SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Sanofi and GSK announce positive preliminary booster data for their COVID-19 vaccine candidate and continuation of Phase 3 trial per independent Monitoring Board recommendation

- Positive booster data show that neutralizing antibodies increased across all primary vaccines received (mRNA or adenovirus) in a 9- to 43-fold range and for all age groups tested, with a good safety and tolerability profile
- Phase 3 trial continues to accrue number of events needed for analysis as populations around the world are increasingly exposed to COVID-19 variants; results expected in Q1, 2022
- Companies intend to file booster data with regulatory authorities following the Phase 3 results

PARIS – December 15, 2021 - Sanofi and GSK announced today that a single booster dose of their recombinant adjuvanted COVID-19 vaccine candidate delivered consistently strong immune responses. Preliminary results from the VAT0002 clinical trial investigating the safety and immunogenicity of the booster showed neutralizing antibodies increased 9- to 43-fold regardless of the primary vaccine received (AstraZeneca, Johnson & Johnson, Moderna, Pfizer/BioNTech) and for all age groups tested. The booster was well tolerated, with a safety profile similar to currently approved COVID-19 vaccines. This is the most comprehensive booster trial to date to explore boosting across different vaccine technologies used for primary vaccination.

The ongoing global Phase 3 trial, VAT0008, includes regular reviews by an independent Data Safety Monitoring Board (DSMB). During its last review, the DSMB identified no safety concerns and recommended the trial to continue into early 2022 to accrue more data.

Regulatory authorities require Phase 3 efficacy to be demonstrated in “naive” populations, i.e. participants who have never been infected by the COVID-19 virus (seronegative). The Phase 3 trial recruited most participants in Q3 2021, coinciding with a significant increase in the number of people infected by the COVID-19 virus globally due to the Delta variant. To provide the necessary data to regulatory authorities for the booster vaccine submission, the trial will continue to accrue the number of events needed for analysis, with results expected in Q1, 2022.

> *“These preliminary data show we have a strong booster candidate, whatever primary vaccine you have received.”* said Thomas Triomphe, Executive Vice President, Sanofi Pasteur. *“This is consistent with our efforts to provide relevant*

responses to evolving public health needs. While pursuing a phase 3 trial is a challenge in a quickly shifting pandemic environment, we look forward to seeing the results to support submissions of our booster vaccine as quickly as possible."

Roger Connor, President of GSK Vaccines, added*: "As the pandemic threat continues with the current dominant Delta variant and Omicron rapidly gaining ground, booster vaccines will continue to be needed to help protect people over time. The initial booster data are promising, and we await the phase III results to determine the next steps on making protein-based adjuvanted COVID-19 vaccines available."*

In parallel, Sanofi continues its contribution to global public health needs with the manufacturing of up to half a billion doses from BioNTech/Pfizer, Moderna, and Johnson & Johnson vaccines.

About the booster trial (VAT0002)

The VAT0002 extension trial is the most comprehensive heterologous booster trial conducted to date. In the first cohort of this trial, the four most-widely approved COVID-19 primary vaccines using mRNA and adenovirus vector technologies were boosted with the Sanofi/GSK protein-based adjuvanted vaccine candidate after full primary vaccination to assess its safety profile and immunogenicity.

Participants in the first cohort (n=521) had previously been vaccinated with the approved dosing schedule of an authorized COVID-19 mRNA vaccine (Moderna, Pfizer/BioNTech,) or adenovirus vector vaccine (AstraZeneca, Johnson & Johnson,). This preliminary analysis includes data from trial participants who received one 5µg booster dose of the adjuvanted recombinant protein vaccine targeting the D614 parent virus, between four and ten months after a complete primary vaccination schedule.

The trial is ongoing across sites in multiple countries, including the U.S., France, and the UK. To address the emergence of COVID-19 variants of concern, additional trial cohorts are assessing the boosting potential of monovalent and bivalent vaccine formulations also containing the Beta (B.1.351) variant. More data from this trial are expected during the first half of 2022. The Omicron variant was not circulating during the trial. Using sera from booster trial participants, testing is underway to establish the ability of the vaccine candidate to cross-neutralize against Omicron.

About the Phase 3 efficacy trial (VAT0008)

The primary endpoint of this ongoing Phase 3, randomized, double-blind, placebo-controlled trial is the prevention of symptomatic COVID-19 in SARS-CoV-2 naïve adults, with secondary endpoints of preventing severe COVID-19 disease and infection. Stage one of the trial is assessing the efficacy of a vaccine formulation containing the spike protein against the original D614 (parent) virus in more than 10,000 participants >18 years of age, randomized to receive two doses of 10µg vaccine or placebo at day 1 and day 22 across

sites in the US, Asia, Africa and Latin America. A second stage in the trial is evaluating a second bivalent formulation, adding the spike protein of the B.1.351 (Beta) variant.

These efforts are supported by federal funds from the Biomedical Advanced Research and Development Authority, part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services in collaboration with the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense under Contract # W15QKN-16-9-1002.

About the Sanofi and GSK collaboration

In the collaboration between the two companies, Sanofi provides its recombinant antigen and GSK contributes its pandemic adjuvant, both established vaccine platforms that have proven successful against influenza.

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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.