

Sanofi-GSK first to report a successful efficacy study against Omicron with COVID-19 Beta-containing vaccine

- Primary vaccination with Beta-containing vaccine candidate delivers 64.7% efficacy against symptomatic infection in adults, and 75.1% efficacy in participants previously infected with COVID-19
- Against Omicron, sequencing analysis performed to date shows 72% efficacy in all adults and 93.2% in seropositives
- Favorable safety and tolerability profile
- First ever reported efficacy data in an Omicron environment support relevance of a Beta-containing vaccine

Paris, June 24, 2022. Sanofi and GSK today announce positive data from their vaccine trial which evaluated an adjuvanted bivalent D614 and Beta (B.1.351) vaccine candidate. Sanofi-GSK's vaccine is the first candidate to demonstrate efficacy in a placebo-controlled trial in an environment of high Omicron variant circulation. The vaccine candidate showed a favorable safety and tolerability profile. Earlier this month Sanofi reported positive data from two trials conducted with its new next-generation COVID-19 booster vaccine candidate modelled on the Beta variant antigen and including GSK's pandemic adjuvant. The data supporting this next-generation booster vaccine will be submitted to regulatory authorities and indicate the potential of Sanofi-GSK's next-generation Beta-based booster to be a relevant response to public health needs.

Thomas Triomphe

Executive Vice President Vaccines, Sanofi

"Today's results reinforce the strong potential for the Beta antigen to confer broad protection against multiple strains that cause COVID-19. With the immunogenicity data from our Beta-booster vaccine, they support our belief that, in a largely seropositive world, a next-generation Beta booster vaccine could provide protection against variants like Omicron. mRNA has proven speed to market; we are demonstrating here the efficacy that our recombinant protein platform can provide to the world. We look forward to completing our submissions to regulatory authorities and are ready to contribute to ongoing vaccination campaigns with our next-generation booster."

Roger Connor

President of GSK Vaccines

"These positive data show efficacy of our protein-based, bivalent adjuvanted vaccine candidate in an environment of high Omicron variant circulation. Our vaccine candidate has the potential to make an important contribution to public health as the pandemic evolves further. We are looking forward to the discussions with regulatory authorities with the aim of making our vaccine candidate available later this year."

In Stage 2 of the Phase 3 COVID-19 vaccine trial VAT08 of more than 13,000 participants 18 and above years of age, the Sanofi-GSK Beta-containing vaccine candidate demonstrated an efficacy of 64.7% (95% confidence interval [CI, 46.6, 77.2]) against symptomatic COVID-19 and 72% efficacy (95% confidence interval [CI, 45.8, 86.6]) in Omicron-confirmed symptomatic cases (sequencing was performed for 71 cases out of 121 total cases to date).

In previously seropositive populations, the Sanofi-GSK vaccine candidate demonstrates an overall efficacy of 75.1% (95% confidence interval [CI, 56.3, 86.6]) against symptomatic infection, and 93.2% (95% confidence interval [CI, 73.2, 99.2]) in Omicron-confirmed symptomatic cases, according to the sequencing analysis performed to date.

Throughout Stage 1 and Stage 2 of the VAT08 trial (~23,000 participants in total), the Sanofi-GSK vaccine demonstrated a favorable safety and tolerability profile.

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 partnership

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

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on Euronext: SAN and Nasdaq: SNY

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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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.