Press Release

Sanofi and GSK's next-generation COVID-19 booster vaccine VidPrevtyn® Beta approved by the European Commission

- First and only next-generation protein-based adjuvanted COVID-19 booster approved in Europe
- Strong immune response against all tested variants of concern
- Ready to supply for fall-winter COVID-19 vaccination campaigns in Europe

Paris, November 10, 2022. After the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for VidPrevtyn® Beta, the vaccine was approved by the European Commission, as a booster for the prevention of COVID-19 in adults 18 years of age and older. Designed to provide broad protection against multiple variants, the protein-based COVID-19 booster vaccine is based on the Beta variant antigen and includes GSK's pandemic adjuvant. VidPrevtyn Beta is indicated as a booster for active immunization against SARS_CoV_2 in adults who have previously received an mRNA or adenoviral COVID vaccine. Shipments of VidPrevtyn Beta are ready to be distributed to European countries as per Advance Purchase Agreements.

> ***Thomas Triomphe***
> Executive Vice President, Vaccines, Sanofi
> *"Today's approval validates our research in developing a novel solution for the COVID-19 pandemic. As we're ready to start first shipments, VidPrevtyn Beta will be an important new option to protect populations against multiple strains of COVID-19."*

> ***Philip Dormitzer***
> Global Head of Research and Development Vaccines, GSK
> *"This EC approval is an important step in providing further vaccine solutions to Europe for the coming winter. Our protein-based, adjuvanted vaccine candidate has the potential to make an important contribution to public health as the pandemic evolves further."*

In registration studies, carried out at times when Omicron strains were predominantly circulating, the vaccine induced a strong immune response against multiple variants. Registration studies included a Phase 3 primary efficacy trial (VAT08 Stage 2) and two separate immunogenicity studies, including one comparative study with approved mRNA booster as comparator[i,ii].

About VidPrevtyn Beta

VidPrevtyn Beta is a monovalent, recombinant-protein next-generation COVID-19 vaccine developed by Sanofi, modelled on the Beta variant and including GSK's pandemic adjuvant. The same recombinant-protein technology is used in Sanofi's approved seasonal flu vaccines. Next-generation COVID-19 vaccines are based on a variant-adapted approach, using a strain other than the parental strain of SARS-CoV-2 (D614 strain).

About COVIBOOST Immunogenicity & Safety Study

The independent COVIBOOST (VAT013) study conducted by the Assistance Publique – Hôpitaux de Paris (AP-HP) investigated VidPrevtyn Beta following primary vaccination with two doses of Pfizer-BioNTech's Comirnaty vaccine (BNT162b2). VidPrevtyn Beta generated a higher immune response (as measured by neutralizing antibody titers) than Pfizer-BioNTech's booster or the Sanofi-GSK first-generation booster, both of which target the original D614 parent strain. In this study, which included 247 adult subjects (18-73 years-old), all three vaccines also elicited neutralizing antibodies against

the Omicron BA.1 variant, with highest responses generated by the Sanofi-GSK next-generation candidate, one month after injection. VidPrevtyn Beta also elicited around 2.5 times more neutralizing antibodies against Omicron BA.1 and, in an exploratory analysis, against BA.4 / BA.5 strains than mRNA COVID-19 booster comparator.

About the VAT02 Immunogenicity & Safety Study

Immunogenicity studies included VAT02 Cohort 2 and COVIBOOST which evaluated the booster formulation modelled on the Beta variant and including GSK's pandemic adjuvant. In the Phase 3 VAT02 Cohort 2 study, the vaccine induced (at day 15 following booster vaccination) a significant boost in antibody titers above baseline against multiple variants of concern (13-fold increase against D614 parent virus, 34-fold increase against the COVID-19 Beta strain) in 18-55 years-old adults previously primed with mRNA COVID-19 vaccines. In the VAT02 cohort 2 study, reactions were mostly mild to moderate, transient and self resolutive.

About the VAT08 Stage 2 Efficacy & Safety Study

The VAT08 Phase 3 Stage 2 study is a randomized, double-blind, placebo-controlled trial investigating primary vaccination with a bivalent COVID-19 vaccine containing both parental (D614) and Beta strains. The results showed a 64.7% efficacy against symptomatic SARS-CoV-2 infection in adults, regardless of their SARS-CoV-2 infection status prior to vaccination, and 75.1% efficacy in participants previously infected with SARS-CoV-2. This study was the first ever to report efficacy data in an Omicron environment.

Across all the above-mentioned studies, the Sanofi-GSK bivalent next-generation vaccine candidate was well-tolerated, with an acceptable safety profile.

About BARDA support

Research and development for VidPrevtyn are supported by U.S. federal funds from the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services under Contract # HHSO100201600005I, and 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 the National Institute of Allergy and Infectious Diseases (NIAID).

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, 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. 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.

i https://www.sanofi.com/en/media-room/press-releases/2022/2022-06-24-05-29-02-2468538
ii https://www.sanofi.com/en/media-room/press-releases/2022/2022-06-13-05-30-00-2460833