# DATED JUNE 11TH 2020

## THE EUROPEAN COMMISSION

# - and -

## SANOFI PASTEUR S.A.

# AND AFFILIATES

# - and -

# GLAXOSMITHKLINE BIOLOGICALS S.A.

# AND AFFILIATES

# TERM SHEET

# FOR THE RESERVATION OF PRODUCTION CAPACITY BY THE EUROPEAN COMMISSION AND SUPPLY TO EUROPEAN MEMBER STATES OF A VACCINE AGAINST, THE COVID 19 IN THE CONTEXT OF THE PANDEMIC

Term sheet SP/GSK -final version 11062020

- 1 -

905227

#### Between:

1- EUROPEAN COMMISSION (hereinafter the "EC"),

And

2- SANOFI PASTEUR S.A., a company existing and organized under the laws of the Republic of France with its registered head-office located at 14 espace Henry Vallée 69007 Lyon, France, acting in its own name and in the name and on behalf of its affiliates, in particular Protein Sciences Corp. (hereinafter referred to as the "<u>Sanofi Pasteur</u>"), represented by 5.1.2e 5.1.2e

And

**3- GLAXOSMITHKLINE BIOLOGICALS S.A.**, a company existing and organized under the laws of Belgium with its registered office located at Rue de l' Institut 89, B-1330 Rixensart, Belgium, (hereinafter referred to as the "GSK"), represented by 5.1.2e and 5.1.2e

## RECITALS

- 1 In the fight against COVID-19 pandemic crisis Sanofi Pasteur and GSK are running a R&D project in order to develop and manufacture an adjuvanted COVID-19 vaccine (hereafter the "Adjuvanted Pandemic Vaccine") composed of Sanofi Pasteur's recombinant Covid-19 Spike protein antigen ("S Antigen") and GSK's squalene-based Adjuvant (the "Adjuvant") both in multidose vials and to be reconstituted at bedside before injection.
- 2 The Adjuvanted Pandemic Vaccine is composed of a Proven adjuvant and a protein expression system.
  - i. S. Antigen expression system is FDA-approved and under EMA review for the flu vaccine (Supemtek) using the same technology.
  - ii. GSK's Adjuvant, AS03, is FDA/EMA approved
- 3 Sanofi Pasteur and GSK are actively building their European production capacities for the Adjuvanted Pandemic Vaccine.

Term sheet SP/GSK -final version 11062020

-2-

- 4 Sanofi Pasteur and GSK aim at making available hundreds of millions of Adjuvanted Pandemic Vaccines doses (amount to be determined as the project develops) which are today targeted for second half of 2021, as soon as possible after clinical trial success and regulatory approval.
- 5 To achieve this ambition in terms of volume manufacturing and time to supply, Sanofi Pasteur and GSK are first and foremost mobilizing their European network of internal industrial sites and Contract Manufacturing Organizations.
- 6 Such efforts will require European Commission to create the environment required to support manufacturing securitization and optimization including enabling free movement of raw materials or final product or intermediates involved in the different manufacturing steps until finished product export. The European Commission is committed to these objectives.
- 7 The EC wishes to secure supply of an Adjuvanted Pandemic Vaccine for human use for certain EU Member States having adhered to this program (the "Relevant Member States") during the Covid 19 Pandemic as promptly as possible.
- 8 Sanofi Pasteur, GSK and the EC entered into the present non binding Term Sheet as a basis for continuing discussions in order to implement the principles outlined in this Term Sheet. A Capacity Reservation Agreement (the "Reservation Agreement") would need to be entered into by the EC, Sanofi Pasteur and GSK in order to implement the principles outlined in this Term Sheet.
- 9 Sanofi Pasteur, GSK and the EC have agreed to collaborate with the aim of achieving the above objective, implementing the principles described hereafter.

# 1. VOLUME OF ADJUVANTED PANDEMIC VACCINE AVAILABLE FOR EU MEMBER STATES

- 1.1 Sanofi Pasteur and GSK aim at making available up to three hundred (300) million doses of Adjuvanted Pandemic Vaccines for the European Union. These three hundred (300) million doses are based on a final drug product dosage of 5.1.1c of antigen per dose. The target product profile is based on a 2 doses regimen.
- 1.2 The three hundred (300) million doses of Adjuvanted Pandemic Vaccines for the European Member States would be manufactured on the European territory as follows:

5.1.2h

1.3 Subject to successful development and an EMA approval of the Adjuvanted Pandemic Vaccine in June 2021 the first doses should be released as early as possible and at the

Term sheet SP/GSK -final version 11062020

- 3 -

latest by Q3-2021. Consequently, the three hundred (300) million doses of Adjuvanted Pandemic Vaccines for the Relevant Member States should be available as follows:

- 150 million doses in Q3-2021
- 150 million doses in Q4-2021

The Adjuvanted Pandemic Vaccine is a refrigerator-stable product, which allows to leverage standard distribution and delivery infrastructure for vaccines.

#### 2. PRICE

- 2.1 It is the common intention of the Parties to make available for Relevant Member States, as soon as possible the Adjuvanted Pandemic Vaccine, which requires to start producing the Adjuvanted Pandemic Vaccine as soon as possible and while the Adjuvanted Pandemic Vaccine is still under development.
- 2.2 In this context, Sanofi Pasteur and GSK can already commit that the Price of the Adjuvanted Pandemic Vaccines would be 5.1.1c per dose based on the dose assumption of 5.1.1c pf antigen per dose.
- 2.3 The total consideration to acquire the three hundred (300) million doses of Adjuvanted Pandemic Vaccines (the "Purchase Price") would therefore be 5.1.1c

#### 3. ADVANCE PURCHASE AGREEMENT MECHANISM

The acceleration of the at-risk production of these three hundred (300) million of doses of Adjuvanted Pandemic Vaccines for the EU Market would require Sanofi Pasteur and GSK to support substantial expenditures related to the manufacturing and supply of such doses.

Considering this, the Parties agreed to share the risks related hereto. This manufacturing risk-sharing should be organized according to the evolution of the clinical development of the Adjuvanted Pandemic Vaccine as follows:

#### Milestone 1 – June 2020:

In order to allow Sanofi Pasteur and GSK to start at-risk production of Adjuvanted Pandemic Vaccines for the EU Market as soon as possible, the EC agrees to support Sanofi Pasteur and GSK for expenditure directly related to the manufacturing of these doses and incurred until the end of Phase I /II of the clinical trial of the Adjuvanted Pandemic Vaccine. To that effect Sanofi Pasteur, GSK and the EC would enter into Reservation Agreement reflecting the provisions of this Term Sheet.

The EC will support these costs through a financial contribution of 5.1.2a of the Purchase price corresponding to three hundred and twenty-four million (324 000 000) euros (the "Milestone 1 Payment").

Term sheet SP/GSK -final version 11062020

- 4 -

The EC will pay the Milestone 1 Payment to Sanofi Pasteur and GSK by the end of June 2020.

The Milestone 1 Payment will not be reimbursable.

#### Milestone 2 – January 2021:

Upon the Phase I/II results which should occur in December 2020, and provided such results are satisfactory, Sanofi Pasteur and GSK will be in a position to confirm to the EC the total volume of the Adjuvanted vaccines available for EU market and consequently to conclude Advance Purchase Agreements ("APA").

In order to allow Sanofi Pasteur and GSK to launch at-risk production of Adjuvanted Pandemic Vaccines for the EU Market in parallel to phase III clinical study, the EC agrees to pay to Sanofi Pasteur and GSK a Milestone 2 Payment corresponding to 48 % of the Purchase Price corresponding to 5.1.1c euros (the "Milestone 2 Payment").

This Milestone 2 Payment shall be paid by January 2021 to Sanofi Pasteur and GSK.

This Milestone 2 Payment will not be reimbursable.

#### Milestone 3 – at delivery:

Upon the Phase III results and EMA approval estimated in June 2021, Sanofi Pasteur and GSK will be in position to prepare shipments to each Relevant Member State according to the volume provided by the EC to Sanofi Pasteur and GSK agreed APAs for a delivery as from Q3-2021.

The EC will pay at delivery to Sanofi Pasteur and GSK 40 % of the Purchase Price corresponding to 5.1.1c euros (the "Milestone 3 Payment").

Costs related to possible Post Marketing Surveillance / Risk Management Plan will require a separate discussion with the EC for funding.

## 4. GLOBAL ACCESS - ACT ACCELERATOR

Sanofi Pasteur and GSK will endeavor to provide at least 5.1.1c doses of its total worldwide available supply capacity of the Adjuvanted Pandemic Vaccine to the global initiative "Access to COVID-19 Tools (act) Accelerator" so as to ensure availability of the Adjuvanted Pandemic Vaccine for all, especially vulnerable countries subject to liability protection clause.

#### 5. WARRANTIES

5.1 Sanofi Pasteur and GSK make no warranties of any kind, express or implied, written or oral, with respect to Adjuvanted Pandemic Vaccine, including any implied

Term sheet SP/GSK -final version 11062020

- 5 -

warranty of merchantability or fitness for a particular purpose. This principle would be detailed in the contract between the Parties.

#### 6. LIABILITY TOWARDS THIRD-PARTIES AND INDEMNIFICATION

- 6.1 If used, the Adjuvanted Pandemic Vaccine shall be used solely as a result of decisions that would be taken at the sole discretion of the EC and Member States in situations of public health emergency, potentially in mass vaccination campaigns, while the efficacy and safety profiles of such Adjuvanted Pandemic Vaccine are not fully documented in an immunologically naïve population and, the virus for which it is intended to immunize is likely to be highly virulent.
- 6.2 Under such circumstances, absent special liability protections, Sanofi Pasteur and GSK's performance under this Term Sheet would subject Sanofi Pasteur and GSK to unusually hazardous risks against which Sanofi Pasteur and GSK in all fairness should be held harmless.
- 6.3 Therefore, Sanofi Pasteur and GSK will seek immunity (through new legislation) as a primary liability protection. If such immunity does not exist, the parties would seek full indemnification; such liability protection from product liability and risk associated with mass vaccination campaigns in the context of a pandemic is a key element of Sanofi Pasteur and GSK's decision to enter into this Term Sheet and any related agreement.
- 6.4 Supply shall be contingent upon the parties receiving the express written agreement and confirmation of any approved purchaser in such country that both parties are covered (including in respect of the supply of each party's respective components) by immunity or full indemnity protections in respect of such supply.
- 6.5 Details of these principles will be included in the agreements.

#### 7. FORCE MAJEURE

7.1 No Party shall be responsible or liable to the other Party for any failure to perform any of its covenants or obligations under this Term Sheet if such failure results from events or circumstances reasonably beyond the control of such Party including, without limitation, war or other national emergency, riot, fire, explosion, pandemic, flood or other Act of God, general and long-lasting strike affecting the activity of either Party, the inability of a Party to perform under this Term Sheet due to an injunction or blockade imposed by a jurisdiction acting further to a claim for infringement of intellectual property rights by a third-party, any injunction, decree, order, law or regulation of any public authority or any decision by a government such as a constraint order or requisition or embargo, or any inability to obtain electricity, fuel or raw material (collectively, "Events of Force Majeure").

Term sheet SP/GSK -final version 11062020

- 6 -

7.2 The affected Party (including the Member States) shall (i) forthwith inform the other Party in writing of the occurrence of the Event of Force Majeure and (ii) exert reasonable efforts to eliminate, cure or overcome any such Event of Force Majeure and to resume performance hereunder with all possible speed; provided, however, that nothing herein shall require the Party to settle on terms unsatisfactory to such Party any strike or dispute. To the extent that an Event of Force Majeure continues for a period in excess of six (6) months, the parties agree to negotiate in good faith either (i) to resolve the Event of Force Majeure, if possible, (ii) to extend the time period to resolve, eliminate or overcome such Event or (iii) to terminate this Term Sheet.

#### 8. FUTURE COOPERATION -NON BINDING

The Parties undertake to cooperate in order to implement the principles outlined in this Term Sheet and negotiate such agreements and documents as are required to do so on the basis of such principles provided that that i) the terms of this Term Sheet are not binding on any Party, ii) that none of the Parties shall be legally bound until such definitive agreements have been finalized and signed, and iii) that any Party can terminate negotiations at any time for any reason.

#### 9. CONFIDENTIALITY

- 9.1 "Confidential Information": shall mean any and all information of any kind disclosed directly or indirectly by one Party and/or any of its affiliates or representatives to the other Party and/or any of its affiliates or representatives, in written, oral, electronic or in any other form. Confidential Information shall not include any information that:
- (i) is or becomes generally available to the public other than as a result of a disclosure by that Party or any of its Representatives in violation of this Article11;
- was lawfully in the possession of that Party or any of its Representatives prior to such information being received from the other Party or its Representatives free of any restriction as to its use and disclosure (as can be demonstrated by that Party's or its Representative's written records);
- (iii)becomes available to that Party or any of its Representatives thereafter, provided that at the time of its receipt such information is not, to the best of that Party's and its Representative's knowledge, subject to any confidentiality or restricted-use obligation for the benefit of the other Party; and/orwas lawfully in the possession of that Party or any of its Representatives prior to such information being received from the other Party or its Representatives free of any restriction as to its use and disclosure (as can be demonstrated by that Party's or its Representative's written records);
- (iv) is independently developed by that Party or any of its representatives without reference to the other Party's Confidential Information (as can be demonstrated by that Party's or its representative's written records).

Term sheet SP/GSK -final version 11062020

-7-

- 9.2 Subject to the provisions of this Article 11, or unless otherwise agreed to in writing by the other Party, during the Term of this Agreement and for a period of five (5) years thereafter, each Party hereby agrees not to:
- disclose any Confidential Information of the other Party to any person other than its representatives who need to know the Confidential Information for the purpose of the consummation of the transactions contemplated by this Term Sheet; and
- use any Confidential Information of the other Party for any purpose other than in connection with the consummation of the transactions contemplated by this Term Sheet.
  - 9.3 If a Party (the "Disclosing Party") is required by applicable law or regulation, by applicable stock exchange regulation, by legal process, or for the purposes of enforcement of its rights under this Agreement, to disclose all or any portion of the Confidential Information of the other Party, the Disclosing Party (or its Representative) may so disclose such Confidential Information, provided that the Disclosing Party shall, to the extent permitted by law:
- provide the other Party with a written notice of such requirement so that the other Party may seek a protective order or other appropriate remedy;
- exercise commercially reasonable efforts to narrow the scope of any such requirement and consult with the other Party to that effect; and
- (iii)if such protective order or other remedy is not obtained, furnish only that portion of the Confidential Information which the Disclosing Party (or its Representative) is compelled to disclose and exercise commercially reasonable efforts to obtain assurance that confidential treatment will be accorded to such Confidential Information.
  - 9.4 In the event of termination of this Term Sheet, each Party shall (and shall ensure that its representatives shall) promptly, upon the other Party's written request, return all copies of Confidential Information of such other Party in its possession or in the possession of any of its representatives and destroy all information or other documents derived from such Confidential Information. If so requested, the other Party shall confirm in writing that its undertakings relating to the return or destruction of any such Confidential Information have been complied with.

Term sheet SP/GSK -final version 11062020

- 8 -

# For the EC

Name: Title:

