was approved Decision C(2020) 4192 final of 18 June 2020 (see Annex III to this *APA*).

third party claims with respect to those risks under the conditions set out in this *APA*. The *Commission* and *Participating Member States* acknowledge that the use of *Products* will happen under epidemic conditions requiring such use, and that the administration of the *Product* will therefore be conducted under the sole responsibility of the *Participating Member States*.

L. The *Participating Member States* acknowledge that, in light of the uncertainties both with respect to the development of the *Product* and the accelerated establishment of sufficient manufacturing capacities, the delivery dates set out in this *APA* are the *contractor*'s current best estimates and may be subject to change. Due to possible delays in the authorisation, production and release of the *Product*, no *Product* or only reduced volumes of the *Product* may be available at the estimated delivery dates set out in this *APA*. In the case of delays to the anticipated availability of the *Product*, the *contractor* aims to allocate the *doses* of the *Product* fairly across the demand of *doses*, which the *contractor* has or will contractually commit to towards its present and future customers, as such *doses* become available.

M. Against this background, the *Commission* wishes to enter into, on behalf and in the name of the *Participating Member States*, an Advance Purchase Agreement with the *contractor* to secure the availability a total of 80 million *doses* of the *Product*, to be allocated among the *Participating Member States* in accordance with the allocation principles set out in this *APA*. The *Commission*, on behalf and in the name of the *Participating Member States*, shall furthermore have the option to order up to a total of 80 million additional *doses* of the *Product*, subject to the terms and conditions of this *APA*.

This APA sets out:

1. the procedure and conditions by which the *Commission* and the *Participating Member States* shall pay for the Product from the contractor;
2. the provisions that apply to any Vaccine Order Form which the *Participating Member States* and the *contractor* conclude under this APA; and
3. the obligations of the *Parties* during and after the duration of this APA.

All documents issued by the *contractor* (end-user agreements, general terms and conditions, etc.) except its tender and subsequent clarifications are held inapplicable, unless explicitly mentioned in the special conditions of this APA. In all circumstances, in the event of contradiction between this APA and documents issued by the *contractor*, this APA prevails, regardless of any provision to the contrary in the *contractor*'s documents.

TABLE OF CONTENT

I. SPECIAL CONDITIONS

I.1. ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this APA, the following rules must be applied:

(a) The provisions set out in the special conditions take precedence over those in the other parts of the APA.
(b) The provisions set out in the general conditions take precedence over those in the Vaccine Order Form (Annex II).

I.2. SUBJECT MATTER

The subject of this APA is the advance purchase of 80 million doses of the Product, as described below in Article I.4.2, to be allocated among the *Participating Member States* by the *Commission* in accordance with the allocation principles set out below in Article I.4.3. Additionally, this APA gives the *Commission* the option to order, on behalf and in the name of the *Participating Member States*, up to 80 million additional doses of the *Product* in accordance with Article I.4.4 such Optional Increase to be allocated between the *Participating Member States* by the *Commission* as set out below in Article I.4.4.

On the basis of this APA, the *contractor* commits to use *Reasonable Best Efforts* (i) to obtain *Marketing Authorisation* for the *Product* and (ii) to establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually agreed volumes of the *Product* to the *Participating Member States* in accordance with the delivery schedule set out below in Article I.4.7.

Each *Participating Member State* shall issue a *Vaccine Order Form* as regards its allocation of the *Initial Doses*, through which the *contractor* shall supply to the *Participating Member States* the *Product* doses in accordance with the terms of this APA. If the *Commission* acting on behalf and in the name of the *Participating Member States* decides to exercise the *Optional Increase* under Article I.4.4, *Vaccine Order Forms* shall also be concluded with regard to such *Optional Increase*.

The delivery of the *Product* to the individual *Participating Member States* shall be carried out in accordance with the terms and conditions of this APA and in particular in accordance with the allocation notified by the *Commission*, as well as the additional delivery details set out in the *Vaccine Order Forms* to be concluded between the *contractor* and the *Participating Member States* using the model *Vaccine Order Form* provided as Annex II to this APA.

The *contractor* shall receive from the *Commission* a down payment, subject to the terms of the APA, to enable the *contractor* to (i) establish, expand and accelerate its manufacturing capacity in Europe in relation to the manufacturing of the *Initial Doses* of the *Product*, (ii) purchase (and make financial commitments for the purchase of) raw materials, supplies, components and equipment necessary for the manufacture of the *Initial Doses* of the *Product*, (iii) commence and continue the at-risk production of the *Initial Doses* of the *Product*, and (iv) establish regulatory and pharmacovigilance capabilities in relation to the *Product* in Europe. Such down payment shall be fully deductible from the price of the *Initial Doses* of the *Product*. In addition, the *Participating*

Member States shall pay the balance of the payments for the supply of the *Initial Doses* of the *Product* in accordance with Article I.4.2.

I.3. ENTRY INTO FORCE AND DURATION OF THE APA

I.3.1 The APA enters into force on the date on which the *contractor* and the *Commission* have signed it.

I.3.2 Unless earlier terminated in accordance with Article II.16 or expired in accordance with Article I.3.3, the APA is concluded for a period of 24 months with effect from the date of its entry into force. Its duration may be extended if at the end of the term of 24 months not all of the *Initial Doses* or *Option Doses*, as the case may be, have been supplied. In such case, its duration will be extended until the delivery of, and payment in full for, all of the *Initial Doses* or all of the *Option Doses*, as the case may be. The *Participating Member States* and the *contractor* may not sign any *Vaccine Order Form* after the APA expires. The APA continues to apply to signed *Vaccine Order Forms* after its expiry. The obligations relating to such *Vaccine Order Forms* must be performed no later than six months after the expiry of the APA.

I.3.3 The APA shall automatically expire on (i) the date on which all the *Initial Doses* have been delivered and paid in full, in the event the *Commission* has not elected an *Option Increase* in accordance with Article I.4.4, or (ii) the date on which all of the *Initial Doses* and the *Option Doses* have been delivered and paid in full, in the event the *Commission* has elected an *Option Increase* in accordance with Article I.4.4.

I.3.4 Articles I.1, I.4.6, I.4.7(c), I.4.7(d), I.5, I.6.5, I.7, I.8, I.11, I.12, I.13, II.1, II.3, II.4, II.5, II.7, II.8, II.12.2, II.16.5, II.17, II.18.4, II.19 and II.20 shall survive the termination or expiry of this APA.

I.4. IMPLEMENTATION OF THE APA

I.4.1 Implementation of the APA

The APA shall be implemented following signature between the Commission on behalf and in the name of the Participating Member States and the contractor as follows:

Following entry into force of this APA, this APA is binding upon the contractor, the Commission and all Participating Member States on behalf and in the name of which the Commission has concluded this APA, as identified in Annex I.

Following entry into force of this APA, the Commission will determine the allocation of the contractually agreed doses of the Product between the Participating Member States in accordance with the procedure set out below in Article I.4.3 and will formally notify this allocation to the contractor. The allocation notified to the contractor by the Commission on behalf and in the name of the Participating Member States is binding upon all Participating Member States.

Each Participating Member State and the contractor will conclude a Vaccine Order Form, using the model Vaccine Order Form attached as Annex II to this APA, setting out the details of the delivery of the doses of the Product allocated to the respective Participating Member State. For the avoidance of doubt, and unless otherwise laid down in this APA, each Participating Member State

is obligated to purchase and pay for the doses contractually allocated to it as notified by the Commission regardless of whether such Vaccine Order Form is concluded or not.

I.4.2 Initial Doses

Without prejudice to the Option Increase (see Article I.4.4), the contractor agrees to supply an initial number of eighty million (80,000,000) doses of the Product (the "**Initial Doses**") to all Participating Member States in accordance with the terms of this APA and the applicable Vaccine Order Forms. Each dose will be one hundred (100)-microgram equivalent of Product in a multi-dose vial, and the Product is administered as a two-dose vaccination regimen according to a drug label for the commercial supply in English, as determined by the contractor and which is not specific to the territory. The Commission and the Participating Member States hereby confirm that such drug label for the commercial supply in English is permissible under applicable law of each Participating Member State.

In order for the contractor to (i) establish, expand and accelerate its manufacturing capacity for the Initial Doses, (ii) purchase (and make financial commitments for the purchase of) raw materials, supplies, components and equipment necessary for the manufacture of the Initial Doses, (iii) commence and continue the at-risk production of the Initial Doses, (iv) establish regulatory and pharmacovigilance capabilities in relation to the Product in the European Union, and (v) guarantee that the Participating Member States are able to acquire the Initial Doses in a given timeframe and at a certain price and conditions, the Commission will contribute to the relevant costs for the Initial Doses in the form of an up-front payment as follows:

- twenty percent (20%) of (i) eighty million (80,000,000) Initial Doses of Product multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within fifteen (15) days after the receipt of an invoice following signature of this APA (the "**Down Payment**").

The balance of payments for the supply of Initial Doses will be paid by each Participating Member State according to the following schedule:

(a) forty percent (40%) of (i) the number of Initial Doses ordered by such Participating Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after the date of receipt of Marketing Authorisation for the Product; and

(b) forty percent (40%) of (i) the number of Initial Doses delivered to such Participating Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after receipt of the contractor's invoice for each delivery.

I.4.3 Allocation between Participating Member States; Vaccine Order Forms

The Commission shall coordinate with the Participating Member States to agree to the allocation of the Initial Doses to be purchased from the contractor. The Commission shall provide to the contractor in writing the allocation for distribution of the Initial Doses among the Participating Member States within 15 calendar days after signature of the APA. Such allocation shall indicate

for each Participating Member State the precise volume of Initial Doses to be delivered to each Participating Member State.

Within 10 calendar days after the notification by the Commission of the allocation for distribution of the Initial Doses among the Participating Member States, each Participating Member State shall place an order for its full allocated portion of the Initial Doses by sending the contractor the duly completed and signed Vaccine Order Form (the format for which is set out in Annex II) in paper format and in PDF format by email to contractor's address specified in the Vaccine Order Form.

Within 10 calendar days of receipt of the Vaccine Order Form from a Participating Member State, the contractor must send back to the Participating Member State the Vaccine Order Form duly signed and dated in paper format or in PDF format by email to the Participating Member State's address specified in the Vaccine Order Form. If the contractor refuses to sign the Vaccine Order Form at the conditions laid down in the APA and in Annex II or fails to supply the Product doses to the Participating Member States on time, the contractor may be considered in breach of its obligations under this APA as set out in Article II.16.2(c).

I.4.4 Option Increase

Subject to the terms of this Article I.4.4, the Commission, acting on behalf of one or more of the Participating Member States, may elect to increase the number of doses of Product by up to an additional eighty million (80,000,000) doses in the aggregate (the "**Option Increase**") at the times set forth below.

An Option Increase will be made by written notice from the Commission to the contractor, which notice shall specify the Participating Member States participating in such Option Increase (the "**Exercising Member States**") and the allocation of doses of Product to be purchased by and delivered to each such Exercising Member State (the "**Option Doses**"). The Option Increase will be paid by the Exercising Member State according to the following schedule:

If the Option Increase is exercised by the Commission on behalf of one or more exercising Member States on or prior to December 31, 2020 ("**December Option Increase**"):

(a) twenty percent (20%) of (i) the number of Option Doses of Product to be delivered to such Exercising Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after the return by the contractor of the Vaccine Order Form;

(b) forty percent (40%) of (i) the number of Option Doses of Product to be delivered to such Exercising Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after the date of receipt of Marketing Authorisation for the Product; and

(c) forty percent (40%) of (i) the number of Option Doses of Product to be delivered to such Exercising Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after receipt of the contractor's invoice for each delivery.

Only those Option Doses for which the December Option Increase was not exercised will remain available for the Deferred Option Increase.

If the amount of Product doses for which the Commission exercised the December Option Increase is less than eighty million (80,000,000) doses, the remaining doses may be ordered by the Commission on behalf of one or more Participating Member States through the exercise of the Option Increase during the period commencing on January 1, 2021 and ending twenty (20) calendar days after the date of receipt of Marketing Authorisation for the Product ("**Deferred Option Increase**"). Within five (5) calendar days after the date of receipt of Marketing Authorisation for the Product, the contractor will provide an estimated delivery schedule for the Deferred Option Increase (including the location(s) of the supply and the estimated timelines for delivery of doses of Product from such location(s)) to enable the Commission and the Participating Member States to determine whether or not to exercise the Deferred Option Increase.

In the event that the Commission exercises the Deferred Option Increase, then the contractor and each of the Exercising Member States shall mutually agree on a delivery schedule for the Product comprising the Deferred Option Increase, based on the estimated delivery schedule for the Deferred Option Increase and adjusted based on the number of Exercising Member States and the actual number of doses of Product in the Deferred Option Increase. If an agreement on a delivery schedule cannot be agreed between the contractor and an Exercising Member State within 15 calendar days from the date of receipt of the signed Vaccine Order Form by the contractor, the corresponding Vaccine Order Form may be cancelled by that Exercising Member State or the contractor upon written notice to the other. The applicable Vaccine Order Form shall be deemed cancelled unless the relevant Exercising Member State and the contractor confirm in writing the agreement on delivery schedule within 15 calendar days from the date of receipt of the signed Vaccine Order Form by the contractor. Such agreement shall be immediately communicated to the Commission and the other Exercising Member States.

The Product doses for which the Deferred Option Increase was exercised shall be paid as follows:

(x) fifty percent (50%) of (i) the number of Option Doses of Product to be delivered to such Exercising Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after the return by the contractor of the signed Vaccine Order Form followed by an invoice for the Deferred Option Increase; and

(y) fifty percent (50%) of (i) the number of Option Doses of Product to be delivered to such Exercising Member State multiplied by (ii) a price in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50), payable within thirty (30) days after receipt of the contractor's invoice for each delivery.

In the event that the Commission exercises an Option Increase on behalf of the Exercising Member States, then each Exercising Member State participating in such Option Increase shall deliver to the contractor a separate Vaccine Order Form within 10 calendar days after delivery of notice of the applicable Option Increase by the Commission. If an Exercising Member State does not provide a Vaccine Order Form for its allocated Product doses for the Option Increase on or prior to such date or cancels its order for the Deferred Option increase due to the failure to agree a delivery schedule, the remaining Exercising Member States participating in the Option Increase may, by written notice to the Commission, increase their respective allocation of Option Doses pro

rata or on the basis of any other allocation communicated to the contractor in writing by the Commission. In such case, (i) the Commission shall provide written notification to the contractor of any such increase in allocation of Option Doses for any such Exercising Member States and (ii) such Exercising Member States shall send to the contractor an updated Vaccine Order Form confirming such increased allocation of Option Doses communicated by the Commission to the contractor, in each case ((i)-(ii)), within 20 calendar days after the initial delivery of the notice of the applicable Option Increase by the Commission on behalf of the Exercising Member States.

In the event the Commission does not exercise any Option Increase on behalf of one or more of the Participating Member States, the contractor may enter into separate agreements with such Member States for the delivery of Product doses to such Member States after the final delivery of the Initial Doses to the Participating Member States hereunder.

I.4.5 Development timeline; Special Commitments

On November 17, 2020, the contractor announced that the EMA human medicines committee (CHMP) has started a rolling review of the Product following the confirmation of eligibility of the Product for submission on October 14, 2020. The contractor currently anticipates that Marketing Authorisation for the Product may be granted on or before the Expected Approval Date, based on anticipated accelerated EMA timelines. However, the Parties acknowledge that there is a risk that Marketing Authorisation for the Product may not be granted as anticipated. For the avoidance of doubt, the Expected Approval Date set forth herein represents the contractor's good-faith expectations and nothing herein shall be construed as an obligation of any kind for the contractor to obtain Marketing Authorisation on or prior to the Expected Approval Date.

To produce the Initial Doses, the contractor may not manufacture or have manufactured the Product at manufacturing sites located outside the territory of the European Union, the EEA or Switzerland without the prior consent of the Commission, which consent may not be unreasonably withheld, conditioned or delayed if the manufacturing at such sites is required to accelerate the production of the Initial Doses. The CMO and their manufacturing sites as identified in Annex V are deemed pre-approved for the Initial Doses.

I.4.6 The possibility to re-sell, export and/or distribute

Each Participating Member State shall be entitled to re-sell, export and/or distribute the Product doses supplied to them pursuant to this APA to any other EU or EEA Member State, provided however that such re-sale, export and/or distribution may not take place before (i) such Participating Member State has paid the contractor in full for all Product doses subject to such re-sale, export and/or distribution and (ii) the other EU or EEA Member State expressly agrees in writing to assume the indemnity and other relevant rights and obligations hereunder. The contractor and the Indemnified Persons will be express third party beneficiaries under such assumption agreement, and the contractor and the Indemnified Persons will have the right to enforce such obligations and make claims thereunder with such other EU or EEA Member States. The Participating Member State re-selling doses to an EEA Member State has an obligation to reimburse the Commission the up-front payment per dose paid by the Commission to the contractor.

The Participating Member States shall take appropriate measures to ensure that the Product doses supplied to them pursuant to this APA will only be (i) exported, distributed or donated to another Governmental Authority in a country outside the EU or EEA, either directly or indirectly through NGOs, the World Health Organization or any international public organization, subject to the prior written consent of the contractor (which consent will not be unreasonably withheld, subject to such Participating Member State's and the applicable third country's compliance with the contractor's reasonable requests) (such Governmental Authority, a "**Donation Country**") or (ii) re-sold to another Governmental Authority in Europe that is not an EU or EEA Member State, subject to the prior written consent of the contractor (which consent will not be unreasonably withheld, subject to such Participating Member State's and the applicable third country's compliance with the contractor's reasonable requests) (such Governmental Authority, a "**Resale Country**") and subject to the terms set forth below.

For the avoidance of doubt and notwithstanding anything to the contrary herein, (a) it will be reasonable for the contractor to withhold its consent to the exportation, distribution, re-sale or donation to a Donation Country or Resale Country, as applicable, under this Article I.4.6 if the use or administration of the Product doses in such country or jurisdiction would require the contractor to obtain a marketing authorisation in connection with such use or administration in such country or jurisdiction, and (b) the Donation Country or Resale Country, as applicable, will only be permitted to use, deploy and administer any Product doses within its own territory.

Each Participating Member State must comply with each of the following obligations in order to provide any Product doses to a Donation Country, and such Participating Member State will provide the contractor with any and all information reasonably requested by the contractor to establish such compliance from time to time until the exportation, distribution or donation is completed.

1. Indemnity. A Participating Member State shall only provide the Product doses to a Donation Country under this Article I.4.6 of this APA if the Donation Country has agreed to indemnification terms satisfactory to the contractor in writing.

2. Transportation of Product. Without prejudice to paragraph 6 of this provision, a Participating Member State that exports, distributes or donates any Product doses to any Donation Country will be responsible for:

(i) seeking, obtaining and maintaining all relevant regulatory authorisations and approvals for the delivery of the Product doses to the applicable Donation Country, including the export of Product doses from the Territory and the import of the Product doses into the country or jurisdiction of the applicable Donation Country; provided, for clarity, that this shall not include seeking marketing authorisation for the Product in the Donation Country, if required;

(ii) packaging, storing and transporting the Product doses to the applicable Donation Country in accordance with the conditions set out in the Specifications, GDP and all applicable laws; and

(iii) delivering to the applicable Donation Country in a timely manner so as to ensure the Product doses have sufficient shelf life remaining following delivery to enable administration of the Product doses prior to the expiry of the Product doses' shelf life as set forth on the label for

such Product doses (which, at the time of delivery to the applicable Donation Country, must be at least thirty (30) days); and

3. Compliance with Applicable Laws. The Participating Member States shall not provide the Product doses to a Donation Country without that Donation Country having confirmed in writing that such Donation Country will comply with all applicable laws in connection with the packaging, storing, transporting, exporting, importing, insuring or distributing of the Product doses.

4. Use and Administration of Product Doses. The Participating Member States shall not provide the Product doses to a Donation Country without that Donation Country having confirmed in writing that the Product doses will be used and administered in its own territory in accordance with the label for the Product and applicable laws.

5. Price. Any Product doses provided by a Participating Member State to any Donation Country will be at no cost to such Donation Country (other than reimbursement of reasonable out-of-pocket costs of such Participating Member State for the provision of such Product doses to such Donation Country).

6. Documentation. A Participating Member State will comply with the points 1 to 5 above by entering into an agreement in writing that is satisfactory to the contractor with the respective Donation Country to the effect that the Donation Country will take over the obligations and responsibilities as set out in points 1-4 above.

The Parties acknowledge that should re-sale to any Resale Country take place, (A) the contractor, the Participating Member State and the applicable Resale Country will enter into a written agreement governing such re-sale, which at a minimum will include the obligations on Participating Member States with respect to Donation Countries set forth in immediately preceding paragraphs 1 through 4 and 6, *mutatis mutandis*, and (B) the Participating Member State re-selling doses to the applicable Resale Country has an obligation to reimburse the Commission the up-front payment per dose paid by the Commission to the contractor. Any Product doses re-sold by a Participating Member State to any Resale Country will not be at a price higher than the purchase price as set forth in Article I.7.1.

I.4.7 Delivery

The contractor shall deliver the Product doses to the Participating Member States in accordance with the allocation and the other terms and conditions of this APA.

(a) Initial Delivery Schedule

The contractor expects, and shall use Reasonable Best Efforts, to deliver Product doses to the Participating Member States in a non discriminatory manner on the schedule and in the quantities as set out in the following initial delivery schedule ("**Initial Delivery Schedule**").

Initial delivery schedule

For Initial Doses

- 10 million doses for Participating Member States in Q1 2021
- 35 million doses for Participating Member States in Q2 2021
- 35 million doses for Participating Member States in Q3 2021

For Option Doses

In the event of the December Option Increase exercise:

- up to 25 million Option Doses for exercising Member States as early as Q3 2021
- up to 55 million Option Doses for exercising Member States as early as Q4 2021

In the event of the Deferred Option Increase exercise, the contractor and the Commission, on behalf of the Exercising Member States, will confirm the delivery schedule for the Option Doses at the time of such Deferred Option Increase exercise once all Exercising Member States have agreed or rejected the delivery schedule with the contractor as the case may be in accordance with Article I.4.4.

The schedule and quantities set out in the Initial Delivery Schedule are based on the contractor's current expectation that Marketing Authorisation for the Product will be granted or issued on or prior to February 28, 2021 (the "**Expected Approval Date**"). Under no circumstances will any delivery of Product doses be required under this APA prior to receipt of Marketing Authorisation for the Product unless mutually agreed by the Commission, the relevant Participating Member State(s) and the contractor. For avoidance of doubt, the Expected Approval Date set forth herein represents the contractor's good-faith expectations and nothing herein shall be construed as an obligation of any kind for the contractor to obtain Marketing Authorisation on or prior to the Expected Approval Date. Nevertheless, the contractor shall use Reasonable Best Efforts as referred to in Article I.12.7 to obtain Marketing Authorisation for the Product as soon as reasonably possible in order to meet the Expected Approval Date.

The contractor shall inform the Commission of any expected change in the initial delivery as per the Initial Delivery Schedule, including any expected change if the Marketing Authorisation for the Product is not granted or issued by the Expected Approval Date. In such case, without prejudice to Articles I.12.7, II.16.1 and II.16.2(a), the contractor shall (after prior consultation with the Commission) as soon as reasonably possible propose to the Commission an updated delivery schedule ("**Updated Delivery Schedule**"). The contractor shall ensure that deliveries of Product doses under the Updated Delivery Schedule are made within a schedule that is as close as reasonably possible to the Initial Delivery Schedule.

If the anticipated delivery date of Product doses per an Updated Delivery Schedule is more than 90 calendar days after the corresponding delivery date for such Product doses in the Initial Delivery Schedule, a Participating Member State (or the Commission, acting on its behalf) may cancel its order for the number of Product doses that will be more than 90 calendar days late by providing

written notice to the contractor within 14 calendar days of the Commission's receipt of such Updated Delivery Schedule. If the Commission or a Participating Member State cancels any Product doses during such 14 calendar day period in accordance with this paragraph, the contractor shall consequently reimburse to the relevant Participating Member State 100% of the payments already made by the relevant Participating Member State to the contractor for such cancelled Product doses.

The schedule set out in the Initial Delivery Schedule reflects the calendar quarter in which Product doses are expected to be delivered.

The actual delivery dates within the applicable Delivery Schedule for the Product doses will be agreed between the contractor and the Participating Member State, and the contractor will use Reasonable Best Efforts to deliver the first delivery of Initial Doses within fifteen (15) business days of receipt of Marketing Authorisation for the Product; provided that the contractor shall have no obligation to deliver any Initial Doses to any Participating Member State until such Participating Member State has completed its payment in respect of contractor's receipt of Marketing Authorisation under Article I.4.2(b). The contractor may agree with the Participating Member States to make multiple deliveries over a calendar quarter, in varying quantities, and on a non-discriminatory basis as between all Participating Member States. Deliveries of Product doses will be made in a rolling, non-discriminatory manner between Participating Member States and pro rata to each Participating Member State based on the allocation provided by the Commission pursuant to Article I.4.3, subject to the contractor's minimum delivery volume and good faith cooperation with the Participating Member States.

(b) Form of Delivery

The supply of Product doses will be delivered by the contractor to the Participating Member States DAP (Delivered At Place) Incoterms 2020, to one recipient at one Delivery Address indicated by the Participating Member State concerned in the Vaccine Order Form, which recipient and Delivery Address is authorized, qualified and licensed to receive the Product in accordance with applicable law.

(c) Distribution

Following delivery of the Product doses, each Participating Member State will solely control and assume all responsibility, at such Participating Member State's own cost and expense, for conducting all distribution and related activities relating to the Product doses in the Participating Member State's territory and to countries in the EU or EEA to which the Participating Member State donates or resells Product doses in accordance with Article I.4.6.

(d) Traceability

During the term of this APA and for a period of ten (10) years thereafter (or longer if required by applicable laws), each Participating Member State will (i) maintain an inventory control system for traceability of the Product supplied to or for the benefit of such Participating Member State, including any Product provided by such Participating Member State to a permitted Donation Country or Resale Country, and (ii) store and promptly make available to the contractor all

traceability records for the Product. The inventory control system is without prejudice to other traceability requirements in accordance with the applicable laws.

I.5. ACCEPTANCE/REJECTION OF PRODUCT

I.5.1 Subject to the terms of this Article I.5, a Participating Member State may claim a remedy (a "**Product Claim**") for any portion of Product delivered to such Participating Member State by the contractor which at the time of delivery (a) does not comply with the final specifications for the Product as approved in the Marketing Authorisation for the Product or (b) has been affected by a failure to comply with GMP ("**Deficient Product**"). Such Participating Member State will visually inspect the Product, or review documentation provided by or on behalf of the contractor, upon delivery or receipt (as applicable) and will give the contractor written notice of all Product Claims within twenty (20) calendar days after such delivery or receipt (or, in the case of any deficiency at the time of delivery to such Participating Member State that was not reasonably susceptible to discovery upon such delivery or receipt, within twenty (20) calendar days after discovery by such Participating Member State Participating Member State, but not after the expiration date of the Product). If Participating Member State fails to provide a Product Claim within the applicable twenty (20) calendar day period, then the Product will be considered to have been accepted by Participating Member State on the twentieth (20th) day. The contractor will have no liability for any deficiency or claim for which it has not received notice from Participating Member State within the applicable twenty (20) calendar day period.

I.5.2 The contractor will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (a) actions or omissions of such Participating Member State or Third Parties occurring after the time of delivery of the Product by the contractor or its designee; or (b) any breach by such Participating Member State of its obligations under this APA or the applicable Vaccine Order Form.

I.5.3 Upon receipt of a Product Claim, the contractor will have twenty (20) days to advise the Participating Member State by notice in writing whether it disagrees with the contents of the Product Claim. If, after joint testing or investigation has been performed, the Parties still cannot agree on whether such Product is Deficient Product, the contractor or the Participating Member State may refer such dispute to a technical expert for resolution in accordance with Article I.5.4 (a "**Technical Dispute**").

I.5.4 If any Technical Dispute arises, the contractor and the Participating Member State will first try to resolve it amicably. The contractor or the Participating Member State may send a notice of a Technical Dispute to the other, and each Party will appoint, within ten (10) working days from receipt of the notice, an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the Technical Dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a Party fails to appoint a representative as required above, the expert determination procedure below may be started by either Party. Within ten (10) working days after the written request, the contractor and the Participating Member State will appoint a single agreed expert with experience and expertise in the subject matter of the dispute. As a condition of the expert's appointment, the contractor and the Participating Member State will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise. The contractor and the Participating Member State do not intend that the expert acts as an arbitrator and therefore any matters requiring

legal interpretation or adjudication including disputes relating to the conduct of the Technical Dispute are solely reserved for the dispute resolution procedure under Article I.11.2. For the avoidance of doubt, any technical determination by the expert under a Technical Dispute may be used as evidence under Article I.11.2. The contractor and the Participating Member State will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) within fifteen (15) working days (or as agreed by the contractor and the Participating Member State with the expert). The contractor and the Participating Member State will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly and in any event within five (5) working days of a written request from the expert to do so. At all times the contractor and the Participating Member State will co-operate and seek to narrow and limit the issues to be determined. The technical determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the contractor and the Participating Member State with respect to the referred Technical Dispute. Each of the contractor and the Participating Member will bear its own costs for any matter referred to an expert under this Article I.5.4 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the contractor and the Participating Member.

I.5.5 If a Participating Member State makes a Product Claim pursuant to this Article I.5 and (a) the contractor and the Participating Member State agree the Product that is the subject of such Product Claim is Deficient Product (such agreement not to be unreasonably withheld, conditioned or delayed) or (b) any previously delivered Product is determined to be Deficient Product, the contractor will replace such Deficient Product as soon as reasonably practicable after the time of such agreement or determination (and in no event later than 90 days after the time of such agreement or determination). If such replacement products are not delivered within this time limit, the contractor shall reimburse the purchase price for the Deficient Product to the Participating Member States in question in so far as that purchase price was already paid.

I.5.6 A Participating Member State will not dispose of any Product for which it intends to assert a Product Claim against the contractor without the contractor's prior written authorization to do so. The contractor may instruct Participating Member State to return the Product to the contractor to a location identified by the contractor. The contractor will bear the cost of return and disposition of any Deficient Product. In all other circumstances, the Participating Member State will bear the cost of return and disposition, including all applicable fees for manufacturing of the Product.

I.5.7 Except as and to the extent required by applicable law, and without prejudice to Articles II.4.6 and II.5, this Article I.5 sets out the only contractual liability of the contractor and the Participating Member States' sole and exclusive remedy for Deficient Products that are unsold or unused and returned, destroyed or otherwise disposed of by the Participating Member States in accordance with this APA.

I.6. WARRANTIES

I.6.1 The Commission and each of the Participating Member States warrant to the contractor that as of the date hereof, this APA has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms.

I.6.2 Each Participating Member State warrants to the contractor that at the time of its delivery to the contractor, each Vaccine Order Form from such Participating Member State has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms.

I.6.3 The contractor warrants to the Commission and the Participating Member States that

(a) as of the date hereof, this APA has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms; and

(b) as of the date hereof, it is not under any obligation, contractual or otherwise, to any third party in respect of the delivery of the Initial Doses or that conflicts with or is inconsistent in any material respect with the terms of this APA or that would impede the complete fulfillment of its obligations under this APA.

I.6.4 The contractor warrants to the Commission and the Participating Member States that

(a) all Product doses supplied to the Participating Member States shall at the time of delivery conform with the final specifications for the Product as approved in the Marketing Authorisation for the Product;

(b) all Product doses supplied to the Participating Member States shall at the time of delivery have been manufactured in conformance with GMP and all applicable laws; and

(c) at the time of delivery, it has good title to the Product doses delivered to the Participating Member States pursuant to this APA and it shall pass such title to the Participating Member States free and clear of any security interests, liens, or other encumbrances, including, to the knowledge of the contractor, having obtained any necessary IP rights.

The Parties agree that the sole and exclusive remedy for a breach of the product warranties set forth in this Article I.6.4 (a) and (b) will be the remedies set forth in Article I.5.

I.6.5 Except as expressly set forth in this APA, the contractor and its Affiliates make no other warranties of any kind, express or implied, including any implied warranties of merchantability or fitness for a particular purpose, or non-infringement, or regarding results obtained through the use of the Product.

I.7. PRICES

I.7.1 Price per Dose of Product

The price per single dose of Product purchased hereunder shall be the equivalent in euros based on Twenty Two U.S. Dollars and Fifty Cents (US$22.50). For clarity, the price for the total Product volume shall be obtained by multiplying the price of a single Product dose by the total number of Product doses covered by this APA. Payments are made in euros by taking into account the Exchange Rate Methodology set out under Article I.8.4.

I.7.2 Down payment under the APA

The Down Payment for the Initial Doses is 318,471,338.00 euros based on Three Hundred Sixty Million U.S. Dollars (US$360,000,000.00) calculated using the Exchange Rate Methodology set out under Article I.8.4. The Down payment shall be fully deductible from the price of each dose of the Initial Doses at a rate of Four U.S. Dollars and Fifty Cents US$ 4.50 per single dose. The price for each dose for the Initial Doses remaining for the Participating Member States after deduction of the Down payment is consequently the equivalent in euros based on Eighteen U.S. Dollars (US$18.00).

The payment schedule for purchases of Initial Doses by or on behalf of Participating Member States is addressed in Article I.4.2.

The payment schedule for purchases of Option Doses by or on behalf of Participating Member States is addressed in Article I.4.4.

I.8. PAYMENT ARRANGEMENTS

I.8.1 Pre-financing (Payment of the Down Payment)

Within ten (10) days following signature of the APA, the contractor shall send to the Commission an invoice for the payment of the Down Payment in paper format or in PDF format by email. The invoice shall indicate the reference number of the APA and comply with the terms of the APA.

The Down Payment shall be paid in a single instalment.

The invoice for the Down Payment must contain the following information:

- Name of the addressee
- APA number
- name and bank account.

The Commission must pay the Down Payment within 15 days after receipt of the invoice as referred to in the first subparagraph.

I.8.2 Utilisation of the Down Payment

The parties acknowledge and agree that the Down Payment is intended to cover costs incurred by the contractor for (i) the establishment, expansion, and acceleration of manufacturing capacities necessary for the manufacture of the Initial Doses, (ii) the purchase (and financial commitments to purchase) raw materials, supplies, components and equipment necessary for the manufacture of the Initial Doses covered by this APA, (iii) the commencement and continuation of at-risk production of the Initial Doses covered by this APA, and (iv) the establishment of regulatory and pharmacovigilance capabilities in relation to the Product doses covered by this APA, in each case prior to the execution of this APA.

The Down Payment is used as further specified in Annex IV.

I.8.3 Payment for Marketing Authorisation and the supply of Product

1. The contractor must send an invoice in paper format or in PDF format by email to the Participating Member States for payment by the Participating Member States under Articles I.4.2 (a), I.4.2(b), I.4.4(b), I.4.4(c), I.4.4(x) and I.4.4(y), as applicable.

Invoices shall be established by the contractor for a given order of the Product and for an identified delivery scheduled within the Vaccine Order Form.

The contractor must send an invoice in paper format or in PDF format by email for payment due under the Vaccine Order Form accompanied by the following documentation (as applicable):

- Proof of delivery of the Products referred to in Article I.4.2 or I.4.4 of this APA, to the place of delivery indicated by the Participating Member State concerned in the Vaccine Order Form

Each invoice must contain the following information (if applicable):

- Name of a concerned Member State
- APA and Vaccine Order Form number/reference
- Order reference
- Date of receipt of Marketing Authorisation for the Product
- Product
- Quantity delivered
- Delivery reference and date
- Contractor name and bank account.

2. The Participating Member States must pay within 30 days from receipt of the invoice.

I.8.4 Currency

Any payments to be made by the Commission or the Participating Member States under this APA, including under any Vaccine Order Form, shall be made, and any invoices issued pursuant to this APA shall be issued, in euros (EUR).

All payments required under this APA (including under any Vaccine Order Form) are based on a unit price set in United States Dollars (USD). As a currency conversion in EUR will be required in connection with such invoices, the amounts payable hereunder shall be expressed in EUR equivalent calculated using the Exchange Rate Methodology (as defined below).

The "**Exchange Rate Methodology**" is calculated as the average of the Euro Foreign Exchange Reference Rates as published by the European Central Bank from the beginning of each calendar year up to the pen-ultimate day of the month preceding the invoice, whereby all days are taken into account on which the Euro Foreign Exchange Rate is published. For the purposes of the Down Payment the conversion between the euro and US $ is calculated by applying the average exchange rate of the Euro Foreign Exchange Reference Rates as published by the European Central Bank from 1 January - 31 October 2020, whereby all days are taken into account on which the Euro Foreign Exchange Rate is published. This rate is US$1.1304 for 1 euro.

Sensitive*
RELEASABLE TO: Need to know basis

I.8.5 Refundability of the Down Payment

If this APA is automatically terminated pursuant to II.16.1 or terminated by the Commission pursuant to Article II.16.2(a) due to the fact that the contractor failed to obtain Marketing Authorisation for the Product, then the Commission will be entitled to a refund of any amounts of the Down Payment in accordance with Article II.16.5.

I.8.6 BANK ACCOUNT

Payments must be made to the contractor's bank account denominated in euro, identified as follows:

Name of bank: Bank of America & BAMLI DAC ZURICH

Full address of branch: Stockerstrasse 23, 8002 Zurich, Switzerland

Exact denomination of account holder:

Full account number including bank codes: CH08 0872 6000 0507 7603 3

Swift code: BofACH2X

I.9. COMMUNICATION DETAILS

For the purpose of this APA, communications must be sent to the following addresses:

The Commission:

European Commission

Directorate-General for Health and Food Safety

E-mail: SANTE-PROCUREMENT@ec.europa.eu

EC-VACCINES@ec.europa.eu

Participating Member States will provide the communication details in the Vaccine Order Forms.

Contractor:

H.W. Jerome Maddox, Vice President and Associate General Counsel

Moderna Switzerland GmbH

Aeschenvorstadt 48 (c/o Katja Schott, Walder Wyss), 4051 Basel, Switzerland

E-mails: legal@modernatx.com and Jerome.Maddox@modernatx.com

By derogation from this Article, different contact details for the Commission, the Participating Member States or the contractor may be provided in Vaccine Order Form.

I.10. EXPLOITATION OF THE RESULTS OF THE APA

The Commission and the Participating Member States acknowledge and agree that the contractor shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Product, including all know-how (collectively, the "**Vaccine IP Rights**"). The contractor shall be entitled to exclusively exploit the results of the APA and any such Vaccine IP Rights. Except as expressly set forth in this APA, the contractor does not grant to the Commission or any of the Participating Member States by implication, estoppel or otherwise, any right, title, license or interest in or to the results of the APA, the Vaccine IP Rights or the contractor's Pre-existing rights. All rights not expressly granted by the contractor hereunder are reserved by the contractor.

The Commission and the Participating Member States acknowledge that the Product Marks and all goodwill pertaining thereto are the exclusive property of the contractor or its Affiliates, that nothing in this APA grants the Commission or the Participating Member States or any Person any right, title or interest therein, and that all use of the Product Marks by the Commission or the Participating Member States or any Person acting under its or their authority or instructions will inure to the benefit of the contractor.

The Commission and the Participating Member States will discontinue use of any Product Marks to which the contractor objects. The Commission and the Participating Member States will not use any of the Product Marks in a manner that diminishes the value of any of the Product Marks or disparages the contractor or its Affiliates or that the contractor otherwise deems to be inappropriate.

The Commission and the Participating Member States will not modify, overprint, distort, change, remove or obscure any Product Marks associated with the Product as delivered by the contractor under this APA or the Vaccine Order Forms.

I.11. APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.11.1 This APA shall be governed by the laws of Belgium.

I.11.2 Dispute Resolution

(a) In the event of a dispute arising under this APA or a Vaccine Order Form between the contractor and the Commission or a Participating Member State, the Parties shall first refer such dispute to informal dispute resolution discussions between their respective representatives. The contractor or the Commission on behalf of itself or of the Participating Member States may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within twenty (20) days of such notice, the representatives shall meet and attempt to resolve the dispute by good faith negotiations.

(b) The Commission, the Participating Member States and the contractor irrevocably submit to the exclusive jurisdiction of the courts located in Brussels, Belgium to settle any dispute

which may arise under or in connection with this APA or the legal relationships established by this APA including under a Vaccine Order Form.

I.12. OTHER SPECIAL CONDITIONS

I.12.1 Each Participating Member State and the contractor will each maintain records necessary to permit a Recall of any Product delivered to such Participating Member State.

I.12.2 Each Participating Member State and the contractor will notify the other party within 5 working days from notifying the European Medicines Agency of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in the Participating Member State's territory.

I.12.3 Upon receiving this notice or upon this discovery, such Participating Member State and the contractor will stop making any further shipments of any Product in their possession or control in such Participating Member State's territory until a decision has been made whether a Recall or some other corrective action is necessary.

I.12.4 The decision to initiate a Recall or to take some other corrective action, if any, with respect to the Product in such Participating Member State's territory will be made by the competent authority concerned, or alternatively by the contractor, in agreement with the competent authority(ies) concerned.

I.12.5 If: (i) any regulatory authority issues a decision, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled in such Participating Member State's territory; (ii) a court of competent jurisdiction orders a recall in such Participating Member State's territory; or (iii) the contractor in agreement with the concerned competent authority(ies) determines that any Product should be recalled in such Participating Member State's territory (each a '**Recall**'), then the contractor, the Participating Member State(s) and the competent authority(ies) shall assist each other in the Recall process, as appropriate, having regard to all applicable laws, and especially (a) the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human Use and Veterinary Use – Part 1 – Chapter 8 "Complaints, Quality Defects and Product Recalls" and (b) the compilation of Community procedures on inspections and exchange information in the meaning of article 3 (1) of the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

In the event of any Recall, the contractor will bear the costs and expenses for the Recall unless such Recall was carried out due to quality defects in the Product or other grounds justifying such recall which were caused by the Gross Negligence or Willful Misconduct of a Participating Member State, in which case such Participating Member State will bear the costs and expenses for the Recall.

Further, in the event of any Recall that was carried out due to quality defects in the Product or other grounds justifying such recall which in each case were caused by the Gross Negligence, Willful Misconduct, Fraud or failure to conform to GMP of the contractor, the contractor shall, at the election of contractor, either (i) replace such Product doses subject to the Recall within a period of 90 calendar days from the moment of the recall at no additional charge to the Participating

Member State(s) or (ii) refund the Participating Member State(s) the applicable price paid by the Participating Member State(s) to the contractor for the Product doses subject to a Recall.

Except as and to the extent required by applicable law, this Article I.12.5 sets out the only liability of the contractor and the sole and exclusive remedy for Participating Member States for a Recall in accordance with this APA.

I.12.6 The contractor shall keep the Commission and the Participating Member States informed about any signal detected during the pharmacovigilance or Product monitoring programmes in relation to the Products which are the object of this APA within 5 working days from notifying the European Medicines Agency in accordance with the European Medicines Agency's guidelines on good pharmacovigilance practices.

I.12.7 The contractor shall use Reasonable Best Efforts to obtain Marketing Authorisation for the Product. To that end, the contractor has submitted a rolling submission for application for Marketing Authorisation for the Product as soon as reasonably practicable after successful clinical development of the Product. If the contractor first obtains a conditional Marketing Authorisation for Product, the contractor shall use Reasonable Best Efforts to obtain full Marketing Authorisation as soon as possible upon completion of the dataset necessary to obtain such full Marketing Authorisation.

I.12.8 The contractor shall provide to the Commission and the Participating Member States, via the Commission, the following information as part of and until its submission for Marketing Authorisation and full production:

(a) summarised key updates on progress made in the clinical development of the Product; final reports of clinical studies and safety evaluations submitted to the European Medicines Agency, promptly after submission to the European Medicines Agency;

(b) key updates on (i) challenges on establishment of the supply chain and (ii) the purchasing of materials necessary for the manufacture of the Product doses, which, in each case, materially affects the delivery schedule set forth in Article I.4.7;

(c) the use of the Down Payment by the Commission and the Participating Member States, linked to points (a) to (b), in general terms every two months after the signature of this APA based on Annex IV; and

(d) scientific publications and public announcements, after such publications and announcements have been published.

I.13. DEFINITIONS

For the purpose of this APA, the following definitions (indicated in *italics* in the text) apply:

'Affiliate': with respect to the contractor, any Person that controls, is controlled by, or is under common control with the contractor. For purposes of this APA, such Person will be deemed to control another Person if it owns or controls, directly or indirectly, more than fifty percent (50%) of the equity securities of such Person entitled to vote in the election of directors (or, in the case that such Person is not a corporation, for the election of the corresponding managing authority), or

otherwise has the power to direct the management and policies of such Person. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence; provided, that such foreign investor has the power to direct the management and policies of such entity;

'APA': has the meaning set forth in the preamble;

'Breach of obligations': failure by the contractor to fulfil one or more of its contractual obligations under this APA;

'Claim': has the meaning set forth in Article II.5.2;

'CMOs': has the meaning set forth in the Recitals;

'Commission': has the meaning set forth in the preamble;

'contractor': has the meaning set forth in the preamble;

'Confidential information or document': any information or document received by either party from the other or accessed by either party in the context of the *implementation of the APA*, that any of the parties has identified in writing as confidential, or, if not so identified, that would be reasonably understood in the biopharmaceutical industry to be confidential. It may not include information that is publicly available;

'Conflict of interest': a situation where the impartial and objective *implementation of the APA* by the contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the APA;

'**COVE Study**': has the meaning set forth in the Recitals;

'**COVID-19**': has the meaning set forth in the Recitals;

'**COVID-19 Pandemic**': has the meaning set forth in the Recitals;

'December Option Increase': has the meaning set forth in Article I.4.4;

'Deferred Option Increase': has the meaning set forth in Article I.4.4;

'**Deficient Product'**: has the meaning set forth in Article I.5.1;

'Donation Country': has the meaning set forth in Article I.4.6;

'Down Payment': has the meaning set forth in Article I.4.2;

'European Institutions': has the meaning set forth in Article II.7.6;

'Exchange Rate Methodology': has the meaning set forth in Article I.8.4;

'Exercising Member State': has the meaning set forth in Article I.4.4;

'Expected Approval Date': has the meaning set forth in Article I.4.7(a);

'Financial Statement': has the meaning set forth in Article II.16.5(a);

'Force majeure': any unforeseeable, exceptional situation or event beyond the control of the Parties that prevents either of them from fulfilling any of their obligations under the APA. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of the subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties, as well as the Covid-19 Pandemic, may not be invoked as *force majeure*;

'Formal notification' (or 'formally notify'): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

'Fraud': an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests;

'Good Manufacturing Practices' or 'GMP': means the then-current good manufacturing practices for manufacture required by the standards, regulations and guidelines set out in Directive 2003/94/EC, Directive 2017/1572 and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, as based on the relevant provisions of Directive 2001/83/EC";

'Governmental Authority': any applicable government authority, court, council, tribunal, arbitrator, agency, department, bureau, branch, office, legislative body, commission or other instrumentality of (i) any government of any country, (ii) any nation, state, province, county, city, or other political subdivision thereof, or (iii) any supranational body;

'Gross Negligence' means "faute lourde" under Belgian law;

'Implementation of the APA': the purchase of the Product envisaged in the APA through the signature and *performance of Vaccine Order Forms*;

'Indemnified Persons': has the meaning set forth in Article II.5.1;

'Initial Doses': has the meaning set forth in Article I.4.2;

'Initial Delivery Schedule': has the meaning set forth in Article I.4.7(a);

'Irregularity': any infringement of a provision of Union law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the Union's budget;

'Losses': has the meaning set forth in Article II.5.1;

'**Marketing Authorisation**': the approval under the relevant provisions of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervisions of medicinal products for human and veterinary use and establishing a European Medicines Agency, by the European Commission necessary for the placing on the market of the Vaccine in the territory of the European Union, including conditional marketing authorisation in accordance with Article 14-a of Regulation 726/2004;

'Notification' (or 'notify'): form of communication between the parties made in writing including by electronic means;

'Option Doses': has the meaning set forth in Article I.4.4;

'Option Increase': has the meaning set forth in Article I.4.4;

'Party' and '**Parties**': have the meaning set forth in the preamble;

'Performance of a Vaccine Order Form': the execution of tasks and delivery of the Product by the contractor to the Participating Member State;

'Person': means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust or joint venture, or a Governmental Authority or political subdivision thereof;

'Pre-existing material': any material, document, technology or know-how which exists prior to the contractor using it for the production of a *result* in the *implementation of the APA*;

'Pre-existing right': any industrial and intellectual property right on *pre-existing material*; it may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the *creator*, the Commission as well as to any other third parties;

'Product': the finished and packaged form of the contractor's proprietary mRNA-1273 vaccine against COVID-19;

'**Product Claim**': has the meaning set forth in Article I.5.1;

'Product Marks': MODERNA, MODERNATX, any Trademark incorporating either term, any Trademark that is used by the contractor in association with the Product, including any Trademarks that accompany the Product when delivered by the contractor to the Participating Member States, and any Trademark for which the contractor has applied for registration in the European Union. The contractor may provide the Commission and the Participating Member States with a list of such Product Marks from time to time;

'Professional conflicting interest': a situation in which the contractor's previous or ongoing professional activities affect its capacity to implement the APA or to perform a Vaccine Order Form to an appropriate quality standard;

'**Reasonable Best Efforts**': a reasonable degree of diligent efforts to accomplish a given task, acknowledging that such things as the complex and highly regulated nature of the Product; the timely availability of raw materials and inventories; the success of necessary clinical trials

programs to support safety and immunogenicity data for the Product; contractor's commitments to other purchasers of the Product; other reasons relating to the uncertainties of producing a new Product for a new disease with an mRNA platform for which Products have not yet been registered by regulatory authorities; and any other currently unknown factors which may delay or render impossible, contractor's successful completion of the particular task, including developing a suitable production process as may be required for a new strain of virus, ramping up capacity at contract manufacturing partners, meeting delivery schedules and obtaining Marketing Authorisation may be beyond the complete control of the contractor, provided, however, that the contractor shall not be required to take any actions inconsistent with past practice, ordinary course of business, prudent and reasonable business behaviour;

'Recall': has the meaning set forth in Article I.12.5;

'Refundable Items': has the meaning set forth in Article II.16.5(a);

'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the contractor, or who has powers of representation, decision or control with regard to the contractor;

'Resale Country': has the meaning set forth in Article I.4.6;

'Result': any intended outcome of the *implementation of the APA*, whatever its form or nature. A *result* may be further defined in this APA as a deliverable. A *result* may, in addition to newly created materials produced specifically for the Participating Member States by the contractor or at its request, also include *pre-existing materials*;

'Vaccine IP Rights': has the meaning set forth in Article I.10;

'Vaccine Order Form': has the meaning set forth in the Recitals;

'Technical Dispute': has the meaning set forth in Article I.5.3;

'Third Party': any Person other than (a) the Commission or any of the Participating Member States or (b) the contractor or its Affiliates;

'Trademark': trademarks, service marks, certification marks, trade dress, internet domain names, trade names, identifying symbols, designs, product names, company names, slogans, logos or insignia, whether registered or unregistered, and all common law rights, applications and registrations therefor, and all goodwill associated therewith;

'Unspent Amounts': has the meaning set forth in Article II.16.5(a);

'Updated Delivery Schedule': has the meaning set forth in Article I.4.7(a);

'Willful Misconduct' means conduct which (i) constitutes an intentional act aimed at achieving a wrongful purpose, (ii) occurs in the absence of a legal or factual justification, and (iii) occurs in disregard of a known or obvious risk of causing harm.

(Signature page follows)

Sensitive*
RELEASABLE TO: Need to know basis

SIGNATURES

For the contractor,

Moderna Switzerland GmbH
Stéphane Bancel, Managing Director

Signature: DocuSigned by: [signature] 4A4C1F93A80A4C7...

Done at Cambridge, MA, USA, ...

For the Commission, on behalf and in the name of the Participating Member States,

Ms Stella Kyriakides, Commissioner for Health and Food Safety

Signature: [signature]

Done at Brussels, 4/12/2020
Nicosia, Cyprus.

In duplicate in English.

II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES

II.1. SEVERABILITY

Each provision of this APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The APA must be interpreted as if it had contained the substitute provision as from its entry into force.

II.2. PROVISION OF PRODUCT

II.2.1 The contractor must supply the Product in accordance with the state of scientific and technical knowledge in the industry for such Product at the time when the contractor put the Product into circulation, the applicable law in the Participating Member States and the provisions of this APA.

II.2.2 The contractor must comply with the requirements provided for in this APA.

II.2.3 All periods specified in the APA are calculated in calendar days, unless otherwise specified.

II.2.4 The contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.3. COMMUNICATION BETWEEN THE PARTIES

II.3.1 Form and means of communication

Any communication of information, notices or documents under the APA must:

(a) be made in writing in paper or electronic format in the language of the contract;

(b) bear the APA number and, if applicable, the Vaccine Order Form number;

(c) be made using the relevant communication details set out in Article I.9; and

(d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

II.3.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this APA contract refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.9. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non- delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 registers it.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

II.4. LIABILITY

II.4.1 Without prejudice to the terms of Article II.5, the Commission and the Participating Member States are not liable for any damage or loss caused by the contractor, including any damage or loss to third parties during or as a consequence of *Implementation of the APA*.

II.4.2 If required by the relevant applicable legislation, the contractor must take out an insurance policy or self-insurance against risks and damage or loss relating to the *Implementation of the APA*. It must also take out supplementary insurance or self-insure as reasonably required by common practice in the pharmaceutical industry for a COVID-19 vaccine. Upon request, the contractor must provide evidence of insurance coverage or self-insurance to the Commission.

II.4.3 If a third party brings any action against the Commission or the Participating Member State in connection with the *Implementation of the APA*, including any action for alleged breach of intellectual property rights, the Commission or the Participating Member State will give prompt written notice to the contractor, along with all documentation in the Commission's or the Participating Member State's possession relating thereto. Thereafter, the contractor must use reasonable efforts to assist the Commission or the Participating Member State as reasonably requested by the Commission or the Participating Member State, including by intervening in support of the Commission or the Participating Member State upon reasonable request.

II.4.4 The Commission or the Participating Member State are not liable for any loss or damage caused to the contractor during or as a consequence of *Implementation of the APA*, unless pursuant to Article II.5, or the loss or damage was caused by its Willful Misconduct, Gross Negligence or breach of this APA or the applicable Vaccine Order Form.

II.4.5 The contractor is not liable to the Commission or any of the Member States for any loss or damages unless the loss or damage was caused by the contractor's Willful Misconduct, Gross Negligence or breach of this APA or the applicable Vaccine Order Form. Except as expressly contemplated in this APA, the contractor is not liable for any loss or damage such as (i) any indirect

loss or damage incurred, including as a result of loss of profits, of anticipated savings, of business, of goodwill, or the cost of any substitute product or services; or (ii) any costs or expenditures incurred to evaluate the viability of entering into this APA or any Vaccine Order Form.

II.4.6 No limitation of the liability of the contractor shall apply as regards damages resulting from the contractor's Gross Negligence, Willful Misconduct, Fraud or failure to comply with Article I.12.7.

The remedies set forth in Article I.5, I.12.5, II.14, or II.16.1 shall be the sole and exclusive remedies available to the Commission and the Participating Member States in case of breach of the obligations laid down in such provisions by the contractor.

Except as otherwise expressly set forth in this Article II.4.6, the contractor's maximum aggregate liability to the Commission or to a Participating Member State under or in connection with this APA or a Vaccine Order Form will not exceed the lesser of (a) (i) with respect to the Commission, twenty percent (20%) of the amount actually paid by the Commission to the contractor under this APA or (ii) with respect to the applicable Participating Member State, twenty percent (20%) of the amount actually paid by such Participating Member State to the contractor under this APA (in each case ((i)-(ii)), net of any credits, offsets or refunds due, paid or payable hereunder) and (b) (i) with respect to the Commission, the most favorable limitation of liability cap provided by the Commission to any other manufacturer or supplier of any vaccine supplied to the Commission or any of the Member States under an Advance Purchase Agreement in connection with the COVID-19 Pandemic, or (ii) with respect to the applicable Participating Member State, the most favorable limitation of liability cap provided by the applicable Participating Member State to any other manufacturer or supplier of any vaccine supplied to the applicable Participating Member State under an Advance Purchase Agreement in connection with the COVID-19 Pandemic.

For the avoidance of doubt, no limitation of liability laid down in this Article II.4.6 shall affect the contractor's obligations vis-a-vis third parties or vis-a-vis the Participating Member States in the circumstances in which indemnification under Article II.5 is not available to the contractor.

II.4.7 For the avoidance of doubt in no event can any limitation under this APA concern Losses suffered by third parties which are subject to indemnification under the conditions set out in Article II.5.

II.5. INDEMNIFICATION

II.5.1 The Commission, on behalf the Participating Member States, declares that the use of Products produced under this APA will happen under epidemic conditions requiring such use, and that the administration of Products will therefore be conducted under the sole responsibility of the Participating Member States. Hence, each Participating Member State shall indemnify and hold harmless the contractor, its present and future Affiliates, collaborators, contractors, sub-contractors, licensees and sub-licensees, and officers, directors, employees and other agents and representatives of each (together, the "**Indemnified Persons**") from and against any and all damages, liabilities, reasonable settlements to which the Participating Member State has given its consent as per Article II.5.3 and reasonable, documented legal costs and expenses (e.g., external law firms, external experts, consultants, and document vending fees) incurred relating to Claims for harm, damages and losses associated with death, physical, mental or emotional injury, illness,

or disability, fear of physical, mental, or emotional injury, illness, or disability (including claims for medical monitoring), property loss or damage or business interruption of an injured party or related claimant (together the "**Losses**" and each a "**Loss**") relating to or arising from use or deployment of the Products supplied to or for the benefit of such Participating Member State under the applicable Vaccine Order Form with such Participating Member State. The indemnification set forth herein (and in the Vaccine Order Form with each Participating Member State) is intended to be interpreted broadly in favor of indemnification and shall be available regardless of whether the Losses originate from Claims regarding testing, development, manufacture, delivery, export, import, distribution, sale, offer for sale, administration, use or deployment of the Product. A Participating Member State will indemnify an Indemnified Person for its reasonable, documented legal costs and expenses (e.g., external law firms, external experts, consultants, and document vending fees) incurred relating to a given Claim as such costs and expenses are incurred on an annual basis, commencing thirty (30) days after the first anniversary of the date of written notice of a Claim and continuing on an annual basis thereafter until resolution of the Claim, unless the Participating Member State challenges such payment based on evidence that the Losses that are the subject of the Claim in question are caused by the Willful Misconduct, Gross Negligence or failure to comply with Good Manufacturing Practices of the Indemnified Party. The indemnification set forth above will not be available to the applicable Indemnified Person only if and to the extent that any such Loss arises out of the Willful Misconduct or Gross Negligence of such Indemnified Person, or if a court of competent jurisdiction makes a final finding or determination that such Loss is caused by a defect in the Product resulting from the failure of the contractor or the Indemnified Persons to comply with Good Manufacturing Practices with respect to the manufacture of the Product supplied to the applicable Participating Member State that is the subject of the Claim. For clarity, the indemnification provisions set forth herein will apply to Losses defined in this paragraph regardless of whether the Claim is based (in whole or in part) on the Product Liability Directive or other applicable causes of action, laws, rules or regulations available in the Participating Member State.

II.5.2 In the event that any Indemnified Person becomes aware of any demand, claim, action, suit or proceeding, or threat of a demand, claim, action, suit or proceeding, against such Indemnified Person which may reasonably be considered likely to cause a Loss or be subject to the indemnity herein (and in the Vaccine Order Form with each Participating Member State) (a "**Claim**"), the contractor shall ensure that such Indemnified Persons shall give the Participating Member State prompt notice of the Claim and that such Indemnified Person shall reasonably cooperate with such Participating Member State and give the Participating Member State in question (at the Participating Member State's cost and expense, which shall be considered Losses of the Indemnified Persons) access to such documents and information as are reasonably necessary and appropriate for the Participating Member State to indemnify such Indemnified Persons with respect to such Claim and to verify whether the conditions pursuant to Article II.5.1 are fulfilled. In the event that a Participating Member State becomes aware of any Claim against an Indemnified Person, such Participating Member State shall promptly provide written notice to the contractor of such Claim along with all information relating to such Claim that is in such Participating Member State's possession or control. Any alleged delay in notice will not relieve the Participating Member State from its indemnification obligations, provided that any delay in notice has not caused actual prejudice to the rights of the Participating Member State hereunder. Notice is presumptively prompt where provided within (30) days from the date of the contractor receiving written notice of a Claim.

II.5.3 The contractor shall have (30) days from the date of receiving written notice of a Claim, to request the relevant Participating Member State, which request shall not be unreasonably withheld, conditioned or delayed, to defend, at its cost and expense and with counsel of its choosing (subject to the consent of the contractor, which shall not be unreasonably withheld, conditioned or delayed), such Indemnified Persons with respect to such Claim. If the contractor does not make such request within such time period, the contractor will be responsible to defend, at its cost and expense and with counsel of its choosing, such Indemnified Persons with respect to such Claim. The contractor, the applicable Indemnified Person and the Participating Member State shall act promptly and reasonably with respect to the defense of any Claim and shall reasonably seek to minimize any Losses. Each of the contractor and the Participating Member State will obtain the consent of the other prior to settling any Claim, provided that such consent shall not be unreasonably withheld, conditioned or delayed.

II.5.4 The Commission, on behalf of itself and the Participating Member States, acknowledges that the indemnity provisions set forth herein and in the Vaccine Order Forms with the Participating Member States are essential inducements to the contractor entering into this APA and the Vaccine Order Forms with the Participating Member States. In the event that any Indemnified Person brings any proceeding or legal action to enforce any right to indemnity under this APA or any Vaccine Order Form with a given Participating Member State and prevails in whole or in any material part, the Participating Member State will pay all reasonable, documented attorneys' fees and other reasonable, documented expenses incurred by such Indemnified Person in connection with any such action. The Indemnified Persons shall be deemed third party beneficiaries with respect to their rights of indemnity under this APA and the Vaccine Order Forms with the Participating Member States.

II.5.5 If, whilst respecting the applicable rules of Union law, a Participating Member State were to introduce legislation to provide for limitations on the liability of developers, suppliers, exporters, importers, manufacturers, distributors or other members of the supply chain of the Product as supplied under this APA or any other COVID-19 Product, the Participating Member State in question will ensure that all Indemnified Persons have the full benefit of any such limitations of liability.

II.5.6 No Person (including any Person to whom the Product has been administered) other than the parties hereto and their respective Affiliates, and in the case of the contractor, the Indemnified Persons, and permitted assignees hereunder, will be deemed an intended beneficiary hereunder or have any right to enforce any obligation or make a claim under this APA or the Vaccine Order Forms with the Participating Member States.

II.5.7 For each Participating Member State that has an existing national Product injury compensation legislation (or in the future enacts such legislation) in the Territory, if, whilst respecting the applicable rules of Union law, a Participating Member State were to add any COVID-19 Product to its national Product injury compensation legislation (or in the future enacts such legislation), the Participating Member State will use reasonable best efforts to ensure that the Vaccine is promptly included within the scope of such national Product injury compensation legislation in the Territory to the same extent as any such other COVID-19 Product, unless there is an objective reason not to do so.

II.6. CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.6.1 The contractor must take all the necessary measures to prevent any situation of *conflict of interest* or *professional conflicting interest*.

II.6.2 The contractor must *notify* the Commission in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the *implementation of the APA*. The contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

(a) verify that the contractor's action is appropriate;

(b) require the contractor to take further action within a specified deadline;

(c) decide not to award a Vaccine Order Form to the contractor.

II.6.3 The contractor must pass on all the relevant obligations in writing to:

(a) its personnel;

(b) any natural person with the power to represent it or take decisions on its behalf;

(c) third parties involved in the *Implementation of the APA*, including subcontractors.

The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.7. CONFIDENTIALITY

II.7.1 The Commission, the Participating Member State and the contractor must treat with confidentiality any information or documents, in any format, disclosed in writing or orally, relating to the *Implementation of the APA* and identified in writing as confidential.

II.7.2 The Commission, the Participating Member State and the contractor shall:

(a) not use *confidential information or documents* for any purpose other than to perform its obligations under the APA or a Vaccine Order Form without the prior written agreement of the other party;

(b) ensure the protection of such *confidential information or documents* with the same level of protection as its own *confidential information or documents* and in any case with due diligence;

(c) not disclose, directly or indirectly, *confidential information or documents* to third parties unless such third parties agree to comply with this Article or are subject to substantially similar confidentiality obligations as provided in this Article.

II.7.3 The confidentiality obligations set out in this Article are binding on the Commission, the Participating Member State and the contractor during the *Implementation of the APA* and for as long as the information or documents remain confidential unless:

(a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;

(b) the *confidential information or documents* become public through other means than a breach of the confidentiality obligation;

(c) any applicable law requires the disclosure of the *confidential information or documents* (including securities laws or as required by the stock exchange rules of the contractor or any of its Affiliates).

II.7.4 The contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the *Implementation of the APA* a commitment that they will comply with this Article or ensure that such person is subject to substantially similar confidentiality obligations. At the request of the Commission, the contractor must provide a document providing evidence of this commitment.

II.7.5 Notwithstanding the other provisions of this Article, the Commission, the Participating Member States and the contractor may issue a press release and/or other public statement. The Parties shall consult together on the timing, contents and manner of any press release relating to this *APA*. A party may subsequently publicly disclose any information previously contained in any public announcement made in accordance with this Article.

II.7.6 Prior to any disclosure by the Commission containing Confidential Information contained in the present document, the draft disclosure shall be submitted by the European Commission to the contractor by any appropriate means in order to provide the contractor the opportunity to make any observation or request for any change to such disclosure to protect the secrecy of business in the sense of the Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets).

The contractor acknowledges that the Commission, along with other agencies and offices of the European Union (collectively, the "**European Institutions**"), are subject to requirements under Regulation (EC) 1049/2001[3], which may require the European Institutions to disclose information to third parties on request. The Commission commits itself to assess any request for access to a document that relates to this contract according to the exclusions or exceptions set forth in Regulation (EC) 1049/2001 apply.

[3] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

II.8. PROCESSING OF PERSONAL DATA

II.8.1 Processing of personal data by the Commission

Any personal data included in or relating to the APA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the APA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at https://ec.europa.eu/info/data-protection- public-procurement-procedures_en.

The contractor or any other person whose personal data is processed by the data controller in relation to this APA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the contractor or any other person whose personal data is processed in relation to this APA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

II.8.2 Processing of personal data by the contractor

The processing of personal data by the contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

II.9. SUBCONTRACTING

II.9.1 The contractor may not subcontract and have the APA implemented by third parties beyond the third parties already mentioned in this APA without prior written consent of the Commission (such consent not to be unreasonably withheld, conditioned or delayed). The Commission confirms its consent for the contractor to subcontract and have the APA implemented by the subcontractors set forth on Annex V.

II.9.2 The contractor will have the right to extend the rights, licenses, and obligations granted or imposed under this APA or any Vaccine Order Form to one or more of its Affiliates. All applicable terms and provisions of this APA and the Vaccine Order Forms will apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the contractor. The contractor will remain at all times primarily liable for any acts or omissions, including financial liabilities, of its Affiliates.

II.9.3 In the case of subcontracting, the contractor remains bound by its contractual obligations and is solely responsible for the *Implementation of the APA*.

II.9.4 The contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this APA.

II.9.5 The Commission may request the contractor to replace a subcontractor found to be in a situation provided for in one of the situations provided for in Article 136(1) and (2) of the Financial Regulation[4].

II.10. AMENDMENTS

II.10.1 Any amendment to the APA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the APA.

II.10.2 No amendment can make changes to the APA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

II.11. ASSIGNMENT

II.11.1 The contractor cannot assign any of the rights and obligations arising from the APA, including claims for payments or factoring, without prior written authorisation from the Commission (such authorisation not to be unreasonably withheld, conditioned or delayed). In such cases, the contractor must provide the Commission with the identity of the intended assignee.

II.11.2 Any right or obligation assigned by the contractor without authorisation is not enforceable against the Commission or the Participating Member States.

II.12. INTELLECTUAL PROPERTY RIGHTS

II.12.1 Identification of pre-existing rights

When delivering the *results*, the contractor must warrant that, for any use that the Participating Member State may envisage within the limits set in this APA, to the knowledge of the contractor, the newly created parts and the *pre-existing material* incorporated in the *results* are free of claims from *creators* or from any third parties and all the necessary *pre-existing rights* have been obtained or licensed.

To that effect, the contractor must establish a list of all *pre-existing rights* to the *results* of this APA or parts thereof, including identification of the rights' owners. If, to the knowledge of the contractor, there are no *pre- existing rights* to the *results*, the contractor must provide a declaration to that effect. The contractor must provide this list or declaration to the Commission together with the invoice for payment of the balance at the latest.

II.12.2 Evidence of granting of pre-existing rights

Upon request by the Commission, the contractor must, in addition to the list mentioned under Article II.12.1, provide evidence that it has the ownership or the right to use all the listed *pre-*

[4] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1.

existing rights, except for the rights owned or licensed by the Union. The Commission may request this evidence even after the end of this APA.

This evidence must include, as appropriate:

(a) the title and number of the patent;

(b) the full identification of the owner(s), inventor(s), assignee(s), licensees(s);

(c) a copy of the licence or of the agreement granting the relevant rights to the contractor or a reference to this licence;

(d) a copy of the agreement or extract from the employment contract granting the relevant rights to the contractor where parts of the *results* were created by its *personnel*;

(e) the text of the disclaimer notice if any.

II.12.3 Disclaimer

When stating opinions about the use of the *results*, the contractor must declare that the opinions expressed are those of the contractor only and do not represent the Commission's official position. The Commission may waive this obligation in writing or provide the text of the disclaimer.

II.13. FORCE MAJEURE

II.13.1 If a party is affected by *force majeure*, it must immediately *notify* the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.13.2 A party is not liable for any delay or failure to perform its obligations under the APA if that delay or failure is a *result* of *force majeure*. If the contractor is unable to fulfil its contractual obligations owing to *force majeure*, it has the right to remuneration only for the services actually provided.

II.13.3 The parties must take all necessary measures to limit any damage due to *force majeure*.

II.14. CONSEQUENCES OF DELAY

If the actual delivery date of Product doses ordered pursuant to a Vaccine Order Form is more than 90 calendar days after the delivery date agreed upon by the contractor and Participating Member State for such Product doses, a Participating Member State (or the Commission, acting on its behalf) may cancel its order for the number of Product doses that are actually more than 90 calendar days late by providing written notice to the contractor within 14 calendar days of the expiration of the 90 day period.

II.15. SUSPENSION OF THE IMPLEMENTATION OF THE APA

II.15.1 Suspension by the contractor

If the contractor is affected by *force majeure*, it may suspend the provision of the services and Product under a Vaccine Order Form.

The contractor must immediately *notify* the Commission and the Participating Member States of the suspension. The *notification* must include a description of the *force majeure* and state when the contractor expects to resume the provision of services and the Product.

The contractor must *notify* the Commission and the Participating Member States as soon as it is able to resume *performance of the Vaccine Order Form*, unless the Commission has already terminated the APA or the Vaccine Order Form.

II.15.2 Suspension by the Commission or the Participating Member State

The Commission or the Participating Member State in question may suspend the *Implementation of the APA* or *performance of a Vaccine Order Form* (of such Participating Member State) or any part of it:

(a) if the procedure for awarding the APA or a Vaccine Order Form or the *Implementation of the APA* proves to have been subject to *irregularities, fraud or* material *breach of obligations* by the contractor;

(b) in order to verify whether the contractor's presumed *irregularities, fraud* or *material breach of obligations* have actually occurred.

The Commission or the Participating Member State in question must *formally notify* the contractor of the suspension and the reasons for it. Suspension takes effect on the date of *formal notification*, or at a later date if the *formal notification* so provides.

The Commission or the Participating Member State in question must immediately *notify* the contractor as soon as the verification is completed whether:

(a) it is lifting the suspension; or
(b) it intends to terminate the APA or its Vaccine Order Form under Article II.16.2(e) or II.16.2(h).

The contractor is not entitled to compensation for suspension of any part of the APA or a Vaccine Order Form under this Article II.15.2.

II.16. TERMINATION OF THE APA

II.16.1 Grounds for automatic termination of the APA

The APA will be automatically terminated if and when the contractor notifies the Commission of the termination of the APA and Vaccine Order Forms pursuant to this Article II.16.1 due to its inability to provide the Product because of, and only because of, the following reasons: (i) the clinical trial results not being satisfactory, (ii) the clinical trial results not meeting their end point

in terms of efficacy or safety or (iii) the Marketing Authorisation for the Product not being granted. The notification of the contractor shall set out in detail the underlying reasons for automatic termination of the APA. The termination will be effective unless the Commission objects in writing within thirty (30) calendar days following the notification by the contractor, such objection may only be issued based on reasonable grounds given the evidence of one the three reasons (points (i) through (iii)) stated above and taking into account the severity of the impact that the continuation of the APA would have on the contractor's business.

II.16.2 Grounds for termination by the Commission

The Commission may terminate the APA or a Participating Member State may terminate its on-going Vaccine Order Form in the following circumstances:

(a) if the contractor is unable to obtain Marketing Authorisation for the Product by 30 September 2021;

(b) if the contractor is unable to complete the delivery of the Initial Doses of Product by 31 December 2021;

(c) if the contractor is in breach of a substantial contractual obligation that is not remedied within a period of thirty (30) days following notice by the Commission or a Participating Member State to the contractor or repeatedly refuses to sign one or several Vaccine Order Forms;

(d) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation[5];

(e) if the contractor or any *related person* is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation;

(f) if the procedure for awarding the APA or the *Implementation of the APA* prove to have been subject to *irregularities*, *fraud* or *breach of obligations*;

(g) if the contractor is in a situation that could constitute a *conflict of interest* or a *professional conflicting interest*;

(h) if a change to the contractor's legal, financial, technical, organisational or ownership situation is likely to substantially affect the *implementation of the APA* or substantially modify the conditions under which the APA was initially awarded or a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;

[5] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 https://eur-lex.europa.eu/legal- content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046

(i) in the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the APA or a Vaccine Order Form would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or contractors.

II.16.3 Grounds for termination by the contractor

The *contractor* may terminate the *APA* or the respective *Vaccine Order Form* in the following circumstances:

(a) If the *Commission* or any of the *Participating Member States* materially fail to comply with their respective obligations.

(b) In the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the *APA* or a *Vaccine Order Form* would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or contractors.

II.16.4 Procedure for termination

A party must *formally notify* the other party of its intention to terminate the APA or a Vaccine Order Form and the grounds for termination.

The other party has 30 days following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed.

If the other party submits observations, the party intending to terminate must *formally notify* it of such party's intention to terminate this APA or a Vaccine Order Form and the grounds for termination. The decision to terminate becomes enforceable the day after this second formal notification.

II.16.5 Effects of termination

(a) In case of an automatic termination pursuant to Article II.16.1:

(i) No liability is incurred by any Party in case of an automatic termination according to Article II.16.1.

(ii) The Down payment shall not be refundable except in the following way:

The contractor shall send to the Commission within sixty (60) days from notifying the Commission about the automatic termination of the APA, a financial statement (the "**Financial Statement**"), detailing for which costs and expenses the Down Payment has been used in relation to the purposes as set out in the APA. Expenses to be taken into account include the full amount of internal and/or external expenses which have been, or will be, incurred whether prior to or after execution of this APA, as well as such which have been committed by, or relate to commitments made by, the contractor at the time

when the contractor notified the Commission, it being understood that such 'expenses' shall include, without limitation, costs, expenses and liabilities, write-offs and value adjustments in connection with research, development, ramp up, IP, real estate, construction, administration, manufacturing, production, packaging, delivery, preservation, transportation, personnel, redundancy, litigation, agreements, terminations of agreements, advice and services, penalties and fines, whether incurred directly or indirectly by the contractor, a provider, a contractor or a subcontractor of the contractor.

In the Financial Statement, the contractor will set out such amounts as well as those amounts of the Down Payment that have neither been incurred nor committed ("**Unspent Amounts**"). Such Unspent Amounts will be reimbursed by the contractor to the Commission within thirty (30) days from the receipt of the Financial Statement by the Commission, it being understood that the Financial Statement and the Unspent Amounts shall be final and binding upon all Parties to the extent the Commission and the Participating Member States have not provided to the contractor a written statement of objections, specifying in reasonable detail the grounds of objections, within thirty (30) days from the receipt of the Financial Statement by the Commission.

(iii) In case of an automatic termination pursuant to Article II.16.1 because the Marketing Authorisation for the Product is not granted, but the contractor is able to sell the Product constituting the Initial Doses (or a portion thereof) to a third party because it has obtained valid marketing authorisation for the Product in a different country or territory, then the contractor will refund fifty percent (50%) of the Down Payment to the Commission within 90 days after the effective date of automatic termination.

(b) In case of a termination by the Commission pursuant to Article II.16.2(a):

(i) The provisions on the effect of the termination and refunding of Unspent Amounts as set out in Article II.16.5(a)(i) and II.16.5(a)(ii) apply mutatis mutandis.

(ii) The provisions on the effect of the termination and refunding of the Down Payment as set out in Article II.16.5(a)(iii) apply mutatis mutandis.

(c) In case of a termination of the *APA* by the Commission or a Vaccine Order Form by a Participating Member State according to Article II.16.2(b) to II.16.2(h), the contractor may be liable for damage incurred by the Commission or the Participating Member State as a direct result of the termination of the *APA* or a Vaccine Order Form in accordance with Article II.16.2(b) to II.16.2(h), it being understood that, in case of a termination pursuant to Article II.16.2(b), all payment obligations with respect to *Products* already delivered or in delivery in compliance with the *APA* at the time of the termination shall remain unaffected. The Commission or the Participating Member State may claim compensation for such damage, as allowed by Article II.4.

(d) In case of termination pursuant to Article II.16.3:

(i) The contractor is not entitled to compensation for any damage resulting from the termination of the APA or a Vaccine Order Form, including loss of anticipated profits,

if the contractor terminated the *APA* or the relevant Vaccine Order Form in accordance with Article II.16.3(b).

(ii) The Commission and the Participating Member State are liable for damage incurred by the contractor as a result of the termination of the *APA* or a Vaccine Order Form by the contractor on the basis of Article II.16.3(a). It is understood that all payment obligations with respect to *Products* already delivered or in delivery in compliance with the *APA* at the time of the termination shall remain unaffected. The contractor may claim compensation for such damage against the Commission and/or the Participating Member State(s), as allowed by Article II.4.

(e) The Parties must take all appropriate measures to minimise costs, prevent damage and cancel or reduce their commitments.

(f) Upon termination, at the written request of the disclosing party, each receiving party will return or destroy the Confidential Information of such disclosing party, provided that (i) one (1) copy of the Confidential Information may be retained by the receiving party for the sole purpose of monitoring its ongoing obligations hereunder; and (ii) one (1) copy of the Commission's or each Participating Member State's Confidential Information may be retained and used by or on behalf of the contractor in connection with regulatory filings for the Product. Notwithstanding the foregoing, no receiving party shall not be obliged to destroy, erase, return or provide to the disclosing party any electronic records of Confidential Information which may be stored in electronic back-ups or other digital archives in the ordinary course; but in each case the receiving party shall continue to treat those, in so far as they contain Confidential Information, as confidential pursuant to the terms of this APA.

(g) Within sixty (60) calendar days of the date of termination, the contractor must submit any report and any invoice for Product that were already delivered or in delivery in compliance with the *APA* at the time of termination. The Commission and the Participating Member States shall pay such invoices within 30 days from receipt of the invoice.

II.17. INVOICES, TAXES, VALUE ADDED TAX AND E-INVOICING

II.17.1 Payment Requests, Invoices and value added tax

Payment requests and invoices shall contain the following information: (i) the *contractor*'s full name and address, (ii) the reference to this APA and to the *Vaccine Order Form* (to the extent already concluded), (iii) the full name and address of the recipient, (iv) the name of the *Participating Member State* concerned, (v) the invoiced amount, (vi) the currency, (vii) the quantity of *Product doses* delivered or in delivery in compliance with the *APA* at the time (or offered to be delivered if the *Participating Member State* illegitimately refuses acceptance of delivery), or, with respect to the *Down Payment*, the quantity of *Product doses* allocated to the relevant *Participating Member State* pursuant to Articles I.4.2 and I.4.4, (viii) the date of delivery (if relevant), and (ix) the date of issuance of the payment request or invoice.

Invoices must indicate the place of taxation of the *contractor* for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT (where VAT is applicable).

For the avoidance of doubt, VAT may be charged on *doses* of the *Product* under the conditions of national legislation. In such cases, the taxable amount may include the amount paid by the *Participating Member State* as well as the respective portion of the *Down Payment* paid by the *Commission*.

For the further avoidance of doubt, the *Parties* agree that all prices set forth in the *APA* shall be exclusive of VAT and that VAT, if any, shall be paid in addition to the prices set forth in the *APA*.

The Parties agree that the contractor shall be indemnified by each Participating Member State against any import duties, charges, levies or imposts that may be required to be paid by the contractor in respect of any supplies of Product to such Member State. The contractor shall further be indemnified against any irrecoverable VAT that it may incur in any Participating Member State in connection with the importation of any Product to that Participating Member State.

II.18. PAYMENTS AND GUARANTEES

II.18.1 Date of payment

The date of payment is deemed to be the date on which the Commission's account or the account of the Participating Member State in question is debited.

II.18.2 Costs of transfer

The costs of the transfer are borne as follows:

(a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;

(b) the contractor bears the costs of receipt charged by its bank;

(c) the party causing repetition of the transfer bears the costs for repeated transfer.

II.18.3 Suspension of the time allowed for payment

The Commission or the Participating Member State in question may suspend the payment periods specified in Article II.4 at any time by *formally notifying* the contractor (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the Commission or the Participating Member State in question may cite for not being able to process an invoice are:

(a) because it does not comply with the APA;

(b) because the contractor has not produced the appropriate documents or deliverables; or

(c) because the Commission or the Participating Member State in question has observations on the documents or deliverables submitted with the invoice.

The Commission or the Participating Member State in question must *formally notify* the contractor as soon as possible of any such suspension, giving the reasons for it. In cases (b) and (c) referred above, the Commission or the Participating Member State in question shall *formally notify* the contractor the time limits to submit additional information or corrections or a new version of the documents or deliverables.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the *formal notification*. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the contractor may request the Commission or the Participating Member State in question to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph of this Article and the new document produced is also rejected, the Participating Member State reserves the right to terminate the Vaccine Order Form in accordance with Article II.16.2(b) after having justified the second rejected and having formally Notified it to the contractor.

II.18.4 Interest on late payment

On expiry of the payment periods specified in Article II.4, the contractor (or leader in the case of a joint tender) is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union,* on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.18.3 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.18.1.

II.19. RECOVERY

II.19.1 Recovery procedure

Before any recovery permitted under this APA, the Commission or the Participating Member State in question must *formally notify* the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the contractor to make any observations within 30 days of receipt. Notwithstanding anything to the contrary herein, the Down Payment will only be subject to recovery as set forth in Article I.8.5.

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by *formally notifying* a debit note to the contractor, specifying the date of payment. The contractor must pay in accordance with the provisions specified in the debit note.

If the contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the contractor in writing, recover the amounts due:

(a) by offsetting them against any amounts owed to the contractor by the Commission or the Participating Member State in question;

(b) by taking legal action.

The contractor will be liable for any losses or damages caused by its late payment.

II.19.2 Interest on late payment

If the contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.18.4. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.20. CHECKS AND AUDITS

II.20.1 The Commission and the European Anti-Fraud Office may check or require an audit on the *Implementation of the APA*. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf.

Such checks and audits may be initiated at any moment during the provision of the Product and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

II.20.2 The contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

II.20.3 The contractor must grant the appropriate right of access to sites and premises where the APA is implemented and to all the information, including information in electronic format, needed to conduct such checks and audits. The contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format.

II.20.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the contractor, who has 30 days following the date of receipt to submit observations. The contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Commission or the Participating Member State in question may recover all or part of the payments made in accordance with Article II.19.

II.20.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against *fraud* and other *irregularities* and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti- Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been *fraud*, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the Product and up to five years starting from the payment of the balance of the last Vaccine Order Form issued under this APA.

II.20.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939[6] ('the **EPPO**') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

[6] Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

ANNEX I: PARTICIPATING MEMBER STATES

Germany
France
Italy
Spain
Austria
Greece
Cyprus
Malta
Denmark
Sweden
Finland
Ireland
Portugal
Belgium
Luxembourg
Netherlands
Poland
Romania
Bulgaria
Slovenia
Croatia
Czech Republic
Hungary
Slovakia
Lithuania
Latvia
Estonia

ANNEX II: MODEL FOR VACCINE ORDER FORM

EXPLANATORY NOTE

✓ ***Who shall send a Vaccine Order Form?***

- Each Participating Member State shall send to the contractor one duly completed and signed Vaccine Order Form in paper format (by registered mail) and in electronic format (PDF by e-mail) for its relevant Allocated **Product doses** (such allocation is as communicated by the Commission to the contractor pursuant to Article I.4.3. or I.4.4 of the APA).
  - ***By when (deadline)?*** Please check Articles I.4.3 and I.4.4 of the APA.
  - ***What are each Participating Member States' allocated Product doses?*** Please contact the Commission, who is responsible for allocating the Products doses among the Participating Member States.

✓ ***To Whom and how shall the Vaccine Order Form be sent?***

- To the contractor:

(1) by registered mail to the following address:

H.W. Jerome Maddox, Vice President and Associate General Counsel
Moderna Switzerland GmbH
Aeschenvorstadt 48 (c/o Katja Schott, Walder Wyss), 4051 Basel, Switzerland

and

(2) by email at the following address legal@modernatx.com and Jerome.Maddox@modernatx.com. Please always send the duly completed and signed Vaccine Order Form as a PDF attachment to the email.

(3) Please check before sending whether the Commission will coordinate all Vaccine Order Forms on behalf of all Participating Member States.

✓ ***How to complete this Vaccine Order Form?***

- The relevant information in square brackets must be completed by each Participating Member State.
- Other than completing such information in square brackets, **no changes or amendments are permitted** to this model Vaccine Order Form unless explicitly agreed by the contractor and the Commission. If any such change or amendment is made, the Vaccine Order Form will be deemed invalid and not conform to the APA requirements.

✓ ***Whom to contact in case of questions re. how to complete this Vaccine Order Form?***

- Commission representatives:
  - Commission will confirm the name after signature. Please copy all communications to EC-VACCINES@ec.europa.eu
- Contractor's representatives:

H.W. Jerome Maddox, Vice President and Associate General Counsel
Moderna Switzerland GmbH
Aeschenvorstadt 48 (c/o Katja Schott, Walder Wyss), 4051 Basel, Switzerland

Jerome.Maddox@modernatx.com and legal@modernatx.com

[Letterhead of Government if available]

This Vaccine Order Form is submitted by:

[*The Government of [•]*] (the "**Member State**"), represented for the purposes of signing this specific order form by [*forename, surname, function, department of authorising officer*],

to:
Moderna Switzerland GmbH

a limited liability company ("Gesellschaft mit beschränkter Haftung") organized and existing under the laws of Switzerland

Company Number CHE-344.522.989

Aeschenvorstadt 48 (c/o Katja Schott, Walder Wyss), 4051 Basel, Switzerland

CHE-344.522.989 MWST
(hereinafter referred to as "the contractor")

The Member State and the contractor are together referred to as the "**Parties**" and each individually as a "**Party**".

WHEREAS

— The contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into an Advance Purchase Agreement for the purchase and supply of the contractor's COVID-19 vaccine for EU Member States **SANTE/2020/C3/054** (the "**APA**"), the terms of which are binding on the Participating Member States.

— The APA provides that:

i. each Participating Member State will submit to the contractor a Vaccine Order Form through which the contractor shall (subject to the terms and conditions of the APA) deliver to the relevant Participating Member State a proportion of the Initial Doses, and

ii. in the event the Commission, acting on behalf of the Participating Member State(s), has exercised the Option Increase, will submit to the contractor a separate Vaccine Order Form through which the contractor shall (subject to the terms and conditions of the APA) deliver to the relevant Participating Member State a proportion of the relevant Option Doses,

both (i) and (ii) at the price and conditions as set out in the APA.

— In accordance with Article I.4.2, the Member State hereby places its order for its full allocation of Initial Doses or the relevant Option Doses (as applicable).

Article I

Definitions

Capitalized terms used but not defined in this Vaccine Order Form shall have the meaning given in the APA.

Article II

Subject matter

1. This Vaccine Order Form is submitted by the Member State to the contractor in accordance with the terms of the APA, and forms an integral part of the APA. The terms and conditions of the APA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the APA, the terms of the APA prevail regardless of any provision to the contrary.

2. This Vaccine Order Form relates to the order for the Member State's full allocated Initial Doses or the relevant Option Doses (as applicable) as set out in the Allocation provided by the Commission to the contractor pursuant to Article I.4.3 or I.4.4 of the APA. The provision of this Vaccine Order Form by the Member State to the contractor constitutes a binding order by the Member State for the purchase of its full allocated Initial Doses or the relevant Option Doses (as applicable) at the Price.

Article III

Delivery; Quality

1. Delivery Address. The Delivery Address for the Member State is as follows:

   [• - *Member State to enter location*]

2. Quality. The roles and responsibilities between the contractor and the Member States in relation to acceptance/rejection matters related to the Product doses are set out in Article I.5 of the APA.

Article IV
Invoices; Notices

1. Invoice and Payments. The contractor shall invoice the Member State in accordance with the terms of the APA. All payments to the contractor shall be made in accordance with the terms of the APA.

2. Notice. Any notice given under this Vaccine Order Form must be made in writing in English in paper or electronic format; bear the APA number and the number of this Vaccine Order Form; be made using the relevant communication details set out below with respect to the Member State and the contractor (as applicable); and be sent by mail and email:

Member State:

[*Name of Member State*]
[*Full official address of Member State*]
[*VAT number*]
[*Full name of addressee physical person (contact person)*]
[*Function of addressee physical person (contact person)*]
E-mail: [*complete email of addressee physical person (contact person)*]

Contractor:

H.W. Jerome Maddox, Vice President and Associate General Counsel
Moderna Switzerland GmbH
Aeschenvorstadt 48 (c/o Katja Schott, Walder Wyss), 4051 Basel, Switzerland

legal@modernatx.com and Jeromc.Maddox@modernatx.com

Article V.

Entry into Force and Duration

1. This Vaccine Order Form shall become effective upon execution and delivery by the Member State to the contractor in accordance with I.4.3 or I.4.4 of the APA as applicable.

2. This Vaccine Order Form shall automatically expire upon Delivery of the Member State's full allocated Initial Doses or the relevant Option Doses (as applicable) as set out in the Allocation provided by the Commission to the contractor pursuant to Article I.4.3 or I.4.4 of the APA as applicable.

3. Expiry of the Vaccine Order Form shall be without prejudice to Article I.3.4 of the APA (*Surviving Provisions*).

Article VI.
Applicable Law and Settlement of Disputes

Article I.11 (*Applicable Law and Settlement of Disputes*) of the APA shall apply *mutatis mutandis* to this Vaccine Order Form.

(Signature page follows)

SIGNATURES

For the **Member State**,

[*forename/surname/position*]

Signature:_____

Done at [*place*], [*date*]

For acceptance of the Vaccine Order Form,

[*forename/surname/position*]

Signature: _____

Done at [*place*], [*date*]

ANNEX III: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020

Agreement

Preamble

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union1as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter "ESI" or "ESI regulation");

***

The European Commission ("the Commission")

and

The following Member States: (XXX), hereinafter referred to as "the Participating Member States"

Together referred to as "the Parties"

Agree on the Following:

Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements ("APA") with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating

Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements ("APA") with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team ("joint negotiation team"), which will work on a continuous basis as one unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participation Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

Advanced Purchase Agreements and conditions

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost

related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;
b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;

and

c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts

corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

ANNEX IV: DESCRIPTION OF THE CONTRACTOR'S INTENDED UTILISATION OF THE DOWN PAYMENT

The Down Payment described in this APA plays a crucial role in Moderna's overall ability to finance the Product, to mitigate the risk of this extraordinary parallel development/manufacturing effort and its ability to potentially contribute to stopping the Covid-19 pandemic. The Down Payment (an amount in Euros equivalent to $360 million in accordance with the Exchange Rate Methodology, expected to be received in Q4 2020), will be used to cover the financing of the following types of activities, each described in further detail below:

- Raw materials
- Tech Transfer
- Facility Investments
- Fill Finish
- Pharmacovigilance and Regulatory/Medical Affairs
- Shipping/warehousing

1. Raw Materials

The materials listed below needed to be secured and delivery schedules aligned to committed production plan in order to deliver 80 million doses of the Product to the European Union. All items have been secured (all required purchase orders have been placed and materials are either on-hand or have confirmed delivery dates to meet production schedule). This list is not an exhaustive list of raw materials costs previously or expected to be borne by Moderna.

- SM102 is a Moderna proprietary lipid that is produced by Corden Pharma. Material supply for Moderna has been from a single Corden site in Switzerland. The scale up development and capacity requirements within Corden's network required a significant commitment from Moderna to follow through on the planned resource requirements and raw consumptions in Fall 2020 to avoid Corden promising capacity and resources to other customers for this fall and winter across their facilities.

- 10R glass vials: Given overall global demand for glass vials in preparation for a pandemic response from several companies, stockpiling 10R glass vials has been required to ensure ability to supply. In conjunction with CMOs, Moderna has secured required supplies of vials from Ompi, Corning and SiO2.

- 20mm stoppers: Given overall global demand for 20mm stoppers in preparation for a pandemic response from several companies, stockpiling stoppers has been critical to ensure ability to supply. Moderna is coordinating with its supplier of stoppers (West Pharmaceuticals) to ensure increased availability of stoppers to meet the pandemic requirements.

2. Tech Transfer

Technology transfer to ROVI has begun, and project plans are in place to enable fill-finish as soon as the initial drug substance batches are completed (planned for December 2020).

3. Facility Investments

Moderna has selected Lonza as its vaccine contract manufacturing partner. Moderna was required to make substantial up-front financial commitment to Lonza in order to secure its capacity and expertise. Moderna and Lonza have agreed to build out 3 dedicated manufacturing kits (Kit 4, Kit 5 and Kit 6), which enable a batch capacity of up to 30-36 batches per month upon completion of ramp up. This is equivalent to 30-36 million doses of mRNA-1273 per month.

Equipment Procurement and Qualification: All equipment and materials have been ordered and delivery dates confirmed.

Hiring and Training: On track, including the ongoing training of Lonza employees at a Moderna Manufacturing Site, as part of capabilities transfer.

Sensitive*
RELEASABLE TO: Need to know basis

4. **Fill Finish**

Moderna and ROVI have established a collaboration for large-scale, commercial fill-finish manufacturing of mRNA-1273 at ROVI's facility in Madrid, Spain. As part of the agreement, ROVI will provide vial filling and packaging (i.e., finishing) capacity by procuring a new production line and equipment for compounding, filling, inspecting and labeling to support production of hundreds of millions of doses of the Product intended in principle to supply markets in Europe and other markets outside of the US. To support the agreement, ROVI plans to hire additional staff to support manufacturing operations and production. Initial contracts are in place enabling the first filling line in Q4 2020 and a new dedicated filling line in Q1 2021.

5. **Pharmacovigilance and Regulatory/Medical Affairs**

Moderna has added Regulatory, Pharmacovigilance, and Medical Affairs personnel in preparation for seeking regulatory approval and providing appropriate pharmacovigilance and Medical Affairs support.

Moderna has secured the services of IQVIA to provide pharmacovigilance services in the European Union. Services include managing Adverse Event intake and Medical Information intake and responses through a call center. Moderna has secured dedicated staffing for these services.

6. **Shipping/Warehousing**

Alloga (in Spain) will be the distribution center for finished product and will provide storage and distribution services. Kuehne+Nagel will provide primary distribution services or mRNA-1273 to the Member States (DAP).

The total spend and cash needs to finance this project in 2020 and 2021 is expected to be at least $365.4 million.

The context provided above highlights that the Down Payment plays a critical role to enable Moderna to (i) establish, expand and accelerate its manufacturing capacity in Europe in relation to the manufacturing of the *Initial Doses* of the *Product*, (ii) purchase (and make financial commitments for the purchase of) raw materials, supplies, components and equipment necessary for the manufacture of the *Initial Doses* of the *Product*, (iii) commence and continue the at-risk production of the *Initial Doses* of the *Product*, and (iv) establish regulatory and pharmacovigilance capabilities in relation to the *Product* in Europe, in order to respond in a meaningful way to the challenge of making as many doses of the Product available as soon as possible after Marketing Authorisation.

Sensitive*
RELEASABLE TO: Need to know basis

Table 1: Total costs per cost category

Raw materials category	Amount committed/spent
Lipids: Advance commitments needed for SM102 Lipids	$59M
Stoppers: Stoppers	$14M
Vials: Glass vials	$11M
TOTAL	**$84M**

Tech transfer/Fill Finish steps	Amount committed/spent
Tech Transfer new fill line ROVI Fill Finish (Filling and autoclaves, AVI, packaging and analytical transfer activities)	$0.5M
Tech Transfer existing line ROVI Fill Finish (Filling and autoclaves, AVI, single multi pack packaging configuration)	$0.4M
Lonza Visp Tech Transfer activities	$3M
Total	**$4M**

Facility investment categories	Amount committed/spent
One time payment - Investment for facilities support for kits at Lonza VISP: • Access roads, services, utilities • Clean room, Floors, fire protection, Building core, plumbing • Clean utilities, piping, HVAC • Building automation, electrical installations • Indirect engineering	$61M
Commitment to Lonza VISP: • $ 46M Suite fees • $ 65M headcount expenses • $ 1M accelerated hiring (one time -payment made)	$112M
TOTAL	**$ 173M**

Fill finish	Amount committed/spent
One time acceleration costs (ROVI)	$ 2M

Equipment support payment to ROVI: • Jacked tanks and analytical equipment • Acceleration to existing line • CO2 installation, freezing tunnels	$ 5M
Validation batches: (ROVI) 1 buffer batch test, 3 Media fill batches, 1 GMP batch and 1 PPQ batch	$ 1M
Non refundable payment for manufacturing exclusivity (ROVI)	$ 10M
Fill finish capacity take or pay (ROVI)	$ 39M
TOTAL	**$57M**

Pharmacovigilance and regulatory investment categories	**Amount committed/spent**
Regulatory/Med affairs/PV support personnel: • PV – 1 EU epidemiologist, 1 EU QPPV • 5 Regulatory – including CMC regulatory • 1 Med Aff – Int'l Med Aff • 1 EU CMO • Ashfield MSL support	$7M
IQVIA Pharmacovigilance support	$30M
Total	**$37M**

Shipping/Warehousing	**Amount committed/spent**
Estimate of shipping to locations	$8.0M
Estimate of warehousing	$0.8M
Estimate of inter site shipping	$1.6M
Total	**$10.4M**

ANNEX V: LIST OF CONFIRMED AND PLANNED MANUFACTURING NETWORK PARTNERS INCLUDING THE LOCATION(S) OF MANUFACTURING

Legal name	Location	Type of Activity
LONZA AG **STATUTORY REGISTRATION NUMBER:** **CHE-101.368.029**	**MIINCHENSTEINERSTRASSE 3 8,** **4002 BASEL** **SWITZERLAND** **LONZASTRASSE** **3930 VISP** **SWITZERLAND**	Manufacturing and releasing of final drug substance.
ROVI PHARMA INDUSTRIAL SERVICES SAU **STATUTORY REGISTRATION NUMBER** **REGISTRO MERCANTILE DE MADRD, TOMO 3516, FOLIO 180, SECCIÓN 8, HOJA U-5937O**	**VÍA COMPLUTENSE 140** **28805 ALCALÁ DE HENARES** **SPAIN** **PASEO DE EUROPA 50** **SAN SEBASTIÁN DE LOS REYES** **28703 MADRID** **SPAIN**	Filling, packaging, labeling and releasing of final drug product.

ANNEX VI: PRELIMINARY SPECIFICATIONS OF THE PRODUCT

HIGHLY CONFIDENTIAL MODERNA INFORMATION

Indication for use	Moderna mRNA-1273 Injection is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus.
Contraindication	Moderna mRNA-1273 Injection is contraindicated in individuals with known severe allergic reactions (e.g. anaphylaxis) to any component of the vaccine or to a previous dose of Moderna mRNA-1273 Injection.
Target Population	Adults aged 18 years and older
Safety/Reactogenicity	The safety the vaccine is currently being evaluated in clinical trials.
Measures of Efficacy	The efficacy of the vaccine is currently being evaluated in clinical trials.
Dose Regimen	Moderna mRNA-1273 Injection should be administered as a two-dose regimen. The second dose should be administered 1 month after the first dose.
Durability of protection	The durability of protection of the vaccine is currently being evaluated in clinical trials.
Route of Administration	Intramuscular injection in the deltoid muscle.
Product Stability and Storage	Shelf life: 6 months at frozen conditions between -25° to -15°C. Stability studies are being executed to determine final expiry at long-term and short-term conditions. Vials are stored frozen between -25° to -15°C until ready for use. Vials can be stored refrigerated between 2° to 8°C for up to 30 days if not entered (needle-punctured). Do not refreeze. The total storage time of an unopened vial after removal from refrigerated conditions should not exceed 12 hours at 8° to 25°C. Do not refreeze. Once the vial has been entered (needle-punctured) to withdraw the initial dose, the vial should be discarded after 6 hours (in

	alignment with the Summary of WHO Multi-dose Vial policy (MDVP), 2014). Do not refreeze.
Co-administration with other vaccines	There are no data to assess the concomitant administration of Moderna mRNA-1273 Injection with other vaccines. Moderna mRNA-1273 Injection should not be mixed with any other vaccine in the same syringe.
Presentation	5 mL suspension in a multi-dose 10R vial with a 20 mm stopper, 20 mm flip-off aluminum seal. Vials are packaged in a secondary carton containing a total of ten (10) Moderna mRNA-1273 Injection vials per carton. Vials are for multiple use. A maximum of 10 doses can be withdrawn from each multiple-dose vial. Each dose is 0.5 mL. Once the vial has been entered (needle-punctured) to withdraw the initial dose, the vial should be discarded after 6 hours (in alignment with the Summary of WHO Multi-dose Vial policy (MDVP), 2014). Do not refreeze. Moderna is proposing to use a single pandemic English language label on both the primary and secondary packaging.
Accessibility	*To be determined.*