

## ADVANCE PURCHASE AGREEMENT (“APA”) FOR THE PRODUCTION, PURCHASE AND SUPPLY OF A COVID-19 VACCINE IN THE EUROPEAN UNION

This Advance Purchase Agreement (this “**Agreement**”) for the production, purchase and supply of the ChAdOx1 nCov-19 vaccine (“**Vaccine**”) in the European Union (the “**EU**”) is entered into as of 27 August 2020 (the “**Effective Date**”), by the following parties:

- the European Commission having a business address of rue de la Loi 200, 1049 Brussels (Belgium) (the “**Commission**” or “**Contracting Authority**”) acting on behalf and in the name of the member states of the European Union (each a “**Member State**”).

- and AstraZeneca AB, a party incorporated in Sweden having a business address of KVARNBORG 16, 151 85 SÖDERTÄLJE (“**AstraZeneca**”, the “**contractor**”).

The Commission, the Participating Member States and AstraZeneca may each be referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

**WHEREAS**, by Decision C(2020) 4192 final of 18 June 2020, the Commission approved the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States (“**the Decision**”). This agreement is based on **Article 4**, paragraph 5, point (b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union<sup>1</sup> (“**the ESI Regulation**”) which provides that the Commission may grant emergency support in the form of procurement on behalf of the Member States based on an agreement between the Commission and Member States. In order to implement such action, the Commission has offered to run a single central procurement procedure on behalf of Member States, with a view to signing EU-level advanced purchase agreements with various vaccine manufacturers.

**WHEREAS**, according to Article 4 of the agreement between the Commission and the Member States, as annexed to the Decision, where the Commission intends to conclude an APA containing an obligation to acquire Vaccine Doses, 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 within five working days after the Commission has communicated its intention to conclude the APA. All Member States not having opted out within the period of five (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 and become thus by operation of law Participating Member States.

**WHEREAS**, the present APA contains obligations to acquire Vaccine Doses.

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<sup>1</sup> 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.

**WHEREAS**, consequently, the Commission can only conclude the APA in the name and on behalf of Participating Member States by signing it with the company concerned once the opt out period has lapsed.

**WHEREAS**, according to Article 5 of the agreement between the Commission and the Member States, once concluded, the terms of the APA shall be legally binding on the Member States, except for those who have exercised their right to opt out. Those Member States for which the agreement has become legally binding are set out in Schedule B (the **“Participating Member States”**).

**WHEREAS**, to combat the current COVID-19 global pandemic (the **“COVID Pandemic”**), AstraZeneca has partnered with Oxford University to rapidly clinically evaluate and scale-up global manufacturing of the Vaccine.

**WHEREAS**, AstraZeneca has accelerated its manufacturing scale-up concurrently with its conduct of global clinical trials to ensure the broadest possible availability of the Vaccine, as quickly as possible.

**WHEREAS**, as part of that scale-up, AstraZeneca has committed to use its Best Reasonable Efforts (as defined below) to build capacity to manufacture 300 million Doses of the Vaccine, at no profit and no loss to AstraZeneca, at the total cost currently estimated to be 870,000,000 Euros for distribution within the EU by the first half of 2021 (the **“Initial Europe Doses”**), with an option for the Commission, acting on behalf of the Participating Member States, to order an additional 100 million Doses (the **“Optional Doses”**).

**WHEREAS**, AstraZeneca will supply the Initial Europe Doses to the Participating Member States according to the terms of this Agreement.

**WHEREAS**, each Participating Member State must execute and deliver an Order Form in the form of Exhibit A (an **“Order Form”**) with the information relevant to such member state filled in.

**WHEREAS** the present Agreement has been awarded to AstraZeneca by decision C(2020) 5707 of 14 August 2020 resulting from the negotiated procedure n° SANTE/2020/C3/037.

**NOW THEREFORE**, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of the Parties hereby agree as follows:

**1. Definitions.**

When used in this Agreement, the following capitalized terms shall have the meanings set forth in this Article 1.

1.1. **“Accounting Standards”** means International Financial Reporting Standards (IFRS).

1.2. **“Additional Doses”** has the meaning given in Section 5.3.

- 1.3. “**Affiliate**” means, with respect to a Party, any Person that Controls, is Controlled by or is under common Control with such Party.
- 1.4. “**Agreement**” has the meaning given in the preamble, namely the Advance Purchase Agreement.
- 1.5. “**Alliance Manager**” has the meaning given in Section 2.3.
- 1.6. “**Applicable Law**” means any law or statute, any rule or regulation (including written governmental interpretations thereof, the guidance related thereto, or the application thereof) issued by a Governmental Authority or Regulatory Authority and any judicial, governmental, or administrative order, judgment, decree, or ruling, in each case as applicable to the subject matter and the parties at issue.
- 1.7. “**AstraZeneca**” has the meaning given in the preamble.
- 1.8. “**AZ Exchange Rate**” has the meaning given in Section 1.15.
- 1.9. “**Best Reasonable Efforts**” means
- (a) in the case of AstraZeneca, the activities and degree of effort that a company of similar size with a similarly-sized infrastructure and similar resources as AstraZeneca would undertake or use in the development and manufacture of a Vaccine at the relevant stage of development or commercialization having regard to the urgent need for a Vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world but taking into account efficacy and safety; and
  - (b) in the case of the Commission and the Participating Member States, the activities and degree of effort that governments would undertake or use in supporting their contractor in the development of the Vaccine having regard to the urgent need for a Vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world.
- 1.10. “**Binding Allocation**” has the meaning given in Section 8.3.
- 1.11. “**CMOs**” means contract manufacturing organizations.
- 1.12. “**Commission**” has the meaning given in the preamble.
- 1.13. “**Confidential Information**” has the meaning given in Section 16.1.
- 1.14. “**Control**” means: (i) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (ii) to own, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Person, or (iii) in the case of a partnership, control of the general partner, and “Controls” and “Controlled” shall be construed accordingly.

1.15. “**Cost of Goods**” means the fully burdened aggregate reasonable direct and indirect costs and expenses incurred by AstraZeneca to manufacture the Vaccine Doses, consisting of:

- (a) direct labor costs (salaries, wages, employee benefits, overtime costs and shift premiums);
- (b) direct materials (including raw materials and intermediates and interim packaging) costs;
- (c) a fair and reasonable allocation of operating costs of facilities and equipment (including start up and cleaning costs of production), including an allocation of the cost of idle capacity at relevant manufacturing sites, in each case, calculated by AstraZeneca in a manner consistent with its treatment of such costs (including idle capacity) with respect to other products;
- (d) quality, release and in-process control costs;
- (e) charges for reasonable spoilage, scrap or rework costs;
- (f) amounts (without mark-up) that are paid to a third party, in connection with their manufacture of the Vaccine or any component thereof including any costs associated with technology transfer and/or establishment of manufacturing capacity;
- (g) the reasonable allocation of facility overhead, both fixed and variable, to such manufacturing operation (including the allocable costs of administrators and managers overseeing manufacturing and production) maintenance, engineering, safety, finance, capital equipment depreciation to the extent such capital equipment is utilized with respect to the Vaccine Doses, supply chain management, management of agreements with third party contract manufacturers, and inventory write off;
- (h) any non-refundable or non-creditable Indirect Taxes, customs and excise duties, or similar Taxes; and
- (i) any royalties paid or payable to third parties in connection with the exploitation of the Vaccine, such royalties to be calculated as a percentage of the costs described in (a) through (h) above.

Costs are incurred in multiple currencies and AstraZeneca will employ the prevailing AZ Exchange Rate to convert such costs to Euros at the time when the costs are incurred. “AZ Exchange Rate” means, on any date, the rate of exchange as published by Reuters as prevailing at 8.00 am (London) usually taken on the 25<sup>th</sup> day of the month prior to such date, where that day is a working day, or if the 25<sup>th</sup> day of the month is not a working day, the first working day following the 25<sup>th</sup> day of the month, or such other IFRS-compliant rate as used by AstraZeneca consistently for the purpose of preparing its consolidated financial statements.



In each case of clauses (a) through (i), inclusive, to the extent specifically attributable to the manufacture of the Vaccine as determined in accordance with IFRS, as applicable, and in each case, calculated by AstraZeneca in a manner consistent with its treatment of such costs with respect to other products, and without disadvantaging the Vaccine on account of the terms of this Agreement or otherwise.

In addition to the costs listed above, “Cost of Goods” will also include each of the following costs and expenses incurred by AstraZeneca to manufacture the Vaccine, consisting of:

- (a) costs and expenses for pharmacovigilance directly incurred for, or fairly allocable to, the Vaccine;
- (b) regulatory filing fees for the Vaccine and other regulatory costs and expenses directly incurred for, or fairly allocable to, the Vaccine;
- (c) supporting functions and the cost of working capital directly incurred for, or fairly allocable to, the Vaccine; and
- (d) any other costs and expenses directly incurred for, or fairly allocable to, the Vaccine (*e.g.*, legal, finance, reporting, compliance and executive management oversight).

The term “Cost of Goods” excludes each of the following:

- (a) costs related to the operation of the facility incurred while using the facility to manufacture other products;
- (b) industrial operations-related corporate costs (such as but not limited to corporate projects, strategic analysis);
- (c) any refundable or creditable Indirect Taxes, customs and excise duties, or similar Taxes
- (d) storage and distribution of the Vaccine;
- (e) destruction for any material produced at risk; and
- (f) costs and expenses directly incurred for, or fairly allocable to, post-launch safety and risk management studies for the Vaccine.

1.16. “**COVID Pandemic**” has the meaning given in the recitals.

1.17. “**Defect**” means the characteristic of a product that does not provide the safety which a person is entitled to expect taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation, in each case as such term is interpreted consistently with the term “defective” under Article 6 of the EU Product Liability Directive 85/374/EEC.

- 1.18. “**Disclosing Party**” has the meaning given in Section 16.1(b).
- 1.19. “**Distribution Hubs**” has the meaning given in Section 8.1.
- 1.20. “**Dose**” means approximately  $5.0 \times 10^{10}$  virus particles/dose in no more than 0.5ml with the understanding that the final commercial dose and dose volume will be informed by the data emerging from the clinical development program and the optimization of the manufacturing process.
- 1.21. “**Effective Date**” has the meaning given in the preamble.
- 1.22. “**EMA**” means European Medicines Agency.
- 1.23. “**Executive Officer**” means, with respect to AstraZeneca, its EVP Europe and, with respect to the Commission, the Director-General of the Directorate General Health and Food Safety (DG SANTE).
- 1.24. “**Fill/Finish/Packaging Costs**” has the meaning given in Schedule A.
- 1.25. “**Funding**” has the meaning given in Section 7.1.
- 1.26. “**Good Manufacturing Practices**” means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2003/94/EC 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”.
- 1.27. “**Governmental Authority**” means any court, agency, department, authority or other instrumentality of any nation, supranational body, state, county, city or other political subdivision.
- 1.28. “**Indemnified Persons**” has the meaning given in Section 14.1.
- 1.29. “**Indemnifying Party**” has the meaning given in Section 14.2.
- 1.30. “**Indirect Taxes**” means value added, sales, consumption, goods and services taxes or other similar Taxes required by Applicable Laws to be disclosed as a separate item on the relevant invoice.
- 1.31. “**Initial Europe Doses**” has the meaning given in the recitals.
- 1.32. “**Initial Funding**” has the meaning given in Section 7.2.
- 1.33. “**Know-How**” means (a) inventions, technical information, know-how, show-how, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), formulae, assays, sequences, discoveries, procedures, processes, practices, protocols, methods, techniques, results of experimentation, knowledge, trade secrets, designs, skill, experience; and/or (b) any

information embodied in compounds, compositions, materials (including chemical or biological materials), formulations, dosage regimens, apparatus, devices, specifications, samples, works, regulatory documentation and submissions pertaining to, or made in association with, filings with any Regulatory Authority.

- 1.34. **“Losses”** has the meaning given in Section 14.1.
- 1.35. **“Order Form”** has the meaning given in Section 3.1.
- 1.36. **“OMCL”** means Official Medicines Control Laboratories.
- 1.37. **“Optional Doses”** has the meaning given in Section 5.2.
- 1.38. **“Participating Member States”** has the meaning given in the preamble.
- 1.39. **“Person”** means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization (whether or not having a separate legal personality), including a government or political subdivision or department or agency of a government.
- 1.40. **“Phase I/II Trial Results”** has the meaning given in Section 4.2(a).
- 1.41. **“Price Per Dose”** has the meaning given in Section 7.4(a).
- 1.42. **“Receiving Party”** has the meaning given in Section 16.1(b).
- 1.43. **“Regulatory Authority”** means the European Medicines Agency (EMA) or any other Governmental Authority regulating the conduct, manufacture, market approval, sale, distribution or use of the Vaccine within the EU.
- 1.44. **“Related Persons”** means spouses, heirs, children (whether natural or adopted), descendants, successors and assigns, estates, or legal representatives, executors, administrators or any other person or entity representing the rights of the injured person or any of the foregoing.
- 1.45. **“Representative”** has the meaning given in Section 2.2.
- 1.46. **“Tax”** means any form of tax or taxation, levy, duty, charge, social security, charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax authority.
- 1.47. **“Tender Specifications”** has the meaning given in Section 18.9.
- 1.48. **“Third Party Claim”** has the meaning given in Section 14.2.
- 1.49. **“Upfront Costs”** has the meaning given in Schedule A.

1.50. “**Vaccine**” has the meaning given in the recitals.

1.51. “**Vaccine IP Rights**” has the meaning given in Section 11.1.

1.52. “**Willful Misconduct**” means an act or omission taken (a) intentionally to achieve a wrongful purpose; (b) knowingly without legal or factual justification; and (c) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. Each of the foregoing conditions must be proven with clear and convincing evidence.

## 2. Roles of the Parties

### 2.1. The Commission:

For the purpose of this Agreement, the Commission hereby represents and warrants that as a result of the Decision, it has the power and authority to act on behalf and in the name of the Participating Member States, in accordance with the terms set forth in this Agreement, for the following subjects:

- (a) Development of the Vaccine as described in Section 4;
- (b) Funding process as described in Section 7, except for the payments resulting from the obligations assumed directly by the Participating Member States as described in Sections 7.3 and 7.4.
- (c) Audit of costs, as described in Section 7.6.
- (d) Allocation, as described in Section 8.3.
- (e) Any other subject not specifically attributed to the Participating Member States according to Section 2.2.

In all dealings concerning those subjects, the Commission represents and warrants that it has full power and authority to: (i) execute, deliver, and receive on behalf of the Participating Member States all notices, requests and other communications hereunder; (ii) act as the point of contact for the Participating Member States; (iii) facilitate communications between the Parties for the purposes of this Agreement; and (iv) take such other administrative actions on their behalf in connection with this Agreement as the Commission and the Participating Member States deem appropriate.

In all dealings concerning those subjects, the Commission agrees on behalf of itself and the Participating Member States that AstraZeneca shall be entitled to act and rely upon any statement, request, notice or agreement made or given by the Commission. Subject to each Participating Member State being bound by Section 16 of this Agreement, the Commission may share with the Participating Member States all information, documentation, data and other materials received from AstraZeneca.

## 2.2. The Participating Member States.

For the purpose of this Agreement, each Participating Member State shall designate a representative (each, a “**Representative**”) concerning the following subjects of this Agreement:

- (a) Manufacturing and supply as described in Section 5.4.
- (b) Payments resulting from the obligations assumed by the Participating Member States as described in Sections 7.3 and 7.4.
- (c) Orders and delivery of the Vaccine Doses to the Distribution Hubs as described in Section 8.1.
- (d) Distribution of the Vaccine Doses as described in Section 8.3.
- (e) Indemnification as described in Section 14.
- (f) Release; Limitation of Liability; Disclaimer of Warranties as described in Section 15.

In all dealings concerning those subjects, each Participating Member State hereby represents and warrants that its Representative will have full power to execute, deliver, and receive on such Participating Member State’s behalf all notices, requests and other communications and each Participating Member State agrees that AstraZeneca shall be entitled to act and rely upon any statement, request, notice or agreement made or given by such Representative. Each Participating Member State shall have the right, power and authority to replace such Representative upon written notice to AstraZeneca stating that such prior Representative is being replaced and providing the name and relevant contact information for the replacing Representative. Each Participating Member State shall bear the costs of its respective Representative.

2.3. Alliance Manager. Promptly after the Effective Date, the Commission and AstraZeneca shall each appoint one Person who shall oversee contact between the Commission, on the one hand, and AstraZeneca, on the other hand, and such appointed Persons shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each appointed Person, an “**Alliance Manager**”). The Alliance Manager appointed by the Commission will act as a point of contact for the various Participating Member States for activities related to this Agreement, including to share information received from AstraZeneca that is intended to be shared with the Participating Member States. The Alliance Managers shall work together to manage and facilitate communications between the Commission and AstraZeneca under this Agreement, and shall meet monthly to perform their responsibilities in accordance with the terms of this Agreement, including the resolution of issues between the Commission and AstraZeneca that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement. Each of the Commission and AstraZeneca may replace its Alliance Manager at any time by seven (7) days’ prior notice in writing to the other

Party. The Commission and AstraZeneca shall each bear the costs of its Alliance Manager.

### 3. Subject matter

#### 3.1. Order Form

(a) Attached as Exhibit A to this Agreement is an Order Form which has been negotiated on behalf of the Member States by the Commission. In order to maintain the right to purchases Doses of Vaccine as contemplated by this Agreement, an EU Member State must execute and deliver an Order Form in the form of Exhibit A with the information relevant to such member state filled in.

(b) The Parties acknowledge and agree that the Order Form is an essential and important part of this Agreement and AstraZeneca has entered into this Agreement in reliance on Member States executing such Order Forms as contemplated hereby. Such Order Forms have to be entered into by each of the Participating Member States within 10 working days following the delivery by the Commission of the Binding Allocation according to Section 8.3 (a). If an EU Member State does not execute and deliver an Order Form within such deadline, such Member State shall not be eligible to receive any portion of the Initial Europe Doses, the Optional Doses and the Additional Doses under this Agreement and shall not be entitled to any benefit of this Agreement.

### 4. Development.

4.1. Development. As between the Parties, AstraZeneca shall have the sole right and responsibility for all aspects relating to the research and development of the Vaccine with the goal of establishing a Vaccine that is safe and efficacious for manufacture and sale as contemplated by this Agreement.

#### 4.2. Reporting.

(a) Along with its offer, AstraZeneca has provided to the Commission reports of the interim and final results of the Oxford University-sponsored Phase I/II clinical study of the Vaccine (the “**Phase I/II Trial Results**”) from Oxford University. AstraZeneca shall provide to the Commission (i) key updates on development of the Vaccine project, including regulatory matters relevant to the Vaccine; and (ii) updates on progress, challenges and opportunities on establishment of the supply chain for the Vaccine. Notwithstanding the foregoing, in no event shall AstraZeneca be obligated to disclose Vaccine development project results or other information concerning development of the Vaccine that AstraZeneca is not legally or contractually permitted to share, including such information which AstraZeneca may be required to first disclose to Oxford University. In the event that AstraZeneca is not legally or contractually permitted to share such information, AstraZeneca shall explain the basis upon which it is not permitted to share such information and provide relevant evidence to the extent legally or contractually permissible.

(b) On reasonable notice and as reasonably requested, AstraZeneca shall enable the Commission (or an independent expert appointed by the Commission as set forth below) to access all clinical trial data (including communications and correspondence with Regulatory Authorities and bodies to include all audit observations, inspection reports, meeting minutes, and all AstraZeneca commitments and responses) and all data relevant to the manufacturing of the Vaccine; *provided*, that AstraZeneca is permitted to share such information with the Commission; and *provided, further*, that if AstraZeneca is not permitted to share such information with the Commission, it shall use its Best Reasonable Efforts to obtain permission to share such information. If the Commission chooses to access such information through a third party, such third party must be an independent expert in the applicable field, the Commission shall notify AstraZeneca of such expert in advance, and such expert shall be subject to Section 15 of this Agreement. The Commission shall choose another expert if AstraZeneca provides reasonable justification upon which such expert should not be permitted access to such information.

## 5. Manufacturing and Supply.

5.1. Initial Europe Doses. AstraZeneca shall use its Best Reasonable Efforts to manufacture the Initial Europe Doses within the EU for distribution, and to deliver to the Distribution Hubs, following EU marketing authorization, as set forth more fully in Section 7.1, approximately (i) 30 million to 40 million Doses by the end of 2020, (ii) 80 million to 100 million Doses in Q1 2021, and (iii) the remainder of the Initial Europe Doses by the end of Q2 2021.

5.2. Optional Doses. The Commission shall have an option to increase its order on behalf and in the name of the Participating Member States of the Vaccine Doses by an additional 100 million Doses (“**Optional Doses**”). In order to exercise such option, the Commission shall deliver an irrevocable notice to AstraZeneca exercising such option within forty-five (45) days of delivery by AstraZeneca to the Commission of the first Phase III Trial report that includes efficacy and safety data. The Optional Doses shall be delivered to the Participating Member States following delivery of the Initial Europe Doses and no earlier than the second half of 2021. As a condition to exercising the Optional Doses, the Commission must provide the necessary information on allocation of the full 100 million Optional Doses among the Participating Member States.

5.3. Additional Doses. AstraZeneca shall consider in good faith any request for additional Vaccine Doses made by the Participating Member States, but shall not be required to manufacture and supply Vaccine Doses in excess of the Initial Europe Doses and the Optional Doses (“**Additional Doses**”). The Commission and the Participating Member States recognize that it may not be possible for AstraZeneca to manufacture any Additional Doses prior to the end of Q2 2021.

5.4. Manufacturing Sites. AstraZeneca shall use its Best Reasonable Efforts to manufacture the Vaccine at manufacturing sites located within the EU (which, for the purpose of this Section 5.4 only shall include the United Kingdom) and may manufacture the Vaccine in non-EU facilities, if appropriate, to accelerate supply of the

Vaccine in Europe; *provided*, that AstraZeneca shall provide prior written notice of such non-EU manufacturing facilities to the Commission which shall include an explanation for such determination to use non-EU manufacturing facilities. If AstraZeneca is unable to deliver on its intention to manufacture the Initial Europe Doses and/or Optional Doses under this Agreement in the EU, the Commission or the Participating Member States may present to AstraZeneca, CMOs within the EU capable of manufacturing the Vaccine Doses, and AstraZeneca shall use its Best Reasonable Efforts to contract with such proposed CMOs to increase the available manufacturing capacity within the EU. The manufacturing site planning is set out in Schedule A.

5.5. Reporting. AstraZeneca shall notify the Commission as soon as (a) it selects initial manufacturing sites and (b) it changes any of its manufacturing sites for the Vaccine.

## **6. Acquisition of Materials and Services.**

6.1. Materials. The Commission and the Participating Member States shall use their Best Reasonable Efforts to enable AstraZeneca to timely supply the Initial Europe Doses. AstraZeneca shall secure the supply of all drug substances needed and drug product capacity (if required) as well as components critical to the development, manufacture, and supply of the Initial Europe Doses (*e.g.* glass vials/stoppers, media, etc.). Notwithstanding the foregoing, the Commission and the Participating Member States shall, on the request of AstraZeneca and in accordance with all Applicable Laws and within the framework of their competencies, use Best Reasonable Efforts to assist AstraZeneca in securing the supply of any drug substances needed and drug filling and finishing capacity as well as components for the development, manufacture, and supply of the Initial Europe Doses.

6.2. Capacity Limitations. In the event AstraZeneca's ability to fulfill its obligations under this Agreement is impeded by a competing agreement entered into by or on behalf of the Commission, AstraZeneca shall promptly inform the Commission. While AstraZeneca shall continue to use Best Reasonable Efforts to engage with its own contract manufacturers and suppliers to utilize the capacity and/or components, the Commission will assist in finding a mutually acceptable solution for this Agreement and the competing agreement. To the extent AstraZeneca's performance under this Agreement is impeded by any such competing agreements, AstraZeneca shall not be deemed in breach of this Agreement as a result of any such delay due to the aforementioned competing agreement(s).

6.3. Reporting and Notification to the Commission. AstraZeneca will report to the Commission in regular intervals on whether it has been able to secure the supply of all drug substances needed and drug product capacity (if required) as well as components critical to the development, manufacture, and supply of the Initial Europe Doses (*e.g.* glass vials/stoppers, media, etc.). AstraZeneca will promptly notify the Commission if it encounters difficulties in this regard that place at significant risk AstraZeneca's ability to manufacture or sell the Vaccine Doses as contemplated by this Agreement.



## 7. Funding Process and Audit.

7.1. Generally. The Commission and the Participating Member States shall provide funding to enable AstraZeneca to: (i) harness sufficient drug substance and drug filling and finishing capacity in Europe, (ii) advance procurement of critical components including glass vials/stoppers, media, and other critical components to supply finished product of the Vaccine, and (iii) fill, finish and package the final Vaccine for distribution (the “**Funding**”). The Commission and the Participating Member States shall provide the Funding in an amount equal to the estimated Cost of Goods which at the Effective Date is estimated to be 870 million Euros for the Initial Europe Doses.

7.2. Initial Funding. In partial consideration of the Vaccine Dose purchase rights granted by AstraZeneca to the Commission acting on behalf and in the name of the Participating Member States hereunder, the Commission shall pay to AstraZeneca a fixed amount equal to 336 million Euros, as an estimate of the Upfront Costs as set forth in Schedule A (the “**Initial Funding**”) as follows:

(a) The Commission shall pay to AstraZeneca two-thirds of the Initial Funding (first Installment) within five (5) working days of the Effective Date; and

(b) The Commission shall pay to AstraZeneca one-third of the Initial Funding (second Installment) within twenty (20) days following the receipt from AstraZeneca of relevant evidence of the use of the first Installment and a relevant progress report of the continued progress towards manufacture of the Initial Europe Doses (e.g., reservation of manufacturing capacity, commencement of technology transfer, purchase of raw materials and purchase of vials). In the absence of reasonable relevant evidence, the Commission will have no obligation to pay the second Installment and may seek to recover the first Installment or a portion of it, if available pursuant to Section 12.2(c).

7.3. Subsequent Funding. The Participating Member States shall pay the Fill/Finish/Packaging Costs, storage and distribution costs of the Vaccine, destruction for any material produced at risk, and costs and expenses directly incurred for, or fairly allocable to, post-launch safety and risk management studies for the Vaccine in accordance with Schedule A and Sections 7.4 and 10.3 and the Order Forms (the “**Subsequent Funding**”). All such costs shall be allocated on a per Dose basis on each shipment of Doses and added to the individual invoices for shipments of Vaccine to each Participating Member State.

7.4. Mechanism for Updated Total Costs of Goods.

(a) The Parties agree that, notwithstanding any other provision of this Agreement, and while AstraZeneca acknowledges its obligation is to supply the Vaccine Doses at no profit, AstraZeneca shall not be requested or required to supply the Vaccine Doses at a loss. The Parties further agree that the estimated Upfront Costs of 336 million Euros and Fill/Finish/Packaging Costs of 534 million Euros (for a total estimated Cost of Goods of 870 million Euros) were determined based upon available estimates at the Effective Date for the Initial Europe Doses. Based on

300 million Initial Europe Doses, the price per Dose is currently estimated to be approximately 2.90 Euros per Dose. Of such amount, 336 million Euros (or approximately 1.12 Euros per Dose) will be paid by the Commission pursuant to the Initial Funding pursuant to Section 7.2 and the remainder (currently estimated to be 1.78 Euros per Dose) shall be paid to AstraZeneca by the Participating Member States as set forth below and in the Order Form. Such total Cost of Goods is subject to adjustment as per paragraphs (b) and (c) below and the price per Dose in the Order Form shall be automatically adjusted to reflect the adjusted price per Dose. Each price per Dose as adjusted from time to time is referred to as the **“Price Per Dose.”**

(b) To the extent that the total Cost of Goods exceed the estimated amount of 870 million Euros by less than 20%, AstraZeneca shall provide an updated purchase and payment schedule to the Commission, which shall state the delivery schedule of the Initial Europe Doses and the corresponding amounts payable by the Participating Member States, along with the corresponding Fill/Finish/Packaging Costs per Participating Member State, within thirty (30) days following invoicing for such Doses.

(c) If AstraZeneca becomes aware that the estimated Cost of Goods are reasonably expected to exceed 870 million Euros by 20% or more, then AstraZeneca shall notify the Commission of such excess and provide the relevant evidence in this respect. Following such notice, AstraZeneca and the Commission shall agree to a payment or other mechanism which will result in AstraZeneca supplying the Participating Member States with a number of Doses without incurring a loss. Such mechanism may include a reduction in the number of Doses and/or a further increase in Price Per Dose.

(d) If following the finalization of the matters contemplated hereby, documentary evidence provided by AstraZeneca indicates that the Cost of Goods for the Initial Europe Doses sold is less than 870 million Euros or the Participating Member States paid more than the Cost of Goods for the Optional Doses or Additional Doses, AstraZeneca shall notify the Alliance Manager and work with the Alliance Manager to establish a fair and equitable way to return the amount of the excess payments to the Commission and/or Participating Member States, as applicable.

7.5. Method of Payments. All payments to AstraZeneca under this Agreement shall be made by deposit of Euros by wire transfer of immediately available funds in the requisite amount to such bank account as AstraZeneca may from time to time designate by written notice to the Commission and the Participating Member States. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to this Agreement, AstraZeneca shall convert any amount expressed in a foreign currency into Euro equivalents using the AZ Exchange Rate. Payments for shipments of Doses shall be due and payable within thirty (30) days following invoicing for such Doses.

7.6. Audits and protection of EU financial interests.

(a) During the term of the Agreement and for a period of five (5) years after termination or expiration of the Agreement, AstraZeneca shall permit the Commission to perform or request an audit of the Cost of Goods of the Initial Europe Doses (and any Optional Doses and Additional Doses, to the extent applicable), no more than once in any twelve (12)-month period. The Commission shall use its Best Reasonable Efforts to ensure that those audits are conducted by an internationally recognized certified public accounting firm authorised on its behalf. AstraZeneca, its affiliates or subcontractors involved in the performance of the Agreement, shall make available to such third-party auditor, upon request, any pertinent documents or information for the purpose of verifying production costs of the Initial Europe Doses (and any Optional Doses and Additional Doses, to the extent applicable). Any such audit shall be conducted on reasonable advanced notice to AstraZeneca, and during normal operating hours in a manner to minimize disruption to AstraZeneca's business.

(b) AstraZeneca must keep all original documents stored on any appropriate medium, including digitised originals, if allowed by the national law, for a period of five (5) years starting from the last payment made under the last Order Form.

(c) 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 performance of the contract and up to five years starting from the payment of the balance of the last Order Form issued under this APA.

(d) Without increasing or decreasing the rights existing under Applicable Laws, the Parties acknowledge that the Court of Auditors and the European Public

Prosecutor's Office established by Council Regulation (EU) 2017/1939<sup>2</sup> ('the EPPO') also have rights of access, audits and investigations under Applicable Laws.

7.7. Late Payments. In the event the Commission or the Participating Member States fail to pay any amount payable under this Agreement or the Order Form within twenty (20) days of the due date for any such payment, without prejudice to any other rights or remedies that AstraZeneca may have hereunder:

(a) interest shall accrue on that outstanding amount for the period beginning on the due date for payment and ending on the date of actual payment at the rate applied by the European Central Bank for its principal 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, and the maximum rate permitted by Applicable Law, for the period from the due date for payment until the date of actual payment; and

(b) without prejudice to Section 7.7(a) and subject to giving the Commission or the Participating Member States twenty (20) days prior written notice of its intention to do so, AstraZeneca shall be entitled to suspend its obligations under this Agreement towards the Commission (if the Commission is defaulting) or the defaulting Participating Member States until such time as any unpaid amounts have been paid in full.

## **8. Delivery, Allocation, Distribution and Storage.**

### **8.1. Delivery.**

(a) AstraZeneca shall notify the Alliance Manager and Representative of each Participating Member State in good time prior to such time that AstraZeneca expects Doses to be available. Such notification shall include an estimate of the total number of Doses expected to be available for delivery and the expected dates that such Doses will be available to be shipped to the Distribution Hubs designated by the Participating Member States. In the case of a delivery of Initial Europe Doses, the number of Doses in such delivery shall be allocated to the Participating Member States *pro rata* based on the Binding Allocation; *provided*, that AstraZeneca shall not be required to make any deliveries to any Participating Member States where the delivery size would be less than one batch (expected size of 1.5 million to 2.0 million Doses). In the case of Optional Doses, the number of Optional Doses in such delivery shall be allocated to the Participating Member States *pro rata* based on the allocation of total Optional Doses defined by the Commission in its notice of Section 5.2. Within five (5) days of receiving such notification, each Participating Member State shall send to AstraZeneca a

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<sup>2</sup> Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

confirmatory notification (including confirmation of delivery instructions to the distribution hub for each Participating Member State as set forth in the Order Form) (“**Distribution Hubs**”).

(b) Following receipt of such notification, AstraZeneca shall issue an invoice to the Participating Member States. Each Participating Member State shall pay such invoice in accordance with Section 7.5. AstraZeneca and the Representative for each Participating Member State shall work together to identify the final delivery schedule for such Doses taking into account the goal of creating an efficient delivery of the Doses. Each Participating Member State shall identify only one Distribution Hub and delivery to each Distribution Hub will be a minimum of one batch as defined in Section 8.1(b) of finished drug product. Delivery at each Distribution Hub will occur CPT (INCOTERMS 2020). The delivery costs shall be borne by the Participating Member States. The Participating Member States shall reimburse AstraZeneca within thirty (30) days of being invoiced therefor.

8.2. Suspension of payments: In case of non-delivery or late delivery past the firm delivery date, the obligation of payment will be suspended. The obligation of payment will resume once the delivery has been completed. In that case, the Commission and/or the Participating Member State will notify AstraZeneca in writing of such late payment and the reason therefor.

8.3. Allocation.

(a) No later than thirty (30) working days following the Effective Date, the Commission shall deliver to AstraZeneca a final and binding written allocation of Initial Europe Doses between the Participating Member States (the “**Binding Allocation**”), which Initial Europe Doses must equal 300 million. The number of Initial Europe Doses set forth in the Binding Allocation shall be the total number of Initial Europe Doses that each Participating Member State is required to purchase pursuant to this Agreement.

(b) In the event that the Commission does not provide a Binding Allocation within the thirty (30) working day period or the number of Doses set forth in the Binding Allocation does not equal 300 million, then, unless otherwise agreed in writing by the Commission and AstraZeneca, the binding allocation of the Initial Europe Doses shall be made on a pro-rata basis to reflect the respective populations of each of the Participating Member States utilizing the population estimate as of 10 July 2020 reported by the statistical office of the European Union, Eurostat. In the event there is an excess of supply of the Initial Europe Doses and Optional Doses, the Participating Member States shall keep their shared rights in the Initial Europe Doses, and shall determine their best use of such excess doses, reserving the possibility to donate them to lower or middle income countries or public institutions and to donate or resell, at no profit, such doses to other European countries that agree to be bound by the terms and conditions of this Agreement applicable to a Participating Member State.

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(c) The Participating Member States may also resell, at no profit, Initial Europe Doses and/or Optional Doses to European countries that are not Member States if such other European countries agree to be bound by the terms and conditions of this Agreement applicable to a Participating Member State. Should such resale take place, the Participating Member States concerned shall reimburse the Commission the part corresponding to the Initial Funding in accordance with Sections 7.2 and 7.4(a).

8.4. Distribution by Participating Member States. Upon and after delivery by AstraZeneca to the respective Distribution Hubs, the Participating Member States shall be responsible for transportation and distribution of the Vaccine Doses allocated to them. For clarity, the Cost of Goods for the Initial Europe Doses shall not include any costs incurred in the distribution of the Vaccine Doses, which costs shall be entirely covered by the Participating Member States.

8.5. Storage and Destruction. Pursuant to Section 8.1 of this Agreement, AstraZeneca will provide the Participating Member States with at least five (5) working days' notice of when the Doses are available for delivery. In the event a Participating Member State fails to permit AstraZeneca to deliver the Doses to the relevant Distribution Hub, the Participating Member State concerned shall be responsible for all storage costs for such Doses. In such event, AstraZeneca will agree to store the Vaccine for up to an additional five (5) working days after such five (5) working day period (at the Participating Member State's cost, including the cost of any amounts required to insure the Doses during such period). After such ten (10) working day period, AstraZeneca may continue to store such Doses at the Participating Member State's cost if the relevant Member State agrees to this. To the extent that either Party does not agree to continue to store the Doses, AstraZeneca may sell the Doses to a third party or destroy the Doses at the cost of the Participating Member State for which the Doses are being stored. The Participating Member States shall reimburse AstraZeneca for all costs associated with distribution, storage, and destruction of the Doses within thirty (30) days of being invoiced therefor provided that AstraZeneca provides to the relevant Participating Member State specific evidence for such costs.

## 9. Pricing.

9.1. Initial Doses. AstraZeneca shall manufacture and supply to the Participating Member States the Initial Europe Doses at a price equal to their total Cost of Goods, with no profit or loss for AstraZeneca, which, as of the Effective Date, is estimated at 870,000,000 Euros, of which 336,000,000 Euros shall be paid by the Commission and 534,000,000 Euros by the Participating Member States. This estimated amount shall be paid through the Initial Funding and Fill/Finish/Packaging Costs according to the terms of Sections 7.1, 7.2 and 7.3 of this Agreement.

9.2. Optional Doses. In the event the Commission exercises the option on behalf of and in the name of the Member States to obtain the Optional Doses in accordance with Section 5.2, AstraZeneca shall manufacture and supply the Optional Doses at a price equal to their Cost of Goods (i.e., the full price is calculated without any credit based on the Initial Funding).

9.3. Additional Doses. AstraZeneca shall provide any agreed Additional Doses at Cost of Goods until 1 July 2021, unless AstraZeneca determines in good faith that the COVID-19 Pandemic has not ceased as of 1 July 2021, in which case AstraZeneca shall provide any agreed Additional Doses at Cost of Goods until such later date as AstraZeneca determines in good faith that the COVID-19 Pandemic has ceased. AstraZeneca shall promptly notify the Commission of any such later date suggested by AstraZeneca.

## 10. Regulatory Matters.

10.1. Compliance; Assistance. AstraZeneca shall be responsible for timely complying with all legal requirements of approval processes of the clinical trials and the market authorization of the Vaccine in the Member States. Notwithstanding the foregoing, the Commission and the Participating Member States shall use Best Reasonable Efforts, within the framework of their competencies, to support AstraZeneca in providing accelerated quality and current Good Manufacturing Practices facility approvals and OMCL testing if the requirements of safety, quality and efficacy of the Vaccine allow it to do so and are fully met. The Commission and the Participating Member States shall use their Best Reasonable Efforts to support, within the framework of their competencies, AstraZeneca in its Best Reasonable Efforts to achieve for the Vaccine fast access to the European population through pan-European access mechanisms, including accelerated regulatory approval processes.

10.2. Reporting. AstraZeneca shall promptly inform the Commission if, in the process of reviewing the results or progress of AstraZeneca's clinical trials, AstraZeneca reasonably determines that the ongoing or planned clinical trials by AstraZeneca and its partners are not likely to be sufficient for approval of the Vaccine by the Commission.

10.3. Post-Launch Safety and Risk Management Studies. In the event that post-launch safety or risk management studies for the Vaccine are (i) required by the EMA, (ii) required by another Regulatory Authority and relied upon by EMA for approval, or (iii) otherwise required or advisable to be conducted for the benefit of any Participating Member States in AstraZeneca's reasonable discretion, AstraZeneca will introduce all such costs and expenses incurred for, or fairly allocable to, such post-launch safety and risk management study activities to the Costs of Goods and include it in the payments to be made by the Participating Member States.

## 11. Intellectual Property.

11.1. Ownership. The Commission acknowledges that AstraZeneca has pre-existing obligations to its upstream licensor and throughout the term of this Agreement, may incur obligations to its CMOs and other contractors in respect of patents, know-how and other intellectual property rights relating to the Vaccine. The Commission acknowledges and agrees that as between the Parties, (i) AstraZeneca shall be the sole owner of all intellectual property rights generated during the development, manufacture, and supply of the Vaccine, including all Know-How (collectively, the "**Vaccine IP Rights**"), and (ii) AstraZeneca shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set forth in this Agreement, AstraZeneca does not grant to the Commission by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by AstraZeneca hereunder are reserved by AstraZeneca.

11.2. IP Rights Following Abandonment. The Commission, or any third party designated by the Commission, shall have the right to obtain a license or sublicense from AstraZeneca for the Vaccine IP Rights to the extent reasonably necessary to



enable the Commission to continue the development efforts for the Vaccine for the EU market in the event that AstraZeneca determines to abandon the development efforts hereunder, subject to the upstream license. To the extent the Commission, or any third party designated by the Commission, obtains any such license or sublicense from AstraZeneca, the Commission, or any such designated third party, shall be solely liable for all royalties, costs and other expenses incurred by AstraZeneca and payable to a third party in consideration for such license or sublicense (including, but not limited to, payment obligations AstraZeneca has to its upstream licensor for the Vaccine). For the avoidance of doubt, the Commission shall not pay any license fees or royalties that AstraZeneca would not have paid had it proceeded with the Vaccine development efforts.

## **12. Term and Termination.**

12.1. Term. This Agreement shall commence on the Effective Date and, unless earlier terminated as provided in Section 12.2 or 12.3 below, shall remain in effect until the last Initial Europe Doses, Optional Doses (if Optional Doses are ordered pursuant to Section 5.2) and Additional Doses (if any are mutually agreed to be ordered pursuant to Section 5.3) are delivered to the Participating Member States pursuant to Article 5. For the avoidance of doubt, this Agreement does not govern the sale of any Doses of Vaccine that do not constitute Initial Europe Doses, Optional Doses or Additional Doses and the terms of this Agreement shall not bind the Parties if they determine to enter into a new agreement governing Doses that do not constitute Initial Europe Doses, Optional Doses or Additional Doses.

### **12.2. Termination for Abandonment.**

(a) In the event that AstraZeneca abandons the development, manufacturing and other efforts hereunder (whether as a result of its determination that the Vaccine cannot be safely or efficaciously developed, manufactured, distributed, or administered or the determination that regulatory approvals for the Vaccine cannot or will not be obtained in a timely manner), AstraZeneca shall notify the Commission of such abandonment and the reasons justifying it and (i) the Commission will have the right to terminate this Agreement upon ten (10) days prior written notice to AstraZeneca, and (ii) AstraZeneca will have the right to terminate this Agreement upon ten (10) days prior written notice to the Commission.

(b) In addition, the Commission can terminate this Agreement if AstraZeneca reasonably determines that the ongoing or planned clinical trials by AstraZeneca and its partners are not likely to be sufficient for approval of the Vaccine as set out in Section 10.2 of this Agreement.

(c) In the event either Party terminates this Agreement pursuant to Section 12.2(a), upon the request of the Commission, AstraZeneca shall use Best Reasonable Efforts to:

(i) ensure the transfer of all purchased vials and stoppers to the Commission (or its designee) to be repurposed;

(ii) assign the Commission (or its designee) all purchased or reserved drug product manufacturing capacity from the applicable CMO (to the extent permitted by the agreement between AstraZeneca and such CMO); and

(iii) return to the Commission (or its designee), within thirty (30) days after the date of termination of this Agreement, any portion of the Funding that is unspent, if any, after deducting all expenses incurred by AstraZeneca including any non-cancellable expenses relating to the activities under this Agreement.

(d) Within thirty (30) days following the date of termination of this Agreement, the Commission (with respect to the Initial Funding) and the Participating Member States (with respect to the Subsequent Funding and any other payment, *pro rata* to the Binding Allocation pursuant to Section 8.3(a) or if there is no Binding Allocation, then *pro rata* in accordance with the method for allocation set forth in Section 8.3(b)) shall reimburse AstraZeneca for all reasonably incurred unpaid expenses and any non-cancellable expenses relating to the activities under this Agreement for which Funding has not yet been provided.

Without prejudice to the indemnification rights of AstraZeneca and the other Indemnified Persons under Article 14, no additional compensation shall be claimed from the Commission or any Participating Member State for any damages AstraZeneca might incur due to the termination.

### 12.3. Termination for cause.

The Commission on behalf of the Participating Member States may terminate this Agreement in the following circumstances:

(a) if AstraZeneca is in material breach of its obligations (considered as a whole) of this Agreement following notice and an opportunity to cure as set forth below;

(b) 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<sup>3</sup>;

<sup>3</sup> 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>

Prior to any termination under this Section 12.3, the Commission must formally notify AstraZeneca of its intention to terminate the Agreement and the grounds for termination as set forth below. AstraZeneca shall have 30 days following the date of receipt of the formal notification to cure such material breach or dispute the existence of such underlying breach by submitting observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. If the Commission confirms that the measures AstraZeneca has taken or will take cure such breach within such 30 days period, the notice of termination submitted by the Commission on behalf of the Participating Member States shall become null and void. In the event of a dispute of the existence or cure status of any material breach, such dispute shall be subject to Section 18.5 of this Agreement prior to any termination of this Agreement.

12.4. Survival. The following provisions shall survive expiration or termination of this Agreement: Sections 2 (“Role of the Parties”), 7.6 (Audit of Production Costs), and 7.7 (Late Payments), and Articles 11 (Intellectual Property), 12 (Term and Termination), 14 (Indemnification), 15 (Release; Limitation of Liability, Disclaimer of Warranty), 16 (Confidentiality), 17 (Data Protection) and 18 (Miscellaneous).

### **13. Representations and Warranties.**

13.1. AstraZeneca. AstraZeneca represents, warrants and covenants to the Commission and the Participating Member States that:

- (a) the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action;
- (b) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
- (c) this Agreement has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms;
- (d) it shall use its Best Reasonable Efforts to ensure that the Initial Europe Doses shall be manufactured in accordance with, and shall comply in all material respects with, current Good Manufacturing Practices in the country where the Initial Europe Doses are manufactured, including adherence to EMA pharmacovigilance regulations;
- (e) it is not under any obligation, contractual or otherwise, to any Person or third party in respect of the Initial Europe Doses or that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the complete fulfillment of its obligations under this Agreement;
- (f) all information, including historic financial information, submitted to the Commission or Participating Member States in relation to this Agreement is true, complete and accurate in all material respects;

(g) it has not received public funding from any source for the same costs that are funded by the Commission or the Participating Member States and

(h) it shall comply with all Applicable Laws that are applicable to its activities and operations under this Agreement.

13.2. Commission. The Commission and the Participating Member States represents, warrants and covenants to AstraZeneca that:

(a) the execution and delivery of this Agreement by the Commission acting on behalf of itself and the Participating Member States, and the performance by each of them of the transactions contemplated hereby have been duly authorized by all necessary action;

(b) the Commission has the power and authority to execute and deliver this Agreement on behalf of itself and the Participating Member States, and the Commission and each of the Participating Member States have the power and authority to perform each of its obligations hereunder, including to satisfy the payment obligations hereunder;

(c) this Agreement has been duly executed by the Commission acting on behalf of itself and the Participating Member States and is a legal, valid and binding obligation on each of them, enforceable against it in accordance with its terms;

(d) the Commission acting on behalf of itself and the Participating Member States is not under any obligation, contractual or otherwise, to any Person or third party that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the complete fulfillment of each of its obligations under this Agreement; and

(e) the Commission and the Participating Member States shall comply with all Applicable Laws that are applicable to each of its activities and operations under this Agreement.

#### **14. Indemnification.**

14.1. Member States. Each Participating Member State shall indemnify and hold harmless AstraZeneca, its Affiliates, subcontractors, licensors, and sub-licensees, and officers, directors, employees and other agents and representatives of each (collectively, the “**Indemnified Persons**”) from and against any and all damages and liabilities, including settlements for which the Indemnifying party has given its consent pursuant to Section 14.2, and necessary legal costs relating to, resulting from or associated with claims for death, physical, mental, or emotional injury, illness, disability, or condition, fear of the foregoing, property loss or damage, and business interruption of the injured party or a Related Person of such injured person (together, “**Losses**”) relating to or arising from the use or administration of the Vaccine shipped or allocated to its jurisdiction. Such indemnification will be available regardless of where the Vaccine is administered, where the claim is brought, and whether the claim

of a Defect originates from the distribution, administration and use, clinical testing or investigation, manufacture, labelling, formulation, packaging, donation, dispensing, prescribing or licensing of the Vaccine in its jurisdiction. Such indemnification will not be available to Indemnified Persons (a) to the extent such Losses are the result of such Indemnified Person's Willful Misconduct, or (b) to the extent that there has been a final determination by a court of competent jurisdiction that a defect in the Vaccine has arisen from AstraZeneca's failure to comply with current Good Manufacturing Practices or EMA pharmacovigilance regulations.

Indemnification under this Section 14.1 will be available for Losses arising from the use and administration of vaccines supplied under this Agreement, regardless of when or where vaccination occurred and regardless of when or where the injury leading to the Losses occurs or is reported.

14.2. Process. The Indemnified Person shall give (or cause AstraZeneca to give) the Participating Members State(s), as applicable (the “**Indemnifying Party**”), prompt notice of any claim or lawsuit served upon the Indemnified Person (a “**Third Party Claim**”) stating the nature and basis of such Third Party Claim and the maximum estimated amount (in euro) of such Third Party Claim, to the extent known (which estimate may be updated from time to time). Notwithstanding the foregoing, no delay or deficiency on the part of the Indemnified Person in so notifying the other shall limit any right of any Indemnified Person to indemnification under this Article 14, except to the extent such failure materially prejudices the defense of such Third Party Claim. The Indemnified Person shall assume and control the defense of any Third Party Claim using legal counsel reasonably chosen by the Indemnified Person. Each of the Parties shall (i) use commercially reasonable efforts to mitigate the effects of the claim and (ii) fully cooperate with the Indemnified Person and its legal representatives in the investigation and defense of any matter which is the subject of indemnification, at the Indemnifying Party's cost and expense. The Indemnified Person shall keep the Indemnifying Party reasonably informed of the progress of the defense of the Third Party Claim. The Indemnifying Party shall pay the invoices of legal counsel and other expenses of the Indemnified Person arising from defending the Third Party Claim promptly upon presentment of an invoice and in any case within ninety (90) days of presentment thereof. The Indemnified Person shall have the right to seek settlement or compromise of, and to so settle or compromise, the Third Party Claim; *provided* that the Indemnified Person shall not settle or compromise a Third Party Claim without the prior written consent of the Indemnifying Party and the Indemnifying Party shall not unreasonably withhold, condition or delay its approval of the settlement of any claim, liability or action covered by this Article 14.

**15. Release; Limitation of Liability for claims other than third party indemnification; Disclaimer of Warranties.**

15.1. Release. The Commission and each of the Participating Member States each within their respective competencies, on behalf of itself, waive and release any claim against AstraZeneca arising out of or relating to: (a) lack of safety or efficacy of the Vaccine, subject to compliance by AstraZeneca with applicable EU regulatory requirements for a pandemic product, limited to manufacture by AstraZeneca of the

Vaccine in accordance with Good Manufacturing Practices; (b) use or administration of the Vaccine under pandemic conditions, except to the extent such claim arises from AstraZeneca's wilful misconduct or failure to comply with EU regulatory requirements applicable to the Vaccine including manufacture by AstraZeneca of the Vaccine in accordance with Good Manufacturing Practices; (c) issues relating to storage or transport conditions including deep cold chain storage; (d) lack of proper aseptic technique or dosing at the point of administration of the Vaccine; or (e) delays in delivery of the Vaccine under this Agreement.

15.2. Limitation of Liability for claims other than third party indemnification. The aggregate liability of AstraZeneca and its Affiliates in respect of claims made by the Commission or Participating Member States, or any affiliates acting on the Commission or Participating Member States' behalf (as distinguished from claims for third party indemnification), whether for breach of contract, another contractual-based claim, arising in tort (including negligence) or otherwise, arising out of, under or in connection with this Agreement shall not exceed the amounts actually paid by the Commission and Participating Member States to AstraZeneca under this Agreement.

15.3. Disclaimer of Warranties. The Parties acknowledge that they are not relying on any understanding, arrangement, statement, representation (including, any negligent misrepresentation but excluding any fraudulent misrepresentation), warranty, condition, term, customary practice, course of dealing or provision except for the warranties set out in this Agreement. All statements, representations, warranties, terms, conditions and provisions (including, any implied by statute or equivalent, case law or otherwise and any implied warranties and/or conditions as to merchantability, satisfactory quality, fitness for purpose and skill and care), other than fraudulent misrepresentations and the provisions set out in this Agreement, are hereby excluded to the maximum extent permissible by law.

## 16. Confidentiality.

16.1. Definition of Confidential Information. In this Agreement, "**Confidential Information**" shall, subject to Section 16.2 mean:

(a) any and all Know-How, software, algorithms, designs, plans, forecasts, analyses, evaluations, research, business information, financial information, business plans, strategies, customer lists, marketing plans, or other information whether oral, in writing, in electronic form, or in any other form; and

(b) any physical items, compounds, components, samples or other materials; disclosed by or on behalf of a Party or any of that Party's Affiliates (the "**Disclosing Party**") to the other Party or any of the other Party's Affiliates (the "**Receiving Party**") before, on or after the Effective Date.

16.2. Exclusions from Confidential Information. In this Agreement, Confidential Information shall not include any information or materials, for which the Receiving Party can prove:

- (a) is or becomes public knowledge through no improper conduct on the part of the Receiving Party, the Receiving Party's Affiliates and/or their respective representatives;
- (b) is already lawfully possessed by the Receiving Party and/or the Receiving Party's Affiliates without any obligations of confidentiality or restrictions on use prior to first receiving it from the Disclosing Party; /or
- (c) is obtained subsequently by the Receiving Party and/or the Receiving Party's Affiliates from an unrelated third party without any obligations of confidentiality and such unrelated third party is in lawful possession of such information or materials and not in violation of any contractual or legal obligation to maintain the confidentiality of such information or materials; and
- (d) the Disclosing Party agreed to release the Receiving Party from the confidentiality obligation earlier.

16.3. Legally Required Disclosure of Confidential Information. The Receiving Party and/or the Receiving Party's Affiliates may disclose Confidential Information to the extent required by law or regulation or by legal, judicial, regulatory or administrative process or pursuant to an audit or examination by a regulator or self-regulatory organization subject to compliance with this Section. If the Receiving Party is so compelled to disclose any Confidential Information, the Receiving Party will provide the Disclosing Party with prompt written notice thereof so that the Disclosing Party may seek a protective order or other appropriate remedy. Subject to its obligations to comply with such subpoenas, court processes or directions, the Receiving Party will reasonably cooperate with the Disclosing Party's counsel in their efforts to obtain a protective order or other similar remedy to accord some form of confidential treatment to any such Confidential Information of the Disclosing Party.

16.4. Limitations on Use of Confidential Information. The Receiving Party shall treat all Confidential Information as secret and confidential and shall not use, copy or disclose to any third party any Confidential Information of the Disclosing Party (whether before, on or after the date of this Agreement) except as set out in Section 16.5 below.

16.5. Use and Disclosures of Confidential Information. The Receiving Party may:

- (a) ensure the protection of confidential information or documents with the same level of protection as its own confidential information or documents and in any case with due diligence;
- (b) use and disclose Confidential Information of the Disclosing Party solely to the extent necessary to enable the Receiving Party to exploit the rights granted under

this Agreement and/or to perform its obligations under this Agreement; provided, that where any disclosure is required to third parties the Receiving Party shall: (1) only disclose Confidential Information to third parties that have entered into appropriate and legally binding confidentiality and non-use obligations in respect of the Confidential Information disclosed; and (2) procure that such third parties do not further disclose or use Confidential Information. For the avoidance of doubt, the Receiving Party shall not use the Confidential Information with respect to or for any other program or project other than the Vaccine and the express objectives set forth herein.

(c) disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Affiliates, officers and employees to whom such disclosure is necessary (and only disclose that part of the Confidential Information which is necessary) to enable the Receiving Party to exploit the rights granted under this Agreement and/or to perform its obligations under this Agreement and provided that the Receiving Party shall remain responsible for procuring that the Receiving Party's Affiliates, officers and employees do not further disclose and/or use the Confidential Information for any other purpose; and

(d) after giving written notice to the Disclosing Party, disclose any part of the Confidential Information of the Disclosing Party solely to the extent that it is legally required to do so pursuant to an order of a court of competent jurisdiction or other Governmental Authority or otherwise as required by Applicable Law including the laws and regulations applying to any public listing authority, provided that the Receiving Party shall use reasonable endeavors to limit such disclosure and to provide the Disclosing Party with an opportunity to make representations to the relevant court or other Governmental Authority, Regulatory Authority, or allied authority or listing authority.



16.6. Protection of Confidential Information. The Receiving Party shall at all times maintain documents, materials and other items (including items in electronic form) containing Confidential Information of the Disclosing Party and any copies thereof, in a secure fashion by taking reasonable measures to protect them from theft and unauthorized use and disclosure. Without prejudice to the foregoing, the Receiving Party shall exercise at least the same degree of care to prevent theft and unauthorized disclosure and/or use of the Disclosing Party's Confidential Information as the Receiving Party exercises in respect of its own confidential material of like importance.

16.7. Losses of Confidential Material. The Receiving Party shall notify the Disclosing Party immediately if the Receiving Party becomes aware of any unauthorized use or disclosure of, or any unauthorized access to or of any theft or loss of any copies of any Confidential Information of the Disclosing Party.

16.8. Survival. The provisions of this Article 16 shall commence on the Effective Date and shall continue for so long as either Party has knowledge of any Confidential Information received or derived from the other Party and shall survive termination or expiry of this Agreement for a period of five (5) years in respect of all Confidential Information.

## **17. Data protection.**

### **17.1 Processing of personal data by the Commission**

The sharing of personal data is necessary to support contact with employees and subcontractors in order to collaborate under this Agreement ("In-Scope Personal Data"). The Party receiving the personal data from the other Party shall not process the In-Scope Personal Data for longer than necessary to fulfil the agreed purposes of this Agreement.

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](https://ec.europa.eu/info/data-protection-public-procurement-procedures_en).

The Parties 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 Parties 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.

## 17.2 Processing of personal data by the Parties

The processing of personal data by the Parties shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the following purposes: Contact with employees and subcontractors in order to collaborate under the Agreement. Both Parties agree each act as Data Controllers with regards to the Processing of Personal Data they each undertake.

Each Party represents and warrants that it has provided an appropriate data privacy notice and obtained appropriate consent (if legally required) from the data subjects whose In-Scope Personal Data is being shared with the other Party and that such notice and consent is in accordance with Applicable Laws regarding data protection and allows for the desired use of such In-Scope Personal Data. Should a Party learn that it has provided In-Scope Personal Data that may not be shared pursuant to a consent or notice, such Party is responsible for promptly notifying the other Party so that the affected In-Scope Personal Data can be deleted as required.

The Parties agree that the responsibility for complying with any communication addressed to one or both Parties under this Agreement made by a Data Subject exercising one or several of his/her data protection rights under Applicable Laws regarding Data Protection (“Data Subjects Requests”) falls to the Party receiving the Data Subject Request in respect of the personal data held and under the responsibility of that Party as data controller. The Parties agree to cooperate and provide reasonable assistance as is necessary to each other to enable them to (1) comply with Applicable Laws regarding Data Protection, (2) comply with Subject Requests and (3) respond to any other queries or complaints from data subjects.

In the event a Party suffers a personal data breach, such Party shall ensure it complies with Applicable Laws regarding Data Protection and, if applicable, complies with any obligations to notify Data Protection Supervisory Authority, data subjects or other regulatory bodies as required by Applicable Law regarding the Personal Data Breach.

To the extent the Commission or Participating Member State suffers a personal data breach that (1) has an impact on the services provided under this Agreement or (2) relates to In-Scope Personal Data AstraZeneca shared with the Commission or Participating Member State, the Commission or Participating Member State shall promptly notify AstraZeneca about such personal data breach.

Both Parties shall indemnify, defend, and hold each other harmless from and against any and all liabilities, claims, losses, suits, judgments, and reasonable legal fees arising from any breach, negligent act, error or omission of relevant data protection obligations under this Agreement by the other Party, its subcontractors or their respective personnel.

## 18. Miscellaneous.

### 18.1. Interpretation. In this Agreement:

- (a) Any phrase introduced by the terms “including”, “include” and “in particular” or any similar expression shall be construed as illustrative only and shall not limit the sense of the words preceding these terms;

(b) the headings are for convenience only and shall not affect the interpretation of this Agreement;

(c) the meaning given to defined terms in this Agreement shall also apply to their grammatical variants provided that the initial letter is capitalized; and

(d) in the event of any inconsistencies between this Agreement and any attachments hereto, the terms of this Agreement shall prevail.

18.2. Notices.

Any notice given under this Agreement shall be in writing in English, shall refer to this Agreement and shall be sent by either pre-paid recorded first class post/pre-paid airmail or courier to the principal office or registered office of the recipient or by electronic transmission to the addresses set forth below:

**AstraZeneca:**

Iskra Reic, EVP Europe & Canada  
Neuhofstrasse 34, 6340 Baar Switzerland  
Email: [ISKRA.REIC@ASTRAZENECA.COM](mailto:ISKRA.REIC@ASTRAZENECA.COM)

Copy to

Mariam Koohdary, Deputy General Counsel  
1800 Concord Pike Wilmington, DE 19850-5437 United States of America  
Email: [MARIAM.KOOHDARY@ASTRAZENECA.COM](mailto:MARIAM.KOOHDARY@ASTRAZENECA.COM)

**Commission:**

Sandra Gallina, Deputy Director General for Health  
Directorate General for Health and Food Safety  
Rue Breydel 4, 1049 Bruxelles, Belgium  
Email: [Sandra.Gallina@ec.europa.eu](mailto:Sandra.Gallina@ec.europa.eu)

18.3. Participating Member States.

(a) Any written notice sent by a Party that is actually received by the other Party shall be deemed to have been properly given and received by that Party irrespective of whether or not the delivery requirements of Section 18.2 have been complied with.

18.4. Governing Law. This Agreement shall be governed by the laws of Belgium.

18.5. Resolution.

(a) In the event of a dispute arising under this Agreement between the Parties, the Parties shall first refer such dispute to informal dispute resolution discussions between their respective Executive Officers. AstraZeneca, on the one hand, or the Commission, on the other hand on behalf of the Commission or the applicable Participating Member State, 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 Executive Officers shall meet and attempt to resolve the dispute by good faith negotiations.

(b) Each of the Commission, the Participating Member States and AstraZeneca 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 Agreement or the legal relationships established by this Agreement.

18.6. Waiver. Failure or delay by either Party to exercise any right or remedy under this Agreement shall not be deemed to be a waiver of that right or remedy, or prevent the Party from exercising that or any other right or remedy on any occasion. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in writing duly executed by or on behalf of the Party waiving such right or remedy. The waiver by either Party of any right or remedy hereunder shall not be deemed a waiver of any other right whether of a similar nature or otherwise.

18.7. Force Majeure. Neither the Commission nor the Participating Member States nor AstraZeneca shall be held liable or responsible to the other Party or be deemed to have breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other employment disturbances (whether involving the workforce of the non-performing Party or of any other person) acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties may not be invoked as force majeure, unless they stem directly from a relevant case of force majeure.

The situation or event must not be attributable to negligence on the part of the parties or on the part of the subcontractors.

The non-performing Party shall notify the other Party of such force majeure promptly following such occurrence takes place by giving written notice to the other Party stating the

nature of the event, its anticipated duration (to the extent known), and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Best Reasonable Efforts to remedy its inability to perform and limit any damage.

18.8. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed in writing by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

18.9. Entire Agreement. This Agreement constitutes the entire agreement and understanding of the Parties relating to the subject matter of this Agreement and supersedes all prior oral or written agreements, representations, understandings or arrangements between the Parties relating to the subject matter of this Agreement including the Tender Specifications set forth in the Commission Call for Tenders SANTE/2020/C3/037 - for the development, production, priority-purchasing options and supply of COVID-19 Vaccines for EU Member States (“**Tender Specifications**”).

18.10. Severability. If any provision of this Agreement is held to be void or otherwise unenforceable by a court of competent jurisdiction from whose judgment no appeal is made within the applicable time limit then the provision shall be omitted and the remaining provisions of this Agreement shall continue in full force and effect.

18.11. Amendment. No amendment shall be made to this Agreement except in writing signed by the duly authorized representatives of the Commission and AstraZeneca.

An amendment shall only be permitted within the limits set out in Regulation 2018/1046 of the European Parliament and of the Council of 18 July of 2018 on the financial rules applicable to the general budget of the Union (“the Financial Regulation”).

18.12. Relationship of the Parties. Nothing in this Agreement shall create or imply an agency, partnership or joint venture between the Parties. No Party shall act or describe itself as the agent of the other Parties nor shall any Party have or represent that it has any authority to make commitments on behalf of the other Parties.

18.13. Opt out and signature. The Commission shall sign this agreement on behalf and in the name of all Participating Member States that have not opted out in conformity with Article 4 of the agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States, as approved by the Decision.

**SENSITIVE\***

*RELEASABLE TO: Need to know basis*

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Agreement.

**ASTRAZENECA AB**

DocuSigned by:

*Derek Seaborn*

8FFD5191CB0E47D...

Name: Derek SEABORN

Title: VP Head of Sweden Operations

Date: 27 August 2020

**THE COMMISSION, on behalf and in  
the name of the participating Member  
States**

*S. Kyriakides*

Name: Stella KYRIAKIDES

Title: Commissioner

Date: 27/8/2020

## ORDER FORM

1.[complete] (the **“Participating Member State”**), represented for the purposes of signing this specific order form by [*forename, surname, function, department of authorising officer*],

and

2. AstraZeneca AB, a party incorporated in Sweden having a business address of KVARNBERGAG 16, 151 85 SÖDERTÄLJE

[*Statutory registration number or ID or passport number*]

[*VAT registration number*]

[appointed as leader of the group by the members of the group that submitted the joint tender]

[**“AstraZeneca”** or **“the contractor”**), represented for the purposes of signing this specific order form by [*forename, surname and function of legal representative,*]

WHEREAS, AstraZeneca and the Commission acting on behalf of and in the name of the Participating Member States entered into that Advance Purchase Agreement for the production, purchase and supply of the ChAdOx1 nCov-19 vaccine in the European Union dated 27 August, 2020 (the **“APA”**).

WHEREAS, the APA provides that each Participating Member State must deliver and execute an Order Form in this form with the information filled in (a **“Order form”**);

WHEREAS, the Participating Member State wishes to order Doses from AstraZeneca in accordance with the terms of the APA.

WHEREAS in accordance with the provisions set out in the APA, AstraZeneca has agreed to supply the Initial Europe Doses allocated to each Participating Member State in a given timeframe, should it manage to develop a safe and effective vaccine against COVID-19 (**“Vaccine”**).

WHEREAS, capitalized terms that are used but not otherwise defined herein shall have the meaning for such capitalized terms set forth in the APA.

HAVE AGREED

### Article 1

#### Subject matter

**1.1** This Order Form is entered into as contemplated by the APA **for the production and purchase of a successful COVID-19 vaccine in the European Union**, signed by the parties on [*complete date*]. This Order Form is an integral part of the APA and the terms and conditions of the APA are incorporated into this Order Form by this reference.

**1.2** By execution of this Order Form, the undersigned Participating Member State hereby:

- (a) shall have a legally binding obligation to purchase a portion of (i) the Initial Europe Doses as set forth in the Binding Allocation to be/as determined pursuant to Section 8.3(a) or 8.3(b), as applicable, of the APA and (ii) the Optional Doses

allocated as set forth in Section 5.2 of the APA, in each case, as set forth in the APA and in this Order Form.

## Article 2

### Entry into force and duration

- 2.1** This Order Form shall become effective upon execution and delivery by the Participating Member State and counter-execution and delivery by AstraZeneca.

## Article 3

### Price and Quantity

- 3.1** Price Per Dose. The Price Per Dose for the Initial Europe Doses and Optional Doses shall equal the amount calculated pursuant to Sections 7.3, 7.4 and 10.3 of the APA, taking into account adjustments provided for therein.
- 3.2.** Initial Europe Doses: Quantity and Binding Order. The precise quantity of the Initial Europe Doses purchased by the [the name of the Participating Member State] as determined pursuant to Sections 8.3(a) and 8.3(b) of the APA is [ ]. The number of Initial Europe Doses allocated to each Participating Member State in the Binding Allocation shall be the number of Initial Europe Doses that the Participating Member State is required to purchase pursuant to this Order Form.
- 3.3.** Optional Doses: Quantity and Binding Order. The precise quantity of the Optional Doses to be purchased by [the name of the Participating Member State] as determined pursuant to Section 5.2 of the APA is [ ]. The number of Optional Doses set forth in such allocation shall be the total number of Optional Doses that the Participating Member State is required to purchase pursuant to this Order Form.
- 3.4.** Additional Doses. Additional Doses may be agreed to by AstraZeneca and [the name of the Participating Member State] in accordance with Section 5.3 of the APA. The Price per Dose for Additional Doses would equal the amount calculated pursuant to Section 7.4 of the APA, taking into account adjustments provided for in the APA.
- 3.5.** Method of Payment. All payments to AstraZeneca under this Order Form shall be made by deposit of Euros by wire transfer of immediately available funds in the requisite amount to such bank account as AstraZeneca may from time to time designate by written notice to the Participating Member State. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to this Agreement, AstraZeneca shall convert any amount expressed in a foreign currency into Euro equivalents using the AZ Exchange Rate. . Payments for shipments of Doses shall be due and payable within thirty (30) days following invoicing for such Doses.
- 3.6.** Distribution Hubs. The Distribution Hub for the Participating Member State is as follows:

[Member State to enter location of Distribution Hub]



## Article 4

### Communication details; Notices

Any notice given under this Order Form shall be in writing in English, shall refer to the APA and this Order Form and shall be sent by either pre-paid recorded first class post/pre-paid airmail or courier to the principal office or registered office of the recipient or by electronic transmission to the addresses set forth below:

#### 4.1 Participating Member State:

[Full name]

[Function]

[Name of Participating Member State]

[Full official address]

E-mail: [complete]

Contractor:

[Full name]

[Function]

[Company name]

[Full official address]

E-mail: [complete]

## Article 5

### Representations, Warranties and Covenants

#### 5.1 The Participating Member State represents, warrants and covenants to AstraZeneca that:

- (b) the execution and delivery of this Order Form and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary action;
- (c) it has the power and authority to execute and deliver this Order Form and to perform its obligations hereunder, including to satisfy the payment obligations hereunder;
- (d) this Order Form has been duly executed and is a legal, valid and binding obligation on it, enforceable against it in accordance with its terms;
- (e) it is not under any obligation, contractual or otherwise, to any Person or third party that conflicts with or is inconsistent in any material respect with the terms of this Order Form or that would impede the complete fulfillment of its obligations under this Order Form;
- (f) it shall comply with all Applicable Laws that are applicable to its activities and operations under the APA;

- (g) Upon request by AstraZeneca and in coordination with the Commission, the Participating Member State will use its Best Reasonable Efforts, in accordance with all Applicable Laws and within the framework of its competencies, to assist AstraZeneca in securing the supply of any drug substances needed and drug filling and finishing capacity as well as components for the development, manufacture, and supply of the Initial Europe Doses; and
- (h) Capacity Limitations. In the event AstraZeneca's ability to fulfill its obligations under this Agreement is impeded by a competing agreement entered into by or on behalf of the Participating Member State, AstraZeneca shall promptly inform the Participating Member State. While AstraZeneca shall continue to use Best Reasonable Efforts to engage with its own contract manufacturers and suppliers to utilize the capacity and/or components, the Participating Member State will assist in finding a mutually acceptable solution for this Agreement and the competing agreement. To the extent AstraZeneca's performance under this Agreement is impeded by any such competing agreements, AstraZeneca shall not be deemed in breach of this Agreement as a result of any such delay due to the aforementioned competing agreement(s).

## **Article 6**

### **Termination**

This Order Form shall terminate concurrent with the APA and with the same effects of termination as set forth in Article 12 of the APA. Within thirty (30) days following the date of termination of this Order Form, the Participating Member State (pro rata to the Binding Allocation pursuant to Section 8.3(b) of the APA or if there is no Binding Allocation, then pro rata in accordance with the method for allocation set forth in Section 8.3(b) of the APA) shall reimburse AstraZeneca for all reasonably incurred unpaid expenses and any non-cancellable expenses relating to the activities under this Agreement for which Funding has not yet been provided.

### **Signatures**

For the Member State authority,

*[forename/surname/function]*

signature:

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

In duplicate in English.

**Schedule A****Total Cost of Goods**

As of the date of this Agreement, the total Costs of Goods for the Initial Europe Doses are estimated to be 870,000,000 Euros.

Drug substance manufacturing at Novasep (FR/BE), Halix Biologics (IIL), Oxford Biomedica (UK), and Cobra Biologics (UK). AstraZeneca is also in discussion with Advent (ITL). Catalent (US) may serve as a back-up supply site and may be used as needed.

Drug product manufacturing at Catalent (ITL), IDT Biologika (DE), Wockhardt (UK) and potential other suppliers.

Drug product fill/finish assumptions are based on current knowledge of sterile filling processes and a 10-dose container closure presentation.

Following execution of manufacturing arrangements for the Initial Europe Doses, AstraZeneca will provide the names of the contracted suppliers to the Commission/Participating Member States.

As set forth more fully in the table below, in order to manufacture the Initial Europe Doses by Q2 2021, AstraZeneca estimates that it must expend approximately 336,000,000 Euros in Q2/Q3 2020 ( the “**Upfront Costs**”) to secure necessary starting materials and drug product manufacturing line capacity.

Activity	Estimated costs (June 2020 - September 2020)
Technology Transfer/Process Performance Qualification/ Technology Support for Drug Substance and Drug Product, TT/PPQ/Tech Support (DS &DP)	41,000,000 Euros
Procurement of critical material (vials/stoppers)	41,000,000 Euros
Drug Product/Packaging Reservation fee	49,000,000 Euros
Drug Substance CMO capacity reservation fee, raw materials, and resins	205,000,000 Euros
Cumulative Commitment	336,000,000 Euros

As set forth more fully in the table below, as of the date of this Agreement, AstraZeneca currently estimates that it will be required to expend approximately 534,000,000 Euros between Q3 2020 and Q2 2021 for the filling, finishing and packaging of the final Vaccine for distribution (the “**Fill/Finish/Packaging Costs**”).

**SENSITIVE\***

*RELEASABLE TO: Need to know basis*

Estimated Delivery Schedule

<i>Number of Doses in Millions*</i>	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21
Monthly Delivery	30	40	30	20	80	40	60
Cumulative Total	30	70	100	120	200	240	300

\*Shows the reserved manufacturing and production schedule to support earliest possible delivery of Doses to the Participating Member States. Final delivery subject to agreement of delivery schedule and regulatory approval. Payments for shipments of Doses shall be due and payable within thirty (30) days following invoicing for such Doses in accordance with Section 7.5 of the Agreement.

## **Schedule B – Participating Member States**

Republic of Austria (AT)  
Kingdom of Belgium (BE)  
Republic of Bulgaria (BG)  
Republic of Croatia (HR)  
Republic of Cyprus (CY)  
Czech Republic (CZ)  
Kingdom of Denmark (DK)  
Republic of Estonia (EE)  
Republic of Finland (FI)  
French Republic (FR)  
Federal Republic of Germany (DE)  
Hellenic Republic (EL)  
Hungary (HU)  
Ireland (IE)  
Italian Republic (IT)  
Republic of Latvia (LV)  
Republic of Lithuania (LT)  
Grand Duchy of Luxembourg (LU)  
Republic of Malta (MT)  
Kingdom of the Netherlands (NL)  
Republic of Poland (PL)  
Portuguese Republic (PT)  
Romania (RO)  
Republic of Slovakia (SK)  
Republic of Slovenia (SI)  
Kingdom of Spain (ES)  
Kingdom of Sweden (SE)