

DATED FEBRUARY 3, 2021

JANSSEN PHARMACEUTICA NV

-and-

GOVERNMENT OF COLOMBIA

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ADVANCE PURCHASE AGREEMENT  
FOR SARS-CoV-2 /COVID-19 VACCINE

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op. a.

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THIS AGREEMENT is made as of February 3, 2021

BETWEEN

1. JANSSEN PHARMACEUTICA NV, incorporated in Belgium with company number 0403834160 whose registered office is at 30 Turnhoutseweg, B-2340 Beerse ("Janssen"); and
2. THE GOVERNMENT OF COLOMBIA, represented by THE NATIONAL FUND FOR DISASTER RISK MANAGEMENT, trust of legal creation, identified with NIT. 900.978.341-9 which acts through FIDUCIARIA LA PREVISORA S.A. as spokesperson and administrator, in accordance with the provisions of article 48 of Law 1523 of 2012 and THE NATIONAL UNIT FOR DISASTER RISK MANAGEMENT who acts as Expenditure Authorizing Officer of the Subaccount for the Mitigation of Emergencies –Covid19- of the National Fund for Disaster Risk Management ("Government Purchaser"), together the "Parties" and each a "Party".

WHEREAS:

- A. The world is experiencing an emergency healthcare crisis from SARS-CoV-2/COVID-19.
- B. The Johnson & Johnson group of companies, to which Janssen belongs, is developing the Vaccine Candidate (as defined below) through its affiliated company Janssen Pharmaceuticals Inc., in response to the current SARS-CoV-2/COVID-19 pandemic, leveraging its proprietary AdVac® and high yielding manufacturing platforms, as well as its experience and capabilities from the development of its Ebola vaccine and investigational HIV, RSV and Zika vaccine candidates, with the aim of making available a safe and efficacious vaccine in 2021.
- C. In response to the current COVID-19 pandemic and in view of the medical urgency, Janssen, together with its Affiliates, is currently executing an accelerated clinical development plan for the Vaccine Candidate, initiating multiple large multi-country studies within highly compressed timelines, based on the outcomes of multiple pre-clinical studies and initial clinical studies performed world-wide.
- D. In parallel, and in an effort to ensure accelerated availability and deployment, Janssen, together with its Affiliates, is at risk expanding its internal and external global manufacturing network for the Vaccine Candidate, i.e. prior to the generation of the clinical data that is usually available before contemplating such further investment in a candidate, and in parallel to the development of the commercial scale, manufacturing process.
- E. Janssen is discussing with regulatory authorities around the world on, when and how Janssen could receive appropriate marketing approvals for the Vaccine Candidate.
- F. Prior to the Effective Date, Government Purchaser has enacted the NFC Law (as defined below). In addition, Government Purchaser is developing the NFC Regulation (as defined below) to ensure that the No Fault Compensation System complies with the minimum requirements set forth in Exhibit B of this Agreement, and such No Fault Compensation System shall be in full force and effect before Janssen makes Available any quantity of the Vaccine Volume under this Agreement.
- G. Government Purchaser and JANSSEN CILAG S.A., a Janssen Affiliate, agreed to the terms of a non-binding term sheet on December 30, 2020 setting forth the general terms and conditions upon which the Parties would attempt to negotiate this Agreement (the "Term Sheet").

H. Government Purchaser now wishes to enter into this Agreement to secure, in advance, the availability of the Vaccine Volume (as defined below) in accordance with the terms and conditions as set out in this Agreement. The Parties intention is that the terms of this Agreement apply to the Vaccine Volume only (and not to any purchase of any Further Vaccine Volume (as defined below) in excess of the Vaccine Volume or for use other than for the Purpose (as defined below), irrespective of the number of individuals who will ultimately be protected with the Vaccine Volume.

#### IT IS AGREED AS FOLLOWS:

#### 1. DEFINITIONS AND INTERPRETATION

##### 1.1 Definitions

"Adjudicated" shall mean a final determination by a court of competent jurisdiction for which the time for filing an appeal has expired and all appeals have been exhausted;

"Adjusted Price" has the meaning given to it in clause 3.2;

"Affiliate" means, with respect to Janssen, any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Janssen. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means:

- (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or
- (b) the ownership, directly or indirectly, of at least fifty per cent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity);

"Agreement" means this Advance Purchase Agreement (including its Annexes and Exhibits), as amended, supplemented, replaced or novated from time to time in accordance with its terms and conditions;

"Approval Long Stop Date" has the meaning given to it in clause 17.3;

"Arbitration Rules" has the meaning given to it in clause 22.2.1;

"Availability" means, with respect to any quantity of the Vaccine Volume, its presence at a Janssen central warehouse, quality released by Janssen, and prior to shipment and Delivery to Government Purchaser; and the terms "Available" and "made Available" (or any similar construct) shall be construed accordingly;

"Business Day" means any day other than a Saturday or Sunday or a day which is a public holiday in Bogota City;

"CDA" means the confidential disclosure agreements dated August 24, 2020 and November 9, 2020 between Government Purchaser and JANSSEN CILAG S.A., a Janssen Affiliate;

"Confidential Information" means any and all information, data, documents and materials (in any form and including all copies), regardless of the form or means of communication and whether such information is

labelled or otherwise identified as confidential, including customer, product, business, commercial, financial, technical, purchasing, specifications, know-how and other information (including analyses, compilations, studies, reports, interpretations, projections, forecasts and records), disclosed by one Party (or its Affiliates) to the other Party (or its Affiliates) before, on or after the Effective Date. For the purpose of this Agreement, Janssen's Confidential Information shall be deemed to include this Agreement as well as any information provided by or on behalf of Janssen or its Affiliates to Government Purchaser (or any ministry or other agency thereof) under or in connection with this Agreement, including such information that was disclosed in connection with the Term Sheet or pursuant to the CDA, and all information that is disclosed in connection with the Vaccine Candidate or COVID Vaccine;

"Cold Chain" means, in relation to the Vaccine Volume, the temperature-controlled storage and transport conditions in accordance with the Specifications as established in the Regulatory Approval;

"COVID Vaccine" means the final drug product form of the Vaccine Candidate, the substance of which has received Regulatory Approval;

"Delivery" means, in respect of any quantity of Vaccine Volume, delivery of that Vaccine Volume by Janssen to Government Purchaser in accordance with the requirements of clause 8, and the terms "Deliver" and "Delivered" shall be construed accordingly;

"Delivery Address" means International Airport of Bogota (El Dorado);

"Dispute" has the meaning given to it in clause 22.2.1;

"Down Payment" has the meaning given to it in clause 10.1;

"Effective Date" means the date mentioned at the beginning of this Agreement;

"Expected Approval Date" has the meaning given to it in clause 8.2.3;

"Failure to comply with cGMP" shall mean a failure of compliance with the cGMP rules directly causing death or serious physical injury or illness of a Vaccinated Individual;

"Final Availability Schedule" has the meaning given to it in clause 8.2.2;

"Further Vaccine Volume" has the meaning given to it in clause 2.2.1;

"Global Not-for-Profit Framework" has the meaning given to it in clause 3.2;

"cGMP" or "current Good Manufacturing Practices" means the current good manufacturing practices required by the standards, rules, principles and guidelines promulgated by (i) EU Directive 2001/83/EC (as amended by Directive 2004/27/EC), EU 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", (ii) the Food and Drug Administration under the United States Federal Food, Drug and Cosmetic Act, 21 C.F.R. § 210 et seq. or under the Public Health Service Act, Biological Products, 21 C.F.R. §§600-610) and (iii) WHO TRS 999 and TRS 961, relating to manufacturing practices for pharmaceutical products (including ingredients, testing, storage, handling, ingredients, seed lots, cell banks and intermediates, bulk and finished products), in each case as applicable to and at the time of manufacture of the COVID Vaccine;

"Good Distribution Practices" or "GDP" means current good distribution practices for medicinal products, as set forth in (i) the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use

(2013/C 343/01) and (ii) WHO TRS 957, Annex 5, WHO Good Distribution Practices for Pharmaceutical Products, in each case as applicable to and at the time of distribution of the COVID Vaccine;

**"Government Purchaser Authority"** means any national, regional, provincial, or territorial authority, state, canton, governmental community or entity, county, city, town, municipality, district, local government, or subnational component of Government Purchaser, including any department, ministry, agency, or other organizational unit thereof;

**"Intellectual Property Rights"** means patents, utility models, rights to inventions, copyright and neighboring and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

**"Janssen Material Breach"** means a failure by Janssen to make Available any quantity of Vaccine Volume by the date which falls one (1) year after the date set out for Availability of such quantity of Vaccine Volume in the Final Availability Schedule, despite all conditions set out in clause 4 being satisfied;

**"Law"** means all civil codes, statutes, legislation, regulations, rules, by laws, instruments, rules of common law, judgments, decrees or orders of any governmental, administrative, supervisory, regulatory or determinative authority, agency, court or other organisation of any jurisdiction, in each case which is established by, or having the authority of, law, and other measures or decisions having the force of law in any jurisdiction from time to time;

**"Losses"** has the meaning given to it in clause 16.1;

**"Material Breach"** means, (i) in the case of Janssen, a Janssen Material Breach or, (ii) in the case of Government Purchaser, any material breach by Government Purchaser of this Agreement (including any breach by Government Purchaser of its payment obligations under clause 10);

**"No Fault Compensation System"** means the no fault compensation system that provides compensation to individuals who have been vaccinated with the COVID Vaccine or Vaccine Candidate and who suffer serious physical injury or death caused by the COVID Vaccine or Vaccine Candidate, without the need to demonstrate a defect in the COVID Vaccine or Vaccine Candidate or any fault by a person, as:

- (i) enacted by the Government Purchaser under Law 2064, 2020 in effect on the date hereof (the "NFC Law"); and
- (ii) to be further complemented by way of a secondary regulation to be enacted as soon as possible after the Effective Date, and in any event prior to Delivery, to ensure that the No Fault Compensation System fully complies with the minimum requirements set forth in Exhibit B of this Agreement (the "NFC Regulation");

it being understood that the No Fault Compensation System, including the NFC Law and the NFC Regulation, must be in full force and effect before Janssen makes Available any quantity of the Vaccine Volume under this Agreement.



The No Fault Compensation System has been established and shall be maintained by Government Purchaser in accordance with the minimum requirements set forth in Exhibit B;

"Nonconforming COVID Vaccine" has the meaning given to it in Exhibit C;

"Price" has the meaning given to it in clause 3.1;

"Price Balance" has the meaning given to it in clause 10.2;

"Product Warranty" means the warranty given by Janssen to Government Purchaser under clause 8.7.1;

"Purpose" means use of the Vaccine Volume, directly by Government Purchaser or indirectly by a Third Party engaged by the Government Purchaser, in the Territory (and only in the Territory) to vaccinate individuals in the Territory against COVID-19 during the emergency pandemic response period, and prior to its applicable Vaccine Expiry Date;

"Regulatory Approval" means regulatory approval (emergency use or otherwise) for the legal marketing, importation, distribution, sale, administration and use of the Vaccine Candidate in the Territory granted or issued by the Regulatory Authority pursuant to Decree 1787, 2020 currently in effect in the Territory.

"Regulatory Authority" means the Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA, or any successor agency thereto, and its divisions;

"Residence" means the place of permanent home or principal establishment;

"Specifications" means the specifications and requirements for the COVID Vaccine as set out in the Regulatory Approval (as may be amended following the relevant regulatory processes and approvals by the Regulatory Authority under applicable Law from time to time);

"Tentative Availability Schedule" means the tentative availability schedule for the Vaccine Volume as set out in Exhibit A;

"Term Sheet" has the meaning given to it in Recital (G);

"Territory" means the Republic of Colombia including all of its local States and the City of Bogota;

"Third Party" means any person other than Government Purchaser, Janssen or Janssen's Affiliates, or the Government Purchaser Authorities;

"Vaccinated Individual" means any individual who has been administered the COVID Vaccine (or, as the case may be, any individual, group, entity or organization purporting to represent, act on behalf or, recover for or in respect of, or seek damages with respect to, any such individual or group of such individuals);

"Vaccine Expiry Date" means, with respect to any vial of the COVID Vaccine, the date on which the shelf life of such vial of COVID Vaccine ends;

"Vaccine Candidate" means Janssen's investigational SARS-CoV-2 vaccine, Ad26.COVS-2, recombinant;

"Vaccine Dose" means, with respect to the COVID Vaccine, one single injection of up to  $1 \times 10^{11}$  viral particles (one dose);

"Vaccine Volume" means a volume of nine (9) million Vaccine Doses;

"Willful Misconduct" shall mean an act or omission that is taken (i) with intentional disregard of a known risk in the manufacture of the COVID Vaccine that is so great as to make it highly probable that the harm will outweigh the benefit, (ii) without legal or factual justification, and (iii) with the intent of achieving a wrongful purpose (it being understood, however, that any action consistent with rules or guidance set out by Government Purchaser or any other government (be it state, provincial, municipal, local or regional) in the Territory, or any public agency, body or other public or regulatory authority in the Territory, and any action, test or results disclosed to a regulatory authority as a part of receiving regulatory approval for the COVID Vaccine in the Territory shall not be considered to be Willful Misconduct).

## 1.2 Interpretation

1.2.1 Unless the context otherwise requires, the following rules of interpretation shall apply to this Agreement:

- (a) words in the singular include the plural and, in the plural, include the singular;
- (b) use of any gender or neuter includes the other genders and neuter;
- (c) references to a particular statute or statutory provision or other Law shall:
  - (i) include all subordinate legislation made from time to time under that statute, statutory provision or other Law; and
  - (ii) be construed as a reference to such Law as amended, re-enacted, consolidated, supplemented, replaced or renumbered (or as its application or interpretation is changed or affected by other Laws) from time to time and as was, is, or will be (as the case may be) applicable at the time in question except that as between the Parties, no such amendment or modification shall apply for the purposes of this Agreement to the extent that it would impose any new or extended liability, obligation or restriction on, or otherwise adversely affect the rights of, any Party;
- (d) references to "clauses" and "Exhibits" are to clauses of, and exhibits to, this Agreement;
- (e) references to a "day" shall mean a period of twenty-four (24) hours running from midnight to midnight and reference to any time or date shall, save where otherwise expressly stated to the contrary, be a reference to the time or date (as the case may be) in Brussels, Belgium and references to a "month" or "year" shall respectively mean a calendar month and calendar year;
- (f) references to a "person" shall be construed so as to include:
  - (i) any individual, firm, body corporate, regulatory authority (including the Regulatory Authority), other governmental authorities, joint venture, association, undertaking, partnership or limited partnership (whether or not having separate legal personality); and
  - (ii) a reference to the estate, successors, permitted transferees and permitted assignees of any of such person;



- (g) any reference to a Party or the Parties is to a party or the parties (as the case may be) to this Agreement and shall include legal successors and/or any permitted assignees of a Party;
- (h) the words "include", "including" or "in particular" shall not limit the generality of any preceding words or be construed as being limited to the same class as any preceding words where a wider construction is possible;
- (i) the words "intends to" shall be construed as a right to do something (and shall not impose an obligation on a Party); and
- (j) references to "written" or "writing" shall include all data in written form in the English language, whether represented in hand-written, facsimile, printed, electronic or other format (including e-mail, but excluding short-message-service (SMS)) or other temporary electronic messages).

## 2. PURCHASE COMMITMENT

### 2.1 Firm Commitment

Government Purchaser shall advance purchase and pay for the Vaccine Volume in accordance with clause 10.

### 2.2 Further Purchases

2.2.1 Government Purchaser may, on written notice to Janssen, request to purchase additional quantities of the Vaccine Doses in excess of the Vaccine Volume. Within thirty (30) days of Janssen's receipt of such request, the Parties shall initiate discussions regarding such request and Janssen may, in its sole discretion, agree to make available additional quantities of the Vaccine Doses in excess of the Vaccine Volume (such additional quantities agreed to be made available, the "Further Vaccine Volume") at such times as may be agreed between the Parties. For clarity, nothing in this Agreement requires Janssen to agree to make available to Government Purchaser any Further Vaccine Volume or obliges Government Purchaser to order or purchase any Further Vaccine Volume.

2.2.2 Any orders for the Further Vaccine Volume, to the extent agreed by Janssen in its sole and absolute discretion, shall be subject to the execution of a separate purchase agreement and the terms and conditions set forth therein. Such Further Vaccine Volume, if agreed to be made available by Janssen, shall be made available at the price agreed between the Parties at that time (which may be higher than the Price set out in this Agreement for the Vaccine Volume). The terms of this Agreement apply to the Vaccine Volume only and, unless agreed otherwise by Janssen, shall not apply to any purchase of Further Vaccine Volume or for use other than for the Purpose.

## 3. PRICE

3.1 The price per single Vaccine Dose of the Vaccine Volume purchased hereunder shall be ten United States Dollars (\$ USD 10) ("Price"). Government Purchaser acknowledges that Janssen is willing to sell the Vaccine Volume at the Price in reliance on Government Purchaser's agreement that the Vaccine Volume shall be used solely for the Purpose.

- 3.2 The Parties acknowledge that Janssen is developing a framework for determining the global price for its Vaccine Dose, to strengthen its commitment to making its initial production allocation of the Vaccine Candidate in 2021 available on a not-for-profit basis. This framework will be subject to a review process by a third party audit firm (such framework, the "Global Not-for-Profit Framework"). Janssen shall review the Price in light of the Global Not-for-Profit Framework, and to the extent Janssen decides, in Janssen's sole discretion acting in good faith, that the Price is higher than the global price for the Vaccine Dose calculated in accordance with its Global Not-for-Profit Framework, Janssen shall notify Government Purchaser in writing thereof and the Price shall then be adjusted in accordance with the Global Not-for-Profit Framework (the "Adjusted Price"). To the extent Government Purchaser has already paid the Price for (any quantity of) the Vaccine Volume, Janssen shall (directly or indirectly through one of its Affiliates) refund the difference between the Price and the Adjusted Price (if any) to Government Purchaser for such Vaccine Volume as soon as reasonably practicable. If the Price is adjusted in accordance with this clause 3.2, references in this Agreement to the "Price" shall be deemed to be references to the "Adjusted Price".
- 3.3 The Parties agree that the Global Not-for-Profit Framework shall remain confidential and that Janssen is under no obligation to disclose to Government Purchaser the Global Not-for-Profit Framework, and nothing in this Agreement shall permit Government Purchaser to assess, audit, analyse, question, or otherwise have access to or evaluate, the Global Not-for-Profit Framework.
- 3.4 The Price shall be exclusive of any and all costs, duties, fees or other compensation in relation to the allocation, maintenance, distribution, storage, transport, administration and management of the Vaccine Volume following Delivery, and, for clarity, of VAT and other taxes (as further set out in clause 10.8). Government Purchaser shall be solely responsible for any and all costs in relation to the allocation, maintenance, distribution, storage, transport, administration, and management of the Vaccine Volume following Delivery and for payment of VAT and other taxes.
- 3.5 Government Purchaser acknowledges that the price payable for any Further Vaccine Volume or for COVID Vaccine that is for use other than for the Purpose, may be higher than the Price, and that the Global Not For Profit framework is expected to apply only to Janssen's initial production of the Vaccine Candidate in 2021, after which Janssen expects to transition to a commercial pricing framework for the COVID Vaccine.
4. CONDITIONS PRECEDENT FOR EXECUTION HEREOF AND DELIVERY OBLIGATIONS.
- 4.1 Government Purchaser represents to Janssen that:
- (a) prior to the Effective Date, it has enacted the NFC Law, and such NFC Law is in full force and effect as at the Effective Date; and
  - (b) it shall further complement the NFC Law by way of the NFC Regulation as soon as possible after the Effective Date and in any event prior to Delivery, to ensure that the No Fault Compensation System fully complies with the minimum requirements set forth in Exhibit B of this Agreement; and
  - (c) the Non Fault Compensation System (including the NFC Law and NFC Regulation) shall be in full force and effect prior to Delivery.

4.2 Janssen's Availability and Delivery obligations in respect of any quantity of the Vaccine Volume under this Agreement shall be subject to and conditional upon the satisfaction of the following cumulative conditions:

- (a) the Regulatory Authority having granted or issued the Regulatory Approval and such Regulatory Approval not having been subsequently withdrawn, suspended or discontinued;
- (b) Janssen having scaled up manufacture and expanded manufacturing capacity of the COVID Vaccine so that it is able to produce and make Available the Vaccine Volume, it being understood that (i) Janssen relies also on third party CMOs to achieve such effect, (ii) Janssen shall use commercially reasonable efforts to scale up and expand its manufacturing processes, and (iii) as at the Effective Date, Janssen has not yet scaled up and expanded its manufacturing processes at anticipated mass scale;
- (c) Janssen being able to export (finished or unfinished portions of) the Vaccine Volume from the applicable country or countries of production to the Territory and, without prejudice to clause 6.4, to import the Vaccine Volume into the Territory;
- (d) the No Fault Compensation System (i) being in full force and effect and remaining in place in accordance with the minimum requirements set forth in Exhibit B and (ii) being enforced and continuing to provide compensation to individuals who have been vaccinated with the COVID Vaccine or Vaccine Candidate and who suffer serious physical injury or death caused by the COVID Vaccine or Vaccine Candidate, without the need to demonstrate a defect in the COVID Vaccine or Vaccine Candidate or any fault by a person;
- (e) Government Purchaser having paid the Down Payment in accordance with clause 10.1 and having paid the applicable Price Balance in accordance with clause 10.4; and
- (f) Government Purchaser having complied with all of its other obligations under this Agreement to be satisfied prior to Delivery of any quantity of the Vaccine Volume.

## 5. VACCINE VOLUME

5.1 Subject to the terms and conditions of this Agreement, Janssen shall Deliver the Vaccine Volume to Government Purchaser.

5.2 Government Purchaser acknowledges and agrees that:

- (a) Janssen's expectation, as at the Effective Date, based on the current status of development of the Vaccine Candidate, is that to address the current pandemic, and depending on the results generated as part of the overall clinical development plan, each Vaccine Dose will consist of one (1) single injection of up to  $1 \times 10^{11}$  viral particles (one (1) dose);
- (b) the final total dosage and administration schedule of COVID Vaccine required to protect one (1) individual against SARS-CoV-2/COVID-19 has not been determined as of the Effective Date and, without prejudice to clause 5.2(c), shall be determined solely by Janssen based on data generated in ongoing clinical trials, the results of which will be generated and/or reported after the Effective Date; Janssen shall be entitled to

unilaterally adjust the definition of Vaccine Dose set out in this Agreement after the Effective Date based on data generated as part of the ongoing clinical trials;

- (c) Janssen provides no warranty that a Vaccine Dose will be sufficient to protect one (1) individual against COVID-19, or that the COVID Vaccine is safe or effective; and
- (d) this Agreement relates only to the Delivery of the Vaccine Volume to Government Purchaser and does not regard or provide any assurances on the number of individuals who can or will ultimately be protected with the Vaccine Volume.

5.3 Once Janssen has determined the final total dosage and administration schedule of the Vaccine Candidate, Janssen shall, as soon as reasonably practicable, inform Government Purchaser of such final total dosage and administration schedule. If, following such information, Government Purchaser desires to purchase Further Vaccine Volume in excess of the Vaccine Volume, the provisions of clause 2.2 shall apply.

## 6. COOPERATION

6.1 Government Purchaser shall assist Janssen, on Janssen's reasonable request, and shall work with the Regulatory Authority and such other governmental authorities to facilitate and expedite the review of all licenses, permits, authorizations, legislative or regulatory exemptions and activities, testing and subsequent releases in relation to the Vaccine Candidate and/or the COVID Vaccine in the Territory, including the Regulatory Approval.

6.2 Government Purchaser shall (i) enact the NFC Regulation as soon as possible after the Effective Date and in any event prior to Janssen making Available any quantity of the Vaccine Volume under this Agreement, (ii) maintain the No Fault Compensation System in full force and effect and in accordance with the minimum requirements set forth in Exhibit B to cover the Vaccine Volume purchased under this Agreement; (iii) adequately fund the No Fault Compensation System; and (iv) require individuals entitled to compensation thereunder to seek redress from the No Fault Compensation System.

6.3 For the avoidance of doubt, Government Purchaser understands and expressly agrees that if at any time after the Effective Date the No Fault Compensation System is cancelled, in any way diminished, limited or reduced in scope such that it no longer satisfies the minimum requirements set forth in Exhibit B, Janssen shall be immediately and automatically released from its obligations to make Available and Deliver any quantity of the Vaccine Volume under this Agreement.

6.4 Government Purchaser acknowledges that (i) Janssen's supply chain for the COVID Vaccine is global, (ii) Janssen will supply the Vaccine Doses from a variety of manufacturing sites and countries, and (iii) in order for Janssen to manufacture the COVID Vaccine at global scale and fulfil its obligations to all purchasers of the Vaccine Candidate and COVID Vaccine (including Government Purchaser), it is necessary that the Vaccine Candidate and COVID Vaccine, and any finished or unfinished portions thereof, including any related raw materials and components, are able to move freely across national borders. Government Purchaser shall permit Janssen and its Affiliates, or procure that Janssen and its Affiliates are permitted, to import into, export from, or otherwise move freely through, the Territory the Vaccine Candidate and COVID Vaccine, and any finished or unfinished portions thereof, including any related raw materials and components. For



clarity, Government Purchaser, shall not impose any embargoes, export or import restrictions, quota or other restrictions or prohibitions on the Vaccine Candidate or COVID Vaccine, and any finished or unfinished portions thereof, including any related raw materials and components, or fail to grant necessary licenses or consents for any such free movement.

6.5

## 7. ORDERS OF VACCINE VOLUME

This Agreement constitutes a binding order by Government Purchaser, and acceptance of such order by Janssen, for the purchase of the Vaccine Volume, such Vaccine Volume to be made Available and Delivered by Janssen in accordance with clause 8.

If and to the extent required by Janssen, Government Purchaser shall issue a purchase order (in the format as required by Janssen) to implement its binding order under this Agreement, it being understood that any such purchase order shall under no circumstances impact Government Purchaser's obligations under this Agreement.

## 8. DELIVERY OF VACCINE VOLUME

### 8.1 Conditionality of Janssen's Delivery Obligation.

Janssen agrees to make Available, for subsequent Delivery, the Vaccine Volume in accordance with the terms of this Agreement, subject to satisfaction of the conditions in clause 4.

### 8.2 Availability Schedule.

8.2.1 As at the Effective Date, Janssen tentatively expects that the Vaccine Volume shall be made Available for subsequent Delivery to Government Purchaser on the schedule and in the quantities as set out in the Tentative Availability Schedule.

8.2.2 After the Effective Date, Janssen intends to refine and, to the extent possible, update the Tentative Availability Schedule with the intention to provide Government Purchaser with a final availability schedule (the "Final Availability Schedule").

8.2.3 The schedule and quantities set out in the Tentative Availability Schedule are based on Janssen's current assumption that Regulatory Approval will be granted or issued on or prior to April 30, 2021 (the "Expected Approval Date"), and Government Purchaser acknowledges that if Regulatory Approval is not granted or issued by the Expected Approval Date, Janssen shall be entitled to adjust such schedule and quantities as Availability (and subsequent Delivery) will likely be delayed.

8.2.4 The schedule set out in the Tentative Availability Schedule reflects, and the schedule that will be set out in the Final Availability Schedule will reflect, the quarter in which the applicable quantity of Vaccine Volume shall be made Available (based on Janssen's standard requirements as to specifications, packaging, labelling, release testing and other matters (other than any such activities that are normally conducted within the Territory by Janssen or its Affiliates)). Government Purchaser acknowledges that:

- (a) such schedule does not necessarily reflect the schedule on which Vaccine Volume will be Delivered to it,
- (b) the exact dates of Delivery of Vaccine Volume will depend on various factors and requirements to be satisfied after Vaccine Volume has been quality released by Janssen, including requirements under local laws and regulations (such as local requirements for testing, evaluation and release by the Regulatory Authority, local testing and local release by competent authorities within the Territory, export and import restrictions, etc.) and shipping time from Janssen's distribution centres to the Delivery Address, and
- (c) accordingly, Janssen cannot provide any assurance or commitment to Government Purchaser as to the schedule and timing of Delivery of Vaccine Volume.

8.2.5 The grant or issuance of the Regulatory Approval earlier than the Expected Approval Date shall not require Janssen to make Available or Deliver any quantities of the Vaccine Volume ahead of the Tentative Availability Schedule or the Final Availability Schedule.

8.2.6 Janssen shall bear no liability if Availability cannot take place in accordance with the Tentative Availability Schedule or Final Availability Schedule and/or if Delivery cannot take place within the time periods expected by Government Purchaser, provided however that Janssen shall then use reasonable commercial efforts to make the applicable quantity of Vaccine Volume Available and/or to proceed with Delivery thereof at the earliest possible date thereafter.

### 8.3 Delivery.

8.3.1 The Vaccine Volume shall be Delivered by Janssen to Government Purchaser, and Government Purchaser shall accept Delivery of the Vaccine Volume, CIP (Incoterm 2020) to the Delivery Address. Government Purchaser acknowledges that Janssen will make multiple Deliveries over a period of time, in varying quantities, depending on Availability.

8.3.2 Title in the Vaccine Volume shall transfer to Government Purchaser upon Delivery in accordance with clause 8.3.1.

### 8.4 Form of Delivery.

8.4.1 Vaccine Volume will be Delivered in collector boxes, each box containing a certain quantity of primary packaged and labelled multi-dose vials without preservative(s), and each vial containing a certain quantity of Vaccine Doses. Janssen shall inform Government Purchaser in due course of any specificities of shipment packaging and of ordering of the Vaccine Volume.

8.4.2 Government Purchaser acknowledges that:

- (a) Janssen's current expectation is that, to address the current pandemic, regulatory authorities will require all Vaccine Doses comprised in a vial to be used within four (4) to six (6) hours after administration of the first dose of the vial (provided the Vaccine Doses are kept refrigerated in accordance with Specifications); and
- (b) given the current pandemic and the urgency of required Delivery of the Vaccine Volume:
  - (i) Janssen may not be able to Deliver the Vaccine Volume to Government Purchaser fully in accordance with the usual packaging and labelling

requirements for medicinal products approved for commercialization within the Territory. Government Purchaser shall accept Delivery of any Vaccine Volume in a generic packaged and labelled form suitable for usage in the Territory; and

- (ii) no paper leaflets will be Delivered, and Government Purchaser acknowledges and accepts that any information with respect to the COVID Vaccine will be provided via electronic leaflets.

#### 8.5 Import.

Government Purchaser is responsible for compliance with all applicable import requirements for its purchases under this Agreement.

#### 8.6 Non-conforming Vaccine Volume

- 8.6.1 If Government Purchaser alleges that any quantity of Vaccine Volume Delivered to it under this Agreement is Nonconforming COVID Vaccine, the provisions of Exhibit C shall apply, it being understood that under no circumstances shall the provisions of Exhibit C impact Janssen's indemnification rights under clause 16.

#### 8.7 Product Warranty

- 8.7.1 Janssen warrants that as at the time of Delivery pursuant to clause 8.3, Janssen has manufactured, filled, stored, packaged, labelled, released and Delivered the Vaccine Volume in compliance with cGMP applicable at the time of Delivery, to the extent that each standard of cGMP is or can be applicable, and taking into account any waiver, forbearance or exemption granted or allowed by Government Purchaser or any other applicable regulatory authority in the Territory.
- 8.7.2 In the event that Janssen is in breach of the Product Warranty with respect to (any quantity of) the Vaccine Volume, then, to the extent such Vaccine Volume has not been administered to individuals at the time such breach is identified, Janssen shall (directly or indirectly through one of its Affiliates), as soon as reasonably practicable, refund the Price for such Vaccine Volume to the extent already paid by Government Purchaser (it being understood, for the avoidance of doubt, that such refund shall then apply only with respect to such Vaccine Volume in respect of which a breach of the Product Warranty has been identified, which has not been administered to individuals, and which Government Purchaser confirms will not be so administered). Such refund shall be the only remedy available to Government Purchaser in respect of this clause 8.7.

#### 9. USE OF VACCINE VOLUME

- 9.1 Following Delivery in accordance with clause 8.3, Government Purchaser shall be solely responsible and liable for the subsequent inspection, allocation, maintenance, distribution, storage, transport, administration, and management of the Vaccine Volume, along with any related follow-on care, for the Purpose and in accordance with this Agreement and applicable Laws.
- 9.2 Government Purchaser acknowledges and agrees that, for any quantity of the Vaccine Volume it receives from Janssen under this Agreement, it shall establish and maintain a Cold Chain distribution channel in compliance with (i) Good Distribution Practices, (ii) Specifications and (iii) Janssen's reasonable instructions for storage and distribution thereof.

- 9.3 Janssen may audit Government Purchaser's distribution channels that are used for Vaccine Volume to determine whether such channels are in compliance with Cold Chain requirements, Good Distribution Practices, Specifications, and Janssen's reasonable instructions for storage and transportation of the Vaccine Volume. If Janssen discovers any non-compliance during such audit and informs Government Purchaser thereof, Government Purchaser shall cure such non-compliance within the cure period communicated by Janssen (acting reasonably). If by the end of such cure period such non-compliance is not cured, Janssen may (after prior consultation with Government Purchaser) take measures and actions it considers reasonably appropriate against Government Purchaser.
- 9.4 Government Purchaser further acknowledges and agrees that incoming inspection of Vaccine Volume shall be performed by it. At Government Purchaser's reasonable request, Janssen will use commercially reasonable efforts to provide such technical assistance as Government Purchaser may reasonably require to enable Government Purchaser to perform such incoming inspection.
- 9.5 Government Purchaser acknowledges and agrees that Janssen is selling the Vaccine Volume to Government Purchaser at the Price solely for use for the Purpose (and Government Purchaser agrees that it shall not use, nor permit the use of, the Vaccine Volume for any purpose other than the Purpose).
- 9.6 Government Purchaser shall:
- (a) not apply any mark-up or other price differentials to any resale price in the distribution of the Vaccine Volume. For clarity, nothing in this clause 9.6(a) shall prevent Government Purchaser from (i) seeking reimbursement from its customers of any additional transport and/or distribution costs it would have incurred in the distribution of the Vaccine Volume in the Territory, and (ii) applying any discounts in the distribution of the Vaccine Volume in the Territory (provided that such discounts are applied uniformly throughout the Territory);
  - (b) except for the Purpose, not re-sell, donate or otherwise distribute any Vaccine Volume to any Third Party (including with a view to vaccinate individuals outside of the Territory) without the prior written approval of Janssen;
  - (c) not use any quantity of the Vaccine Volume after the Vaccine Expiry Date; and
  - (d) in case Government Purchaser has any unadministered stock of the Vaccine Volume past the Vaccine Expiry Date, Government Purchaser shall promptly notify Janssen thereof and destroy such Vaccine Volume at its own cost and provide Janssen with a certificate of destruction;

## 10. FINANCIAL PROVISIONS

### 10.1 Down Payment.

Government Purchaser shall make a non-refundable down payment of \$ USD twenty two million five hundred thousand (United States Dollars 22,500,000) to Janssen ("Down Payment") within five (5) Business Days after the Effective Date, by wire transfer of immediately available funds on the following bank account of Janssen: IBAN: BE92320035555523, BIC: BBRU8EBBXXX.

### 10.2 Credit.





Janssen shall credit the Down Payment toward the price for the Vaccine Volume Delivered by Janssen to Government Purchaser at a rate of \$ USD 2.50 (United States Dollars two and fifty cents) per Vaccine Dose (such amount, the "Credit") and Government Purchaser shall be liable, for each Vaccine Dose, to pay the difference between the Price and the Credit (the "Price Balance") in accordance with clause 10.4.

**10.3 Refundability.**

The Down Payment shall not be refundable by Janssen to Government Purchaser in any circumstances, including, if the Vaccine Candidate does not receive Regulatory Approval, if development and/or manufacturing of the Vaccine Candidate is unsuccessful, or any other condition set out in clause 4 is not satisfied.

**10.4 Price Balance.**

Prior to Delivery of any quantity of the Vaccine Volume and as soon as any such quantity of the Vaccine Volume is Available, Janssen shall invoice Government Purchaser in accordance with clause 10.7 and Government Purchaser shall pay to Janssen the Price Balance for such quantity of Vaccine Volume prior to Delivery thereof, in accordance with the payment terms set out in Janssen's invoice.

**10.5 Payment Default.**

If Government Purchaser fails to pay (any portion of) the Down Payment or Price Balance (as applicable) for any quantity of the Vaccine Volume in accordance with this clause 10, Janssen may, refuse or delay any and all future Availability and Delivery of the Vaccine Volume, or, pursuant to clause 17.2, terminate this Agreement.

**10.6 Currency.**

**10.6.1** Any payments to be made by Government Purchaser under this Agreement shall be made, and any invoices issued pursuant to this Agreement shall be issued, in United States Dollars (\$ USD).

**10.6.2** The currency of payment –United States Dollars (\$ USD) - is a strict condition under this Agreement. Therefore, the Government Purchaser shall only fulfill its payment obligations hereunder by tendering to Janssen the United States Dollars (\$ USD) relevant amount and the Government Purchaser's obligations shall not be deemed discharged until Janssen receives the full amount of United States Dollars (\$ USD) owed by the Government Purchaser to Janssen, in freely available United States Dollars (\$ USD). The Government Purchaser assumes the risk of contracting in a foreign currency with no legal tender in the Territory and waives any right of conversion and the right to invoke any defense to avoid fulfilling its payment obligations in United States Dollars (\$ USD), including force majeure, unconscionability, impossibility or excessive onerosity defense.

**10.7 Invoice.**

As and when each quantity of the Vaccine Volume is made Available, Janssen shall issue a valid invoice for payment of the aggregate Price Balance in respect of such quantity pursuant to clause 10.4 to the Government Purchaser at the following address:

**THE NATIONAL RISK MANAGEMENT FUND**, Nit. 900.978.341-9, Subaccount for emergency mitigation COVID-19, Avenida Calle 26 No. 92 – 32, Piso 2, Edificio Gold 4, Bogotá – Colombia, Adriana Lucia Jiménez Rodríguez - Subaccount Manager COVID-19.

**10.8 Taxes.**

10.8.1 All amounts payable by Government Purchaser under this Agreement are exclusive of amounts in respect of value added tax chargeable from time to time ("VAT"), sales taxes and all other taxes, as well as customs and import fees and duties. Government Purchaser is responsible to pay all such taxes, customs and import fees and duties in addition to any payments for the Vaccine Volume under this Agreement as required by applicable Laws. To the extent Janssen has paid any customs and import fees and duties in relation to the import of the Vaccine Volume, Government Purchaser shall reimburse Janssen in respect of such costs. Where any taxable delivery for VAT purposes is made under this Agreement by Janssen, Government Purchaser shall, on receipt of a valid VAT invoice from Janssen, pay to Janssen or directly towards the relevant taxing authorities, in case required by applicable Laws, such additional amounts in respect of VAT as are chargeable on such delivery. Where a payment is to be made on account before the goods are Delivered, VAT shall become chargeable on receipt of the payment and on the amount received.

10.8.2 For the avoidance of doubt, where legally required, VAT may be charged on any quantity of the Vaccine Volume under the conditions of applicable Laws. In such cases, the taxable amount for each Vaccine Dose shall be the Price (including the respective portion of the Down Payment).

**10.9 Late payments.**

10.9.1 Without prejudice to Janssen's other remedies under this Agreement, if Government Purchaser fails to make a payment due to Janssen under this Agreement by the due date, then, Government Purchaser shall pay interest on the overdue sum from the due date until payment of the overdue sum, whether before or after judgment. Interest under this clause 10.9 shall accrue each day at four percent (4%) a year above the Bank of England's base rate from time to time, but at four percent (4%) a year for any period when that base rate is below zero percent (0%), or any lower figure otherwise required by applicable Laws.

**10.10 Set off.**

All amounts due under this Agreement from Government Purchaser to Janssen shall be paid in full without any set-off, counterclaim, deduction or withholding (other than any deduction or withholding of tax as required by applicable Laws). If any deductions or withholding of tax is required by applicable Laws to be made from any amounts due under this Agreement from Government Purchaser to Janssen, Government Purchaser shall pay to Janssen such sum as will, after the deduction or withholding has been made, leave Janssen with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

**11. REGULATORY APPROVAL**

11.1 Janssen intends to submit, either in its own name or through one of its Affiliates or subcontractors, an application for Regulatory Approval as soon as reasonably practicable after successful development of the Vaccine Candidate, having regard to the estimated time required to secure the Regulatory Approval in order to make the Vaccine Volume Available in accordance

with the Tentative Availability Schedule. If, in the process of reviewing the results or progress of its clinical trials with respect to the Vaccine Candidate, Janssen reasonably determines that the ongoing or planned clinical trials are likely to be insufficient for Regulatory Approval, Janssen shall inform Government Purchaser thereof and Janssen shall have no obligation to submit an application for Regulatory Approval of the Vaccine Candidate.

11.2 Government Purchaser shall cooperate with Janssen and share any relevant information to facilitate the grant or issuance of the Regulatory Approval.

## 12. PHARMACOVIGILANCE AND QUALITY

12.1 Government Purchaser shall inform Janssen of any Adverse Events Following Immunisation and Special Situations following use of the COVID Vaccine (together, if available, with the relevant lot/batch numbers of the relevant COVID Vaccine), within one (1) day of date of first receipt. Such information shall be sent to Janssen in accordance with the method of exchange below:

Address: 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4DP

Primary Fax: +44 1494 658 079 (High Wycombe)

Secondary Fax: +44 1494 658 273 (High Wycombe)

General Mailbox: (secure e-mail only): GMS\_AE\_Inbo@its.jnj.com

For the purposes of this clause 12.1:

"Adverse Events Following Immunisation" shall mean any untoward medical occurrence in a patient or a clinical-trial subject following immunisation, which does not necessarily have a causal relationship with usage of the COVID Vaccine. An Adverse Event Following Immunisation can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product; and

"Special Situations" shall mean any special situation, including reports of exposure during pregnancy or breastfeeding, overdose, abuse and misuse, medication errors, suspected transmission of any infectious agents, outside of label use, occupational exposure, inadvertent or accidental exposure, failure of expected pharmacological action, unexpected therapeutic or clinical benefit, expired drug use and falsified medicine.

12.2 The allocation of roles and responsibilities between Janssen and Government Purchaser set out in Exhibit D shall apply in relation to quality assurance matters in respect of the Vaccine Volume.

## 13. REPRESENTATIONS AND WARRANTIES

13.1 Each Party represents and warrants to the other Party that:

- (a) it has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and
- (b) this Agreement has been duly executed and delivered by it and constitutes a valid and legally binding obligation enforceable against it in accordance with the terms of this Agreement.

13.2 Government Purchaser warrants to Janssen that:

- (a) it has the right to order, purchase allocate, maintain, distribute, store, transport, administer, and manage the Vaccine Volume in accordance with any applicable Law, including the provisions of national procurement Laws; and
- (b) it is executing the Agreement on behalf of the government of Colombia in its entirety; and
- (c) by executing this Agreement on behalf of the government of Colombia in its entirety, such government is irrevocably and unconditionally bound by, and shall not challenge, the terms of this Agreement (including, without limitation, the provisions of clause 16 (*Indemnification*)) and this Agreement comprises a valid and legally binding obligation enforceable against such government in accordance with the terms of this Agreement.

13.3 Janssen warrants to Government Purchaser that:

- (a) as of the Effective Date, it is not under any contractual obligation to any Third Party in respect of the Vaccine Volume or that conflicts with or is inconsistent in any material respect with the terms of this Agreement; and
- (b) it shall comply with all Laws that are applicable to its activities and operations under this Agreement;

13.4 Except for the warranties set out in clauses 8.7, 13.1 and 13.3, Janssen disclaims all warranties, express or implied (whether by Law, custom or course of dealing), including the implied warranties of merchantability and fitness for a particular purpose, and any warranty relating to the sufficiency of a single Vaccine Dose to protect one (1) individual against SARS-CoV-2/COVID-19 or the safety or effectiveness of the COVID Vaccine.

#### 14. INTELLECTUAL PROPERTY

14.1 Nothing in this Agreement shall grant either Party any rights to the other Party's Intellectual Property Rights. Under no circumstances does Janssen grant to the Government Purchaser or to any Third Party, by transfer, implication, estoppel or otherwise, any right, title, license or interest in any Intellectual Property Rights it or any of its Affiliates owns or controls in relation to, in connection with or resulting from the Vaccine Candidate, the COVID Vaccine or the Vaccine Volume.

#### 15. CONFIDENTIALITY

15.1 Each Party (a "Receiving Party") shall keep confidential and not disclose to any Third Party, nor use other than for the purpose of exercising its rights and performing its obligations under this Agreement, any Confidential Information of the other Party (a "Disclosing Party").

15.2 The obligations of confidentiality in clause 15.1 shall not apply to any use or disclosure expressly authorised by the Disclosing Party in writing or any information, data or materials which:

- (a) is already lawfully possessed by the Receiving Party without any obligations of confidentiality or restrictions on use prior to receiving it from the Disclosing Party (whether before, on or after Effective Date), as documented by prior written records;

- (b) is already in, or comes into, the public domain otherwise than through the Receiving Party's unauthorised disclosure;
- (c) is obtained subsequently by the Receiving Party from a Third Party, which Third Party is not itself subject to any obligations of confidentiality; or
- (d) has been developed by the Receiving Party independently of any access to or use of any Confidential Information disclosed hereunder, as documented by the Receiving Party's written records.

15.3 The Receiving Party may only disclose Confidential Information to its employees, consultants, agents, officers, advisers and other representatives, and including in the case of Janssen, to its Affiliates and sub-contractors, on a need to know basis solely for the purpose of performing its obligations and exercising its rights under this Agreement, provided that the Receiving Party shall be responsible for actions and omissions of such employees, consultants, agents, officers, advisers, representatives, Affiliates or sub-contractors (as applicable), to whom Confidential Information is disclosed pursuant to this clause 15.3, and shall be liable as if such actions or omissions were of the Receiving Party. Notwithstanding the forgoing, Government Purchaser may only disclose Janssen's Confidential Information pursuant to this clause 15.3 to the government of any province or territory within the Territory, including any agency thereof after providing advance written notice to Janssen of its intention to disclose such Confidential Information, and (ii) to the extent such government of any province or territory within the Territory, including any agency thereof agrees in writing to comply with the confidentiality provisions set out in this Agreement (including, without limitation, clause 15.4 below).

15.4 The Receiving Party may disclose any part of the Confidential Information solely to the extent that it is legally required to do so pursuant to an order of a court or arbitral tribunal of competent jurisdiction or any applicable Law or, in the case of Janssen, a competent governmental authority, or the rules of any securities exchange to which Janssen or its Affiliates may be subject or under applicable securities Laws; provided that and subject to clause 15.56 the Receiving Party shall (a) unless prohibited by Law, promptly notify the Disclosing Party prior to making such disclosure and limit such disclosure and, if permitted, provide the Disclosing Party with an opportunity to intervene to protect its Confidential Information, including an opportunity to make representations to the relevant court, arbitral tribunal, or governmental authority (as applicable) objecting to disclosure, and (b) use reasonable efforts to obtain assurances that confidential treatment will be accorded to the Confidential information to be disclosed pursuant to this clause 15.4. Without prejudice to the generality of the foregoing, Government Purchaser acknowledges and agrees that Janssen's Confidential Information (a) constitutes commercial, financial, scientific and/or technical information supplied to Government Purchaser in confidence, and (b) is competitively sensitive and proprietary information of Janssen that, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Janssen and its Affiliates. Accordingly, Janssen reserves and relies upon all of its rights under any applicable freedom of information Laws, and Government Purchaser shall assist Janssen in protecting Janssen's Confidential Information and take all other reasonable steps to prevent disclosure of any such Confidential Information under such applicable Laws.

15.5 The obligations contained in this clause 15 shall continue for ten (10) years following the expiry or termination of this Agreement.

15.6 Neither Party shall issue any press release or make any other public statement disclosing the other Party's Confidential Information without the prior written consent of the other Party, provided that Janssen or its Affiliates may issue any press release or other public statement required under the rules of any securities exchange to which Janssen or its Affiliates may be subject or applicable securities Laws.

## 16. INDEMNIFICATION

16.1 Government Purchaser shall indemnify and hold harmless Janssen, its affiliates, sub-contractors and sub-licensees, all of its partners and third party contractors involved in or otherwise contracted for the design, research, development (including pre-clinical and clinical testing), manufacturing (including contract manufacturers), packaging and labelling (including warnings), procurement, storage, distribution and deployment of the COVID Vaccine, as well as its and their respective officers, directors, employees and other agents and representatives (together, the "Indemnified Persons") from any and all (i) losses, claims (including claims for personal injury or death), actions, liabilities, damages, judgments and awards, (ii) costs and expenses pertaining to or resulting from the defense, resolution (including settlement) or processing of any such losses, claims, actions, liabilities, damages, judgments or awards (including attorneys' and other professional advisors' fees and expenses (including taxation)), and (iii) procedural costs (including penalties, interest, fines and taxes on court ordered payments) ((i) to (iii) together, the "Losses") suffered or incurred by, or against, the Indemnified Persons in connection with any demands, claims, actions or proceedings of any kind:

a) involving, relating to, or arising out of or in connection with the COVID Vaccine (including, and regardless of whether the alleged cause of the damage originates from, the design, research, development, testing, manufacture, labelling, packaging, sale, procurement, delivery, deployment, distribution, storage, administration, effects and/or use of the COVID Vaccine); and

b) brought or initiated by or on behalf of:

- i. the Government Purchaser or any state, provincial, municipal, local or regional governments or competent public authorities within the Territory, or any of its or their respective agencies, departments, ministries, bodies, governments (local, regional or federal) or other public authorities of any kind; or
- ii. a Vaccinated Individual whose Residence is in the Territory (irrespective of the nationality, citizenship or country of origin or incorporation of such Vaccinated Individual); or
- iii. a Vaccinated Individual who has been administered the COVID Vaccine in the Territory (even if such Vaccinated Individual's Residence is not in the Territory); or
- iv. any other person in the courts of competent jurisdiction of the Territory, including within any state, province, municipality or locality thereof.



- 16.2 The indemnification right under clause 16.1 will not be available to the Indemnified Persons to the extent that their Losses result directly from the Adjudicated Wilful Misconduct or Adjudicated Failure to comply with cGMP of such Indemnified Persons.
- 16.3 If any person makes a claim or initiates a demand, claim, action or proceeding (or notifies in writing an intention to do so) against an Indemnified Person which, in the reasonable opinion of Janssen is considered likely to result in indemnification under clause 16. 1 above (a "Claim"), Janssen shall:
- (a) as soon as reasonably practicable, give written notice of the Claim to the Government Purchaser, specifying the nature of the Claim in reasonable detail (insofar as available), provided that the failure to promptly provide such notice shall not relieve the Government Purchaser of its indemnification obligations under clause 16.1; and
  - (b) in Janssen's sole discretion:
    - i. either take such actions as it may consider reasonable and appropriate to avoid, dispute, compromise or defend the Claim (with all related costs, fees and expenses, as well as Losses, to be paid by the Government Purchaser), provided that Janssen may settle the Claim only with the prior consent of the Government Purchaser (such consent not to be unreasonably withheld, conditioned or delayed); or
    - ii. require the Government Purchaser to assume (with its own counsel and at its own costs) sole control of the defence or settlement of the Claim and substitute, where possible under applicable Law, the Government Purchaser as the defendant; provided that in such case:
      - A) the Government Purchaser shall reasonably take into consideration the interests (commercial, corporate, reputational or other) of Janssen and shall not conclude any agreement or make any compromise or settlement with any person in relation to such Claim without the prior written consent of Janssen (such consent not to be unreasonably conditioned, withheld or delayed); and
      - B) Janssen shall have the right, but not the obligation, to participate in the defence or settlement of the Claim and to retain its own counsel in connection with such Claim; and
      - C) Janssen shall provide assistance and information reasonably required by the Government Purchaser in the defense of the Claim (at the expense of the Government Purchaser), provided that (a) any information reasonably considered by Janssen as confidential or proprietary information shall be provided by it only if and when satisfactory confidentiality arrangements are put in place, and (b) under no circumstances shall Janssen provide any information (including trade secrets) which it reasonably believes would cause material harm to it or other Indemnified Persons if disclosed.
- 16.4 Government Purchaser's obligation to indemnify the Indemnified Persons for Claims under clause 16.1 is not subject to a financial limitation or maximum, nor is it limited by the number of indemnifiable Claims brought against the Indemnified Persons.
- 16.5 It is the intention of the Government Purchaser to constitute Janssen as a trustee for and agent of the Indemnified Persons that are not party to this Agreement of the covenants of the Government Purchaser contained in clauses 16.1 to 16.4 above and Government Purchaser

agrees that Janssen may enforce the indemnity covenants of the Government Purchaser contained in clauses 16.1 to 16.4 above for and on behalf of each applicable Indemnified Person and, in such event, the Government Purchaser will not, in any proceeding to enforce the indemnity by or on behalf of the applicable Indemnified Persons, assert any defense thereto based on the absence of authority or consideration or privity of contract and irrevocably waives the benefit of any such defense.

16.6 The Parties acknowledge and agree that the provisions of clauses 16.1 to 16.5 are reasonable and necessary to protect the legitimate interest of the Indemnified Persons. However, if any provision in clauses 16.1 to 16.5 is held to be illegal, invalid or unenforceable, in whole or in part, under any applicable law, then such provision shall not be nullified but the Parties shall be deemed to have agreed to such provision that conforms with the limitations imposed by applicable law and that is as close as possible to the original intention of the Parties and has the same or as similar as possible economic effect, and such provision shall be automatically reformed accordingly.

## 17. TERM AND TERMINATION

17.1 Without prejudice to clause 18.4, this Agreement shall automatically expire at such time as Janssen shall have Delivered the Vaccine Volume and received payment in full of the aggregate Price for the Vaccine Volume by Government Purchaser.

17.2 Without prejudice to clause 18.4, either Party may terminate this Agreement with immediate effect on notice if at any time the other Party commits a Material Breach of this Agreement and fails to remedy that breach within ninety (90) days, or, in the case of a breach by Government Purchaser of its payment obligations under clause 10, fifteen (15) days, of that Party being notified in writing to do so.

17.3 Without prejudice to any other right under this Agreement and to clause 18.4, Janssen may terminate this Agreement with immediate effect on notice to Government Purchaser in the following circumstances:

- (a) if Janssen abandons its development program in respect of the Vaccine Candidate (including in case of inadequate safety profile); or
- (b) if Janssen has not been able to obtain Regulatory Approval by December 31, 2021 (the "Approval Long Stop Date"); or
- (c) in the circumstances set out in clause 19 (*Force Majeure*), where resuming implementation of the Agreement is considered impossible by Janssen (acting reasonably).

## 18. EFFECTS OF TERMINATION OR EXPIRY

18.1 On termination or expiry of this Agreement, each Party shall promptly:

- (a) return to the other Party all equipment, materials and property belonging to the other Party that the other Party had supplied to it in connection with the purchase of the Vaccine Volume under or in connection with this Agreement;
- (b) return to the other Party all documents and materials (and any copies) containing the other Party's Confidential Information;



- (c) subject to clause 18.1(b), erase all the other Party's Confidential Information from its computer systems (to the extent possible); and
- (d) on request, certify in writing to the other Party that it has complied with its obligations under this clause 18.1.

18.2 On termination of this Agreement, Janssen shall immediately be relieved from any outstanding obligations to make Available or Deliver the Vaccine Volume. Subject to the foregoing, termination or expiry of this Agreement shall not affect any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination or expiry, including the right to claim damages in respect of any breach of this Agreement which existed at or before the date of termination or expiry.

18.3 On termination of this Agreement, including where termination of this Agreement occurs pursuant to applicable Laws, but except where Government Purchaser terminates this Agreement in accordance with clause 17.2, Government Purchaser shall reimburse Janssen for all costs and expenses incurred or otherwise committed by Janssen in the performance of this Agreement, as of the date of such termination.

18.4 Clauses 1, 6.2, 6.4, 10 (to the extent any payment obligations are still outstanding), 12, 13, 14, 15 (for the period stated therein), 16, 18, 20, 21, and 22 shall survive the termination or expiry of this Agreement.

## 19. FORCE MAJEURE

If and to the extent that Janssen, its Affiliates or its or their respective sub-contractors are prevented from performing any or all of Janssen's obligations under this Agreement because of any cause which arises from or is attributable to acts of regulatory or governmental authorities or entities (including embargoes, export or import restrictions, quota or other restrictions or prohibitions, or failures to grant necessary licenses or consents) or acts, events, omissions or accidents beyond the reasonable control of Janssen, its Affiliates and/or its or their subcontractors, including strikes, lock-outs or other industrial disputes (whether involving the work force of Janssen and/or its Affiliates and/or sub-contractors, of Government Purchaser or of any Third Party), fire, storm, flood, earthquake or other acts of god or nature, disease (including SARS-CoV-2/COVID-19 or other pandemics), shortage of materials (including raw materials for the manufacture of the COVID Vaccine), unavailability of transport, default by suppliers, war, riot, civil commotion, malicious damage, any Law or direction issued by any judicial, arbitral, governmental, quasi-governmental or other competent institution (including the Regulatory Authority), or the inability of Janssen and/or its Affiliates to operate manufacturing or development activities due to lack of staff as a consequence of any of the foregoing, then Janssen shall be excused performance of its obligations to the extent and for the period required by such cause.

## 20. NOTICES

### 20.1 Method of service

A notice given under this Agreement by any Party to the other Party shall be in writing (which shall include e-mail), signed in manuscript by or on behalf of the Party giving it (which includes a scanned manuscript signature or, in the case of e-mail, that the message was sent from an e-mail address of the Party giving it (and which sender's e-mail address is one to which notices and other

communications may also be validly delivered to that Party under this clause 20.1), in the English language and may be either:

- (a) delivered personally by hand; or
- (b) if sent from within the same jurisdiction in which the recipient's address is located, then sent by first class pre-paid recorded delivery post or courier (or, if sent from outside the jurisdiction in which the recipient's address is located, then sent by international courier); or
- (c) sent by e-mail,

in each case addressed as follows:

For Janssen:

Address: 30 Turnhoutseweg, B-2340 Beerse

E-mail address: [jpeeter8@its.jnj.com](mailto:jpeeter8@its.jnj.com); [jkwik@its.jnj.com](mailto:jkwik@its.jnj.com); [fverhoev@its.jnj.com](mailto:fverhoev@its.jnj.com)

For the attention of: Managing Director

With a copy to Janssen-Cilag S.A.:

Address: AC 26 No. 69-76, Piso 11, Torre Fuego, Bogotá.

E-mail address: [mperezan@ITS.JNJ.com](mailto:mperezan@ITS.JNJ.com); [cforero1@its.jnj.com](mailto:cforero1@its.jnj.com)

For the attention of: Mario Francisco Perez Anzola, Managing Director

For Government Purchaser:

Address: **THE NATIONAL UNIT FOR DISASTER RISK MANAGEMENT**  
Avenida Calle 26 No. 92 – 32, Piso 2, Edificio Gold 4, Bogotá – Colombia.

E-mail address: [adriana.jimenez@gestiondelriesgo.gov.co](mailto:adriana.jimenez@gestiondelriesgo.gov.co)

For the attention of: Adriana Lucía Jiménez Rodríguez - Subaccount Manager COVID-19

With a copy to THE NATIONAL RISK MANAGEMENT FUND:

Address: Calle 72 No. 10 – 03 piso 5, Bogotá – Colombia.

E-mail address: [ssuancha@fiduprevisora.com.co](mailto:ssuancha@fiduprevisora.com.co)

For the attention of: Saul Hernando Suancha Talero

## 20.2 Deemed service

Without prejudice to any earlier time at which a notice may be actually given and received, a properly addressed notice will in any event:



- (a) if personally delivered, be deemed to have been given and received upon delivery at the relevant address;
- (b) if posted to an address in the same jurisdiction as that from which it was sent by first class pre-paid recorded delivery post or courier (which courier advises of delivery within two (2) Business Days), be deemed to have been given and received two (2) Business Days after the date of posting;
- (c) if sent to an address in a different jurisdiction as that from which it was sent by international courier (which courier advises of delivery within seven (7) Business Days), be deemed to have been given and received seven (7) Business Days after the date of posting; or
- (d) if sent by e-mail and no delivery failure is reported to or by the sender's e-mail server, be deemed to have been given and received on the date such e-mail was sent (or, if such day is not a Business Day, then the next Business Day).

### 20.3 Proof of service

In proving service, it shall be sufficient to prove that:

- (a) the envelope containing the notice was addressed to the address of the relevant Party as set out in clause 20.1 (or as otherwise notified by that Party pursuant to clause 20.5) and delivered either to that address or into the custody of the postal authorities as first class pre-paid recorded delivery post or custody of the courier, or international courier firm; or
- (b) the e-mail was correctly addressed and that no delivery failure was reported to or by the sender's e-mail server.

### 20.4 Receipt outside business hours

If receipt or deemed receipt of a notice occurs before 9.30 a.m. in the country of receipt on a Business Day, the notice shall be deemed to have been received at 9.30 a.m. (in the country of receipt) on that day. If deemed receipt occurs after 5.30 p.m. (in the country of receipt) on a Business Day or on a day which is not a Business Day, the notice shall be deemed to have been received at 9.30 a.m. (in the country of receipt) on the next Business Day.

### 20.5 Change of address

Any Party to this Agreement may give at least five (5) Business Days' notice to the other Party to change its address or other details specified in clause 20.1.

### 20.6 Service of proceedings

- 20.6.1 Clauses 20.1 to 20.5 do not apply to the service of any documents relating to any Disputes or where applicable, any arbitration or other method of dispute resolution. Notwithstanding this, and without prejudice to clause 20.6.2 below, in the event either Party commences an arbitration pursuant to clause 22.2 below, a copy of the Request for Arbitration and all accompanying documents shall be sent to the other Party in accordance with clause 20.1 above.

20.6.2 The Government Purchaser hereby appoints the Consulate General of Colombia in New York, at its address located at 10 E 46<sup>th</sup> St, New York, NY 10017, United States of America (the "Authorized Agent") upon whom process may be served in connection with any Dispute or where applicable, any arbitration or other method of dispute resolution or any action or proceeding to enforce or execute any award brought against it pursuant to clause 22.2. Such appointment shall be irrevocable. If for any reason, such Authorized Agent ceases to be able to act as Authorized Agent or to have an address in the Borough of Manhattan, The City of New York, the Government Purchaser will appoint another Person in the Borough of Manhattan, The City of New York, selected in its discretion, as such Authorized Agent. The Government Purchaser shall take any and all action including the filing of any and all documents and instruments that may be necessary to continue such appointment or appointments in full force and effect as aforesaid. Service of process upon the Authorized Agent at the address indicated above, as such address may be changed within the Borough of Manhattan, The City of New York, by notice given by the Authorized Agent, shall be deemed, in every respect, effective service of process upon the Government Purchaser.

## 21. MISCELLANEOUS

### 21.1 Assignment and other dealings

21.1.1 Other than with the written consent of Janssen, Government Purchaser may not assign, transfer, mortgage, charge, or otherwise grant any other person any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this Agreement.

21.1.2 Janssen may assign, transfer, mortgage, charge or grant to any of its Affiliates any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this Agreement.

21.1.3 Janssen may perform its obligations under this Agreement through any of its Affiliates, provided that Janssen remains bound by its contractual obligations and responsible for the implementation of this Agreement.

### 21.2 Entire agreement

21.2.1 This Agreement constitutes the whole agreement and understanding between the Parties relating to the subject matter of this Agreement and supersedes and extinguishes any previous agreement or arrangement between the Parties relating to the subject matter of it (including the CDA and Term Sheet entered into between the Parties and/or Janssen Affiliate) and excludes any representation, promise, assurance or other undertaking implied by Law, custom or course of dealing.

21.2.2 Nothing in this clause 21.2 shall limit or exclude any liability or remedy for fraud or wilful misconduct.

### 21.3 Language

This Agreement shall be executed in the English language. In the case of any translation of this Agreement, the English version of this Agreement shall prevail.

### 21.4 Variation

No amendment to or variation of this Agreement is effective unless it is in writing and signed by a duly authorized representative of each Party to this Agreement.

**21.5 Severance**

21.5.1 If any provision of this Agreement is held by any court or arbitral tribunal of competent jurisdiction to be invalid, unenforceable or illegal, in whole or in part, such provision shall apply with whatever deletion or modification is necessary so that the provision is valid, enforceable or legal and gives effect to the intention of the Parties.

21.5.2 To the extent it is not possible to delete or modify the provision, in whole or in part, under clause 21.5.1, then such provision or part of it shall, to the extent that it is illegal, invalid or unenforceable, be deemed not to form part of this Agreement and the legality, validity and enforceability of the remainder of this Agreement shall, subject to any deletion or modification made under this clause 21.5, not be affected.

**21.6 Counterparts**

This Agreement may be executed in any number of counterparts, each of which is deemed to be an original and which together have the same effect as if each Party had signed the same document. The Parties acknowledge and agree that this Agreement may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. "Electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature or signatures affixed via e-signing platforms (such as Adobe Sign or DocuSign).

**21.7 No agency, joint venture or partnership**

Nothing contained in this Agreement shall constitute or be deemed to constitute an association, joint venture or partnership between the Parties and neither Party shall be, or be construed to be, the agent of the other Party for any purpose or to have any authority to bind or incur any liability on behalf of the other Party, save as otherwise expressly provided in this Agreement.

**21.8 Waiver**

No failure to exercise, nor any delay in exercising, any right, power, privilege or remedy under this Agreement shall in any way impair or affect the exercise of such right, power or privilege or remedy, or operate as a waiver of such right, power or privilege or remedy in whole or in part. The waiver by any Party of any of its rights or remedies arising under this Agreement or by Law shall not constitute a continuation of that or any other right or remedy. No single or partial exercise of any right, power, privilege or remedy under this Agreement shall preclude or restrict the further exercise of that or any other right, power, privilege or remedy.

**21.9 Third party rights**

A person who is not a Party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.

**22. GOVERNING LAW, DISPUTE RESOLUTION AND WAIVER OF SOVEREIGN IMMUNITY**

**22.1 Governing law**

This Agreement (including the agreement to arbitration in clause 22.2 below) and all matters relating to or in connection with it shall be governed by, and construed in accordance with, the Laws of England and Wales, without regard to any conflicts of law principles. The Parties specifically disclaim the UN Convention on Contracts for the International Sale of Goods.

## 22.2 Dispute Resolution

22.2.1 In the event of any contractual or non-contractual dispute, controversy or claim arising out of or in connection with this Agreement (including any question regarding its existence, validity or termination) (a "Dispute"), the Dispute shall be referred to and finally resolved by arbitration under the LCIA Arbitration Rules (the "Arbitration Rules"), which Arbitration Rules are deemed to be incorporated by reference into this clause. The number of arbitrators shall be three. Each Party shall nominate in the Request and the Response (both terms as defined in the Arbitration Rules), respectively, one co-arbitrator for appointment by the LCIA Court. If a Party fails to nominate a co-arbitrator in the Request or the Response, the selection and appointment of the co-arbitrator shall be made by the LCIA Court. The presiding arbitrator shall be jointly nominated by the two co-arbitrators for appointment by the LCIA Court. If the two co-arbitrators fail to reach agreement regarding a nomination within thirty (30) days of their appointment by the Court, the selection and appointment of the presiding arbitrator shall be made by the LCIA Court. The seat, or legal place, of arbitration shall be New York, New York, United States of America. The language to be used in the arbitral proceedings shall be English.

22.2.2 Judgment upon the award may be entered by any court of competent jurisdiction.

## 22.3 Waiver of sovereign immunity


Government Purchaser hereby expressly, unconditionally, and irrevocably waives, to the extent possible, in respect of itself and its assets, any right of immunity under the laws of any jurisdiction on the grounds of sovereignty or otherwise which may now or hereafter exist, whether immunity from service, from any legal or arbitral process, from jurisdiction of any court or arbitral tribunal, from attachment prior to judgment, in aid of execution or execution, or claim thereto, which may now or thereafter exist, and agrees not to assert any such right or claim in any legal or arbitral action or proceeding, whether in the United States or otherwise. This waiver includes but is in no way limited to waiving any right of sovereign immunity as to the Government Purchaser and any of its property, regardless of the commercial or non-commercial nature of this property, including any bank account belonging to the Government Purchaser (whether held in the name of a diplomatic mission or otherwise) or bank accounts, belonging to the Government Purchaser's central bank or other monetary authority. For the avoidance of doubt, the irrevocable waiver in this clause 22.3 includes a waiver of any right of sovereign immunity in respect of pre-judgment interim relief and post-judgment execution of any arbitral award, wherever such relief or execution is sought. Without limiting the generality of the foregoing, Government Purchaser agrees that the waiver set forth in this clause 22.3 shall be to the fullest extent permitted under the United States Foreign Sovereign Immunities Act and is intended to be irrevocable for purposes of such Act.

SIGNATURE PAGE TO ADVANCE PURCHASE AGREEMENT

This Agreement has been entered into on the date stated at the beginning of it.

EXECUTED by JANSSEN

acting by its duly authorised officer



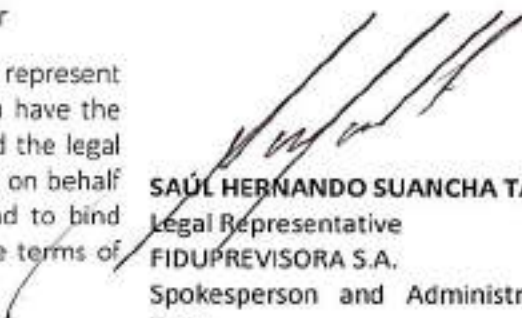
Role) MANAGING DIRECTOR  
FEB. 3, 2021  
MARIO PÉREZ A.

Name

EXECUTED by GOVERNMENT PURCHASER

acting by its duly authorised officer

By signing this Signature Page you represent and warrant to JANSSEN that you have the requisite power and authority and the legal right to enter into this Agreement on behalf of GOVERNMENT PURCHASER and to bind GOVERNMENT PURCHASER to the terms of this Agreement.



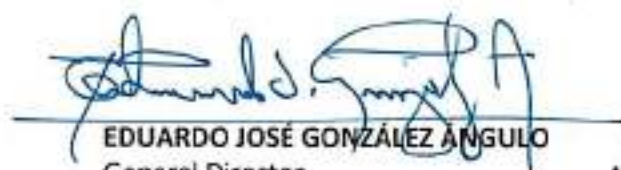
SAÚL HERNANDO SUANCHA TALERO

Legal Representative

FIDUPREVISORA S.A.

Spokesperson and Administrator of the Trust

NATIONAL FUND FOR DISASTER RISK MANAGEMENT



EDUARDO JOSÉ GONZÁLEZ ANGULO

General Director

THE NATIONAL UNIT FOR DISASTER RISK MANAGEMENT

Expense Officer FNCRD

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EXHIBIT A

TENTATIVE AVAILABILITY SCHEDULE

Based on assumptions as at the Effective Date (certain of which are outlined below), after Regulatory Approval and subject to the conditions of the Agreement, Janssen tentatively expects to be able to make Available to Government Purchaser allocations of the Vaccine Volume as follows.

The Parties acknowledge that actual Availability of the Vaccine Volume may differ from what is currently expected, as described on this Exhibit A, and Janssen may, in its sole discretion, amend the timelines and volumes set out in the table below.


<i>Expected Calendar Quarter(s) of Availability</i>	<i>Vaccine Volume per Quarter</i>	<i>Vaccine Volume Cumulative</i>
3Q 2021	3.2 million	3.2 Million
4Q 2021	5.8 million	9 Million

Notes and Assumptions:

- Commencement of Availability (and subsequent Delivery) of Vaccine Volume is dependent on Regulatory Approval as well as on the local quality release of Vaccine Volume by local competent authorities, and is based on current expectation as to timing of regulatory approvals globally and process and timing for local quality release of Vaccine Volume by local competent authorities. Should certain jurisdictions obtain regulatory approval prior to or later than the current assumption or should the current expectations regarding process and timing for local quality release of Vaccine Volume by local competent authorities prove to be incorrect, the foregoing allocation may be changed by Janssen.
- The foregoing assumes that all contemplated Janssen manufacturing capacity produces at expected volumes and that the jurisdictions of production allow free export of the Vaccine Volume. Should one or more facilities (or portions thereof) fail to come online as expected or should there be any issues with export or transport, this allocation may be changed by Janssen.
- The timing reflected in the above table assumes that the Vaccine Volume will be released for sale based solely on Janssen's standard requirements. If importation or sale of the Vaccine Volume is subject to local release testing or other requirements that are in addition to Janssen's standard requirements, Delivery of the Vaccine Volume may take longer than the Availability schedule set forth above.
- Final dose and administration schedule will be determined in ongoing clinical studies. If concentration and/or dosing and/or administration schedule change, this allocation may be changed by Janssen.

This exhibit has been entered into on the date stated at the beginning of this Agreement.

EXECUTED by JANSSEN  
acting by its duly authorised officer




[Role] MANAGING DIRECTOR  
FEB 3, 2021  
MARIO PERET A.

Name

EXECUTED by GOVERNMENT PURCHASER

acting by its duly authorised officer

By signing this Signature Page, you represent and warrant to JANSSEN that you have the requisite power and authority and the legal right to enter into this Agreement and Exhibits on behalf of GOVERNMENT PURCHASER and to bind GOVERNMENT PURCHASER to the terms of this Agreement and Exhibits.



**SAUL HERNANDO SUANCHA TALERO**  
Legal Representative  
FIDUPREVISORA S.A.  
Spokesperson and Administrator of the Trust  
NATIONAL FUND FOR DISASTER RISK  
MANAGEMENT



**EDUARDO JOSÉ GONZÁLEZ ANGULO**  
General Director  
THE NATIONAL UNIT FOR DISASTER RISK  
MANAGEMENT  
Expense Officer FNGRD

EXHIBIT B

No Fault Compensation System

The Government Purchaser has established and shall maintain the No Fault Compensation System in accordance with the following minimum requirements:

<b>1 No-Fault Compensation System (also referred to in this Exhibit B as the "System"):</b>
a. Victims should only be required to demonstrate a causal link between the vaccine and the relevant damages, without the need to prove negligence, fault or product defect.
b. Victims should be required to demonstrate causation by a preponderance of the evidence (or a similar evidentiary standard).
<b>2 Administrative structure</b>
a. System should be administered by a public administrative body.
b. System should include an adequate public funding mechanism but additional financing sources can be added.
<b>3 Governance structure</b>
a. Administrative bodies should include representation from diverse stakeholders.
b. Decision making panels should be composed of experts with clearly defined requirements (medical, legal).
<b>4 Covered vaccines</b>
a. Systems should cover injuries resulting from Covid-19 vaccines. Systems may cover injuries from other classes of vaccines as well, but the funding needs to be separate for Covid-19 vaccines.
b. Applicants can be anyone who has been administered a Covid-19 vaccine in the Territory.
<b>5 Covered damages</b>




a. System should cover a reasonably broad class of damages, including death, injury, disability, pain and suffering, and other forms of economic and noneconomic loss resulting from the injury.
b. Minor injury and resulting damages should not be covered.
<b>6 Compensation</b>
a. The level of compensation offered by the System, as supplemented by other governmental arrangements (e.g., social security programs), should be sufficient to provide long-term relief to victims.
b. Compensation could be tariff-based, consistent with the level of compensation as per 6a.
<b>7 Accessible and Efficient Procedures</b>
a. System should use simple and easily available intake forms.
b. Bringing claims should not require legal assistance
c. Bringing claims should be free of charge.
d. The review and decision-making process should be well-defined and easily understood by victims.
e. System should have reasonably efficient timelines for processing claims and rendering decisions.
f. System should allow victims to appeal decisions within the compensation system and finally through a court system (adequate legal remedies), with such appeal being directed against the compensation system (not against the manufacturer or any other party).
g. The Government Purchaser should implement strategies to ensure broad public awareness of their compensation system.
h. System need to be properly resourced (personnel, funding, organization) and have the proper infrastructure, in particular IT, to handle the case load.



<b>8 Transparency</b>
a. System should include formal, well-defined transparency measures, such as mandatory annual reports and/or requirements to regularly provide public access to system information (e.g., claims received, claims excepted, and compensation amounts).

This exhibit has been entered into on the date stated at the beginning of this Agreement.


EXECUTED by JANSSEN  
acting by its duly authorised officer

  
 [Role] MANAGING DIRECTOR  
 FEB. 3, 2021  
 MARIO PÉREZ A.

Name

EXECUTED by GOVERNMENT PURCHASER  
acting by its duly authorised officer

By signing this Signature Page, you represent and warrant to JANSSEN that you have the requisite power and authority and the legal right to enter into this Agreement and Exhibits on behalf of GOVERNMENT PURCHASER and to bind GOVERNMENT PURCHASER to the terms of this Agreement and Exhibits.

  
**SAÚL HERNANDO SUANCHA TALERO**  
 Legal Representative  
 FIDUPREVISORA S.A.  
 Spokesperson and Administrator of the Trust  
 NATIONAL FUND FOR DISASTER RISK MANAGEMENT

  
 C. EDUARDO JOSÉ GONZÁLEZ ÁNGULO



General Director  
THE NATIONAL UNIT FOR DISASTER RISK  
MANAGEMENT  
Expense Officer FNGRD



## EXHIBIT C

### Non-conforming Vaccine Volume

**Section 1.01. Defective COVID Vaccine.** All COVID Vaccine Delivered to Government Purchaser under this Agreement may be inspected by Government Purchaser by means of (i) a customary visual inspection of the shipment (without opening secondary packaging) and (ii) by consulting the certificate of analysis accompanying such COVID Vaccine. If any of such inspections referenced above under (i) and (ii) reveal that any COVID Vaccine Delivered to Government Purchaser does not meet the Specifications (any such COVID Vaccine, the "Nonconforming COVID Vaccine"), Government Purchaser may reject such Nonconforming COVID Vaccine by delivering a written notice (a "Rejection Notice") to Janssen describing, in reasonable detail, the alleged nonconformity and, if requested by Janssen, providing sample(s) of the alleged Nonconforming COVID Vaccine. If Government Purchaser does not deliver a Rejection Notice within (a) in the case of a visible defect, five (5) Business Days after Delivery of such COVID Vaccine or (b) in the case of a defect not detectable through initial customary visual inspection, within ten (10) Business Days after the date Government Purchaser discovered or should have reasonably discovered such nonconformity, the received COVID Vaccine shall be deemed to be in compliance with the Specifications and accepted by Government Purchaser.

**Section 1.02. Janssen's Right to Verify Nonconforming COVID Vaccine.** Following receipt of a Rejection Notice pursuant Section 1.01 above, Janssen will have ten (10) Business Days to inspect the Nonconforming COVID Vaccine and make a reasonable assessment of the alleged nonconformance, provided that Government Purchaser has provided Janssen appropriate sample(s) of the Nonconforming COVID Vaccine or such other reasonably available evidence Janssen may reasonably specify. If Janssen agrees that any Delivery contains Nonconforming COVID Vaccine and that such non-conformance was caused by Janssen or any of Janssen's suppliers or subcontractors, Janssen shall either (i) replace such Nonconforming COVID Vaccine as soon as commercially practicable at no additional charge to Government Purchaser or (ii) refund Government Purchaser the applicable Price paid by Government Purchaser to Janssen for the Nonconforming COVID Vaccine. Any such replacement and reimbursement to which Janssen is obliged in accordance with the foregoing shall constitute Janssen's sole and exclusive liability for such Nonconforming COVID Vaccine and Government Purchaser waives any and all other remedies it may be entitled to under applicable Laws.

**Section 1.03. Disagreements Regarding Nonconforming COVID Vaccine.**

(a) **Independent Third Party Laboratory.** If Janssen disagrees with Government Purchaser's determination that certain COVID Vaccine Delivered is a Nonconforming COVID Vaccine, then Janssen shall promptly notify Government Purchaser thereof and, if the Parties are unable to resolve such disagreement within a five (5) Business Days period after delivery of such notice and Government Purchaser still alleges that such COVID Vaccine Delivered, as applicable, is Nonconforming COVID Vaccine, then sample(s) of such COVID Vaccine Delivered shall be submitted for testing to a qualified independent Third Party laboratory mutually agreed to by Janssen and Government Purchaser ("Third Party Lab"), for analytical testing to verify the COVID Vaccine Delivered conformance to the Specifications.

(b) **Resolution Process.** The determination of such Third Party Lab with respect to all or part of such COVID Vaccine Delivered being a Nonconforming COVID Vaccine or not, shall be final and binding on the Parties, absent manifest error. All costs, fees and expenses of the Third Party Lab testing, as well as any freight and disposition costs of COVID Vaccine and samples sent to the Third Party Lab, and related dispute resolution costs (collectively, "Third Party Lab Fees"), shall be paid as follows:

(i) In the event the Third Party Lab determines the COVID Vaccine Delivered not to be Nonconforming COVID Vaccine, (a) all Third Party Lab Fees shall be paid by Government Purchaser and (b) Government Purchaser shall accept the applicable Delivery of and, if it has not already done so, pay the applicable Price for such COVID Vaccine, as applicable.

(ii) In the event the Third Party Lab determines the COVID Vaccine Delivered to be Nonconforming COVID Vaccine and such laboratory determines that such non-conformance was caused by Janssen prior to the Delivery of the relevant COVID Vaccine to Government Purchaser, (a) all Third Party Lab Fees shall be paid by Janssen and (b) Janssen shall, at Janssen's election, either replace such Nonconforming COVID Vaccine as soon as commercially practicable at no additional charge to Government Purchaser or refund Government Purchaser the applicable Price paid by Government Purchaser to Janssen for the Nonconforming COVID Vaccine.

(iii) In the event (i) the Third Party Lab cannot determine if the COVID Vaccine Delivered is a Nonconforming COVID Vaccine, or (ii) the COVID Vaccine Delivered is a Nonconforming COVID Vaccine, but the Third Party Lab cannot determine the cause of such non-conformance; (a) all such Third Party Lab Fees shall be equally borne by the Parties and (b) Government Purchaser shall accept the Delivery of and, if it has not already done so, pay the Price for such COVID Vaccine, as applicable.

(iv) In the event the Third Party Lab determines (i) the COVID Vaccine Delivered to be Nonconforming COVID Vaccine and (ii) such non-conformance was caused by (a) Government Purchaser or any of Government Purchaser's contractors, or (b) improper handling after the Delivery, then (x) all Third Party Lab Fees shall be borne by Government Purchaser and (y) Government Purchaser shall accept the Delivery of and, if it has not already done so, pay the Price for such COVID Vaccine, as applicable.

**Section 1.04. Handling of Rejected COVID Vaccine.** Government Purchaser shall not destroy, and shall be required to keep and store in accordance with cGMP and GDP, any allegedly Nonconforming COVID Vaccine until (i) it receives written notification from Janssen that Janssen does not dispute that the COVID Vaccine Delivered is Nonconforming COVID Vaccine; (ii) following completion of the resolution process set forth in Section 1.03(b), where such COVID Vaccine Delivered is determined by the Third Party Lab to be Nonconforming COVID Vaccine and (A) it receives written notification from Janssen that Janssen does not desire return of such Nonconforming COVID Vaccine, (B) it receives written authorization from Janssen to destroy such Nonconforming COVID Vaccine, or (C) it receives no notice, authorization or other instruction from Janssen regarding such Nonconforming COVID Vaccine within ten (10) Business Days following such completion of the resolution process pursuant to Section 1.03(b); or (iii) following completion of the resolution process set forth in Section 1.03(b), where the COVID Vaccine Delivered is determined by the Third Party Lab not to be Nonconforming COVID Vaccine, it elects to do so in its sole discretion. Upon the occurrence of any of the foregoing events under (i) through (iii), Government Purchaser shall destroy or have destroyed such Nonconforming COVID Vaccine promptly and provide Janssen with certification of such destruction. The expense of such destruction shall be borne (1) by Janssen in the event that Janssen does not dispute that the COVID Vaccine is Nonconforming COVID Vaccine or (2) in the event the Parties resort to the resolution process, by the Party responsible to pay for the Third Party Lab Fees as described in Section 1.03(b).

**Section 1.05. Recalls.**





(a) In the event of an actual or threatened Recall of COVID Vaccine required or recommended by a Regulatory Authority within the Territory, or if a Recall of COVID Vaccine is reasonably deemed advisable by Government Purchaser, or jointly deemed advisable by Janssen and Government Purchaser due to the COVID Vaccine that is the subject of such Recall being determined to be a Nonconforming COVID Vaccine pursuant Sections 1.01 to 1.03 above, such Recall shall be promptly implemented and administered by Government Purchaser in a manner which is appropriate and reasonable under the circumstances and in conformity with applicable regulatory requirements (accepted trade practices). Janssen shall assist Government Purchaser as requested by Government Purchaser to ensure a timely, accurate and complete Recall. The aggregate out-of-pocket expenses of such Recall shall be borne by (i) Government Purchaser where its acts or omissions resulted in the need for the Recall; or (ii) Janssen where its acts or omissions resulted in the need for the Recall, or (iii) equally by both Parties where each Party's acts or omissions resulted in the need for the Recall.

(b) Janssen and Government Purchaser shall keep each other fully and promptly informed of any notification, event or other information, whether received directly or indirectly, which might reasonably affect the marketability, safety or effectiveness of COVID Vaccine or might reasonably result in a Recall of COVID Vaccine by a Regulatory Authority.


(c) In the event of any Recall, other than to the extent caused by Government Purchaser's, Government Purchaser Third Party's or Government Purchaser customers' handling of the COVID Vaccine following the Delivery thereof, Janssen shall, at the election of Janssen, either (i) replace such Nonconforming COVID Vaccine subject to the Recall as soon as commercially practicable at no additional charge to Government Purchaser or (ii) refund Government Purchaser the applicable Price paid by Government Purchaser to Janssen for the Nonconforming COVID Vaccine subject to a Recall.

(d) Notwithstanding the final sentence of Section 1.05(a), in the event of any Recall caused by Government Purchaser's, Government Purchaser Third Party's or Government Purchaser customers' handling of the COVID Vaccines following the Delivery thereof, Government Purchaser shall pay Janssen's reasonable out-of-pocket expenses incurred in connection with such Recall in accordance with this Section.

For the purpose of this Section 1.05, "Recall" means a recall, correction or market withdrawal relating to COVID Vaccine and shall include any post-sale warning or mailing of information.

This exhibit has been entered into on the date stated at the beginning of this Agreement.

EXECUTED by JANSSEN  
acting by its duly authorised officer

  
[role] MANAGING DIRECTOR  
FEB 3, 2021  
MARIÓ PÉREZ A.




Name

EXECUTED by GOVERNMENT PURCHASER

acting by its duly authorised officer

By signing this Signature Page, you represent and warrant to JANSSEN that you have the requisite power and authority and the legal right to enter into this Agreement and Exhibits on behalf of GOVERNMENT PURCHASER and to bind GOVERNMENT PURCHASER to the terms of this Agreement and Exhibits.



**SAUL HERNANDO SUANCHA TALERO**

Legal Representative

FIDUPREVISORA S.A.

Spokesperson and Administrator of the Trust

NATIONAL FUND FOR DISASTER RISK MANAGEMENT



**EDUARDO JOSÉ GONZÁLEZ ÁNGULO**

General Director

THE NATIONAL UNIT FOR DISASTER RISK MANAGEMENT

Expense Officer FNGRD

EXHIBIT D

Quality Requirements

The table below defines the roles and responsibilities between Janssen and Government Purchaser (for the purpose of this Exhibit D, the "GP") with respect to compliance with applicable quality assurance requirements in respect of the Vaccine Volume and the COVID Vaccine.


1. Notification	Janssen	GP
Promptly notify Janssen about any regulatory inspections related to COVID Vaccine, while under its control, including observations and actions taken to mitigate those observations.		X
Promptly communicate any untoward incident that occurs after Delivery and while COVID Vaccine is under its control and that impacts COVID Vaccine safety, quality or compliance.		X
Notify Janssen of any instance of suspected counterfeit, tampered or diverted COVID Vaccine within 24h of awareness		X
2. Permits & Regulatory Requirements	Janssen	GP
Have and maintain or ensure that its contractors have and maintain all necessary licenses, regulatory approvals and certificates required by competent authorities to perform all activities under its control with the COVID Vaccine up until Delivery.	X	
Comply and ensure that its contractors comply with all laws, regulations and policies applicable to the activities performed under its control with COVID Vaccine up until Delivery, including Good Distribution Practices and cGMP	X	
Have and maintain or ensure that its contractors have and maintain all necessary licenses, regulatory approvals and certificates required by competent authorities to perform all activities under its control with the COVID Vaccine after Delivery, including but not limited to the receipt, storage, distribution, transport and handling thereof.		X
Comply and ensure that its contractors comply with all laws, regulations and policies applicable to the activities performed under its control with COVID Vaccine after Delivery, including Good Distribution Practices and cGMP		X
Ensure distribution of the COVID Vaccine from Delivery only to entities that have the required licenses, regulatory approvals and certificates as applicable.		X

Unless otherwise authorized by Janssen, ensure that from Delivery up until administration the COVID Vaccine remains in the same form of primary and/or secondary packages as originally Delivered by Janssen without altering the product, nor remove, deface, tamper the primary and/or secondary packages of the COVID Vaccine or affix any logo or words to the product or their primary and/or secondary packages that overwrite or destroy the product lot traceability and product information.		X
Do not sell, trade or donate any expired COVID Vaccine to anyone. Expired COVID Vaccine are not to be used as sales samples		X
<b>3. Facilities and Equipment</b>	Janssen	GP
Ensure sufficient space, suitable and adequate premises, installations and equipment, so as to ensure proper storage and handling of the Vaccine Volume according to specifications at all times. Premises and facilities must comply with all regulations for performing all agreed activities, including Good Distribution Practices.		X
<b>4. Field Actions</b>	Janssen	GP
Provide final decision and authority to initiate any field action.	X	
Provide all communications to the competent authority related to field actions.	X	
Assist, adhere to and execute all requested actions from Janssen in a timely manner related to field actions.		X
<b>5. Cold Chain</b>	Janssen	GP
Ensure that it and any and all of its government entities and contractors involved in receiving, handling, storage, distribution, delivery and similar actions with the COVID Vaccine have appropriate procedures in place (incl. training and monitoring) to effectively handle cold chain products in compliance with the prescribed conditions and requirements. These procedures shall include handling temperature excursion that may occur		X
Ensure that any COVID Vaccine for which cold chain requirements have not been maintained or met at any point in time following Delivery are appropriately disqualified and labelled to ensure such products are not administered to individuals.  Take all necessary measures to prevent diversion of disqualified COVID Vaccine, obtain and keep destruction certificates as required by applicable law, provide Janssen with such destruction certificates promptly upon request by Janssen		X
<b>6. Complaint Handling</b>	Janssen	GP
Report all the available information to Janssen within 24 hours of becoming aware of any product complaint in relation to COVID Vaccine.		X

This exhibit has been entered into on the date stated at the beginning of this Agreement.



EXECUTED by JANSSEN  
acting by its duly authorised officer




.....  
[Role] MANAGING DIRECTOR  
FEB. 3, 2021  
MARIO PEREZ A.  
.....


Name

EXECUTED by GOVERNMENT PURCHASER  
acting by its duly authorised officer

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**SÁUL HERNANDO SUANCHA TALERO**  
Legal Representative  
FIDUPREVISORA S.A.  
Spokesperson and Administrator of the Trust  
NATIONAL FUND FOR DISASTER RISK MANAGEMENT



U. **EDUARDO JOSÉ GONZÁLEZ ÁNGULO**  
General Director  
THE NATIONAL UNIT FOR DISASTER RISK MANAGEMENT  
Expense Officer FNGRD

