

Sanofi and GSK to support COVAX with 200 million doses of adjuvanted, recombinant protein-based COVID-19 vaccine

- * COVAX Facility is led by Gavi and aims to secure successful and equitable access to COVID-19 vaccines worldwide

PARIS and LONDON – October 28, 2020 – Sanofi and GSK have signed a Statement of Intent with Gavi, the legal administrator of the COVAX Facility, a global risk-sharing mechanism for pooled procurement and equitable distribution of eventual COVID-19 vaccines.

Sanofi and GSK intend to make available 200 million doses of their adjuvanted recombinant protein-based COVID-19 vaccine, if approved by regulatory authorities and subject to contract, to the COVAX Facility. Both Companies intend to contribute to COVAX's ambition to ensure successful COVID-19 vaccines reach those in need, whoever they are and wherever they live, once they obtain appropriate approvals.

“To address a global health crisis of this magnitude, it takes unique partnerships. The commitment we are announcing today for the COVAX Facility can help us together stand a better chance of bringing the pandemic under control,” said Thomas Triomphe, Executive Vice President and Global Head of Sanofi Pasteur. *“This moment also reflects our long-term commitment to global health and ensures our COVID-19 vaccines are affordable and accessible to those most at risk, everywhere in the world.”*

Roger Connor, President of GSK Vaccines added, *“Since we started working on the development of COVID-19 vaccines, GSK has pledged to make them available to people around the world. We are proud to be working with Sanofi to make this adjuvanted recombinant protein-based vaccine available to the countries signed up to the COVAX Facility as soon as possible - this has the potential to be a significant contribution to the global fight against COVID-19.”*

The COVAX Facility is part of COVAX, a global collaboration of governments, global health organizations, businesses and philanthropic organizations working to accelerate development, production, and equitable access to COVID-19 vaccines. COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO and forms the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator. More than 180 countries and economies [recently](#) signed onto the COVAX Facility to get timely and cost-effective access to vaccines to meet the global scale of the COVID-19 pandemic.

Through the COVAX Facility's efforts, vaccines will be distributed in participating countries through the WHO's recently published Allocation Framework, and the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) Values Framework which has begun to frame future guidance on vaccine use. These allocation principles aim to ensure that people in all parts of the world will get access to COVID-19 vaccines once they are available.

Status of the adjuvanted recombinant protein-based vaccine development

Sanofi and GSK initiated a Phase 1/2 study on September 3 with a total of 440 subjects enrolled, and anticipate first results in early December 2020, to support the initiation of a pivotal Phase 3 study before the end of the year. If these data are sufficient for licensure application, it is planned to request regulatory approval from the first half of 2021. In parallel, the Companies are scaling up manufacturing of the antigen and adjuvant respectively.

On the front lines in the fight against COVID-19

In addition to the recombinant protein-based vaccine in collaboration with GSK, Sanofi is developing a messenger RNA vaccine in partnership with Translate Bio. With several innovative vaccine platforms currently being investigated across the industry, mRNA is considered among the most promising. Preclinical data showed that two immunizations of the mRNA vaccine induced high neutralizing antibody levels that are comparable to the upper range of those observed in infected humans. Sanofi expects the Phase 1/2 study to start in the fourth quarter of 2020, with earliest potential approval in the second half of 2021. Translate Bio has established mRNA manufacturing capacity and Sanofi expects to be able to supply annual capacity of 90 to 360 million doses.

About GSK

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. GSK is the leading manufacturer of vaccines globally. For further information, please visit www.gsk.com

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.