

CONFIDENTIAL



*Non Binding Term Sheet dated June 29<sup>th</sup>, 2020*

To: European Commission Negotiation Team

Due to the urgency and degree of the COVID-19 pandemic, Sanofi and GSK are fully committed to developing, manufacturing, and providing affordable access to COVID-19 vaccines for the European and global population.

To advance this intention, Sanofi and GSK seek to enter into an agreement with the European Commission, representing the Member States, within the framework of the EU Strategy for COVID-19 vaccines. To develop, test and manufacture a COVID-19 vaccine at-risk and at-speed will require that risks are shared. The accompanying Term Sheet provides for this risk to be jointly borne by the EU, Sanofi, and GSK, to provide the best possible chance for successful delivery of a COVID-19 vaccine in as short a time as possible. The Term Sheet also proposes advance purchase agreement (APA) milestones offering flexibility to the European Commission and its Member States at critical time points in the development and manufacturing plan, to opt-out while giving the ability to Sanofi and GSK to secure immediate readiness to produce.

The Sanofi/GSK collaboration provides confidence from the companies' foundation and history of vaccine expertise and track record of producing a variety of vaccines and underlying technologies for a variety of infectious diseases. While many vaccines against COVID-19 are in development globally, the Sanofi/GSK partnership offers a tried and proven approach: an adjuvanted protein subunit vaccine against the COVID-19 Spike (S) protein, leveraging two well-established platforms already used in approved vaccines and proven to permit manufacture at scale:

- Sanofi's baculovirus recombinant protein manufacturing platform proven to produce a vaccine and to manufacture at scale as exemplified via the US Food and Drug Administration (FDA)-approved Flublok influenza vaccine. The European Medicines Agency (EMA) is currently reviewing an influenza vaccine based on this platform.
- GSK's ASO3 adjuvant approved by both FDA and EMA as part of the company's H5N1 influenza vaccine with proven ability to manufacture at scale.

The combination of these two established platforms provides a credible path towards the speed and scale necessary to address the COVID-19 situation as well as an encouraging probability of success.

In addition to combining these assets, Sanofi and GSK are compressing timelines as much as possible for development and initiation of at-scale manufacturing, endeavouring to register a vaccine by June 2021 (target date dependent on review by EMA), given the scale and urgency of the current pandemic and its devastating impact. This approach is underscored by substantial risk. Bulk drug substance (protein) and final product will be made at-scale while clinical studies are conducted such that useable doses will be available immediately upon regulatory approval with the attendant uncertainties of manufacturing process protein yield, amount of protein per dose, number of doses required, and safety and efficacy of the product. As such, the timeline for a typical vaccine of 10-15 years will be reduced to approximately 18 months.

CONFIDENTIAL



Such acceleration necessitates a sharing of risk as outlined in the accompanying Term Sheet and encompasses the following principles:

- Supply of up to [ 5.1.1c ] vaccine doses for Europe from the targeted registration date, June 2021, to end 2021.
- Reinforcement of long-term production capacities for COVID-19 vaccine on European soil
- An endeavour to provide at least [ 5.1.1c ] to the Act Accelerator
- Long-term investments in European pandemic preparedness with commitments from Sanofi and GSK to reinvest potential profits in vaccine R&D and industrial capacities.

These goals and immediate availability of vaccine post-approval require initiation of drug substance (bulk protein) and bulk adjuvant production as soon as possible (as informed by the results of phase I/II clinical studies). As such, Sanofi and GSK have already mobilized their respective European networks of industrial sites and Contract Manufacturing Organizations (CMOs).

To further advance, significant steps and investments during 2020 are required to ensure no delay in vaccine availability:

- Technology transfers for antigen and adjuvant production using Sanofi and GSK assets in [ 5.1.1c ] European countries [ 5.1.1c ]
- Manufacturing development and scale-up, reserving Sanofi and GSK production capacity for COVID-19 vaccine
- Production of qualification batches
- Purchasing of raw materials and primary components due to the unprecedented level of competition to source those materials due to the pandemic and similar sourcing strategies
- Recruitment and training of skilled workers on Sanofi and GSK sites to enable production at commercial scale from January 2021, in compliance with current good manufacturing practices
- Focus significant numbers of both Sanofi and GSK skilled workers on the COVID-19 project instead of other projects
- Securing additional capacity from CMOs: as the relevant antigen dosage and the manufacturing yield are not yet known, Sanofi and GSK aim to secure additional capacity to match European needs.

The accompanying Term Sheet provides for risk sharing in these activities balanced with opt-out provisions for EC through two steps:

- Down Payment for manufacturing preparedness (July 2020): risk sharing agreement with fixed fee paid by European Commission for Sanofi and GSK to cover:
  - Project costs, including technology transfers to industrial sites for drug substance and drug product across Europe/CMO, qualification batches and development/scale up
  - Raw materials and primary components (vials, stoppers, proprietary media for cell culture, chromatography gel), specific to the Adjuvanted Pandemic Vaccine.
  - Direct costs, including hiring and training of additional skilled work force for Europe
  - CMO take or pay contracts to expand manufacturing capacity

Sanofi and GSK take the risks related to the other factors of readiness above listed i.e. 7 manufacturing sites and [ 5.1.1c ] supporting delivery for Europe, managing process

CONFIDENTIAL



development, optimization and qualification, technology transfers, and manufacturing activities across industrial sites, exclusively dedicated to COVID-19.

The down payment is deductible from the payment for doses purchased by the European Commission as further explained in the attached Term Sheet. The down payment is non-refundable as it corresponds to an investment to initiate full scale production and also includes opportunity costs to prioritise COVID-19 response.

- Advanced Purchase Agreement Milestone #1 (December 2020/January 2021): Sanofi and GSK will be in a position to share with the European Commission and EMA critical data from the non-clinical studies, Phase I/II clinical trials, study protocol of the Phase III, detailed manufacturing plan regarding volumes and proposed final price per dose. Based on this information and any other information already in their possession, the European Commission will be in a position to (i) opt-out from the agreement with no refund or (ii) agree on advance purchase with Sanofi and GSK with the final price and for the volume of doses requested by the European Commission and its Member States. The milestone payment is detailed in the term-sheet. Since our last meeting with the European Commission, Sanofi and GSK have agreed to revise downwards this milestone payment.
- Advanced Purchase Agreement Milestone #2 (estimated June 2021): Assuming EMA grants marketing authorisation based on the clinical data from the Phase III, anticipated in June 2021, Sanofi and GSK will be able to deliver the agreed volume of doses to the participating Member States. This milestone payment will correspond to the remainder of the APA. If the Sanofi/GSK vaccine is not registered or the agreed volume not delivered, the European Commission and/or its Member States will not pay the remainder.

In addition to at-risk investments made by Sanofi and GSK, in a spirit of partnership, the companies are collaborating with regulators, including EMA to secure fast EU approval, sharing an unprecedented amount of information in advance.

The COVID-19 pandemic situation is urgent and requires vaccination campaigns of unprecedented proportion, with immunization of exceedingly large numbers of healthy people in a short timeframe. While vaccine manufacturers will develop, register, manufacture, and supply COVID-19 vaccines consistent with applicable laws, regulations, and good industry practices, the circumstances could lead to an increased number of adverse events reportings, and, consequently, increased number of liability claims. Sanofi and GSK stress the necessity of appropriate and fast access to streamlined, comprehensive, no-fault compensation systems across Europe for any individual suffering from an unexpected serious adverse event that may be associated with COVID-19 vaccination. The support of the European Commission and the Member States is essential to implement harmonized principles either at the European level or amongst Member States, since currently existing systems in various countries are not fully adapted to a pandemic situation. Such compensation mechanisms would, above all, maintain public confidence in vaccination (in general) and avoid any negative impact on the future uptake of COVID-19 vaccination, and vaccines in general. The exceptional pandemic context also requires a COVID-19 specific, harmonized Member State legislation granting vaccine manufacturers and other stakeholders immunity/exemption from liability or, as an alternative, full contractual indemnification, as further detailed in the Term Sheet.

CONFIDENTIAL



This Term Sheet demonstrates Sanofi's and GSK's commitment to work with the European Commission to develop a COVID-19 vaccine to address this historic public health threat. Further, Sanofi and GSK remain committed to develop and produce other vaccines essential to the European market.

Sanofi and GSK remain available to provide any further explanation. We look forward to receiving feedback from the European Commission and Member States.

Sincerely,

For Sanofi Pasteur

Jun 29, 2020

5.1.2e

For GSK

For GSK

5.1.2e 5.1.2e

Jun 29, 2020

Jun 29, 2020