Press Release

Sanofi and GSK to seek regulatory authorization for COVID-19 vaccine

* Final analysis of the global VAT02 booster trial confirms universal ability to boost neutralizing antibodies 18- to 30-fold across vaccine platforms (mRNA, adenovirus)

* In the VAT08 Phase 3 primary series trial, two doses of the Sanofi-GSK vaccine in seronegative populations demonstrated:
    * 100% efficacy against severe COVID-19 disease and hospitalizations
    * 75% efficacy against moderate or severe COVID-19 disease
    * 57.9% efficacy against any symptomatic COVID-19 disease, in line with expected vaccine effectiveness in today's environment dominated by variants of concern

* Favorable safety profile following both primary series and booster vaccinations

Paris, February 23, 2022. Sanofi and GSK today announce that they intend to submit data from both their booster and Phase 3 efficacy trials as the basis for regulatory applications for a COVID-19 vaccine.

The public health relevance of the refrigerator temperature-stable adjuvanted protein-based Sanofi-GSK vaccine is strongly supported by the induction of robust immune responses and a favorable safety profile in multiple settings. In participants who had received a primary series of an already authorized mRNA or adenovirus vaccine, the Sanofi-GSK booster vaccine induced a significant increase in neutralizing antibodies of 18- to 30-fold across vaccine platforms and age groups. When the Sanofi-GSK vaccine was used as a two-dose primary series followed by a booster dose, neutralizing antibodies increased 84- to 153-fold compared to pre-boost levels.

> ***Thomas Triomphe***
> Executive Vice President, Sanofi Vaccines
> *"We're very pleased with these data, which confirm our strong science and the benefits of our COVID-19 vaccine. The Sanofi-GSK vaccine demonstrates a universal ability to boost all platforms and across all ages. We also observed robust efficacy of the vaccine as a primary series in today's challenging epidemiological environment. No other global Phase 3 efficacy study has been undertaken during this period with so many variants of concern, including Omicron, and these efficacy data are similar to the recent clinical data from authorized vaccines."*

> ***Roger Connor***
> President of GSK Vaccines
> *"The evolving epidemiology of COVID-19 demonstrates the need for a variety of vaccines. Our adjuvanted protein-based vaccine candidate uses a well-established approach that has been applied widely to prevent infection with other viruses including pandemic flu. We are confident that this vaccine can play an important role as we continue to address this pandemic and prepare for the post-pandemic period."*

When used as a two-dose primary series, the Sanofi-GSK vaccine delivered robust levels of neutralizing antibodies, with GMTs reaching 3711 units. For comparison, a panel of sera from volunteers in the same age range who received two doses of an already approved and highly effective mRNA vaccine displayed a GMT of 1653 units, measured simultaneously in the same laboratory.

Data from the VAT08 efficacy study showed that two doses of Sanofi-GSK vaccine generated an efficacy of 57.9% (95% confidence interval [CI, 26.5, 76.7]) against any symptomatic COVID-19 disease in the seronegative population. The Sanofi-GSK vaccine provided 100% protection (0 vs 10 cases post-dose 1, 0 vs 4 cases post-dose 2) against severe disease and hospitalizations

and 75% (3 vs 11 cases) efficacy against moderate-to-severe disease in seronegative populations. While sequencing is still in progress, early data indicate 77% efficacy against any Delta variant-associated symptomatic COVID-19 disease, in line with expected vaccine effectiveness.

Across both studies, the Sanofi-GSK vaccine was well-tolerated in younger and older adults with no safety concerns.

The companies are in discussions with regulatory authorities, including the US FDA and European Medicines Agency (EMA), and plan to submit the totality of the data generated with this vaccine candidate to support regulatory authorizations.

About VAT08 and VAT02
The Phase 3 trial, VAT08 is evaluating a 10µg antigen formulation of the SARS-CoV-2 adjuvanted recombinant protein-based vaccine for efficacy, immunogenicity and safety compared to a placebo. 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. Enrolment recently completed for a second stage in the trial, evaluating a second bivalent formulation, including the spike protein of the B.1.351 (Beta) variant. The Phase 3 trial follows positive initial results from a Phase 2 clinical trial (VAT00002). In that trial, the COVID-19 vaccine candidate was administered to 722 adults to assess the safety, reactogenicity and immunogenicity of 2 doses and to identify an optimal dosing for use as a booster. Results showed strong rates of neutralizing antibody response with 95% to 100% seroconversion following a second injection in all age groups (18 to 95 years old), across all doses.

Full study results for both VAT08 and VAT02 will be published later this year.

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 and by the National Institute of Allergy and Infectious Diseases (NIAID). The NIAID provides grant funding to the HIV Vaccine Trials Network (HVTN) Leadership and Operations Center (UM1 AI 68614HVTN), the Statistics and Data Management Center (UM1 AI 68635), the HVTN Laboratory Center (UM1 AI 68618), the HIV Prevention Trials Network Leadership and Operations Center (UM1 AI 68619), the AIDS Clinical Trials Group Leadership and Operations Center (UM1 AI 68636), and the Infectious Diseases Clinical Research Consortium (UM1 AI 148684, UM1 AI 148450, UM1 AI 148372 , UM1 AI 148574).

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