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.

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

**Media Relations**

Sandrine Guendoul | +33 6 25 09 14 25 | sandrine.guendoul@sanofi.com
Victor Rouault | +33 6 70 93 71 40 | victor.rouault@sanofi.com
Sally Bain | +1 617 834 6026 | sally.bain@sanofi.com
Evan Berland | +1 215 432 0234 | evan.berland@sanofi.com

**Investor Relations**

Eva Schaefer-Jansen | +33 7 86 80 56 39 | eva.schaefer-jansen@sanofi.com
Arnaud Delépine | +33 6 73 69 36 93 | arnaud.delepine@sanofi.com
Corentine Driancourt | +33 6 40 56 92 21 | corentine.driancourt@sanofi.com
Felix Lauscher | +1 908 612 7239 | felix.lauscher@sanofi.com
Priya Nanduri | +1 617 764 6418 | priya.nanduri@sanofi.com
Nathalie Pham | +33 7 85 93 30 17 | nathalie.pham@sanofi.com
Sanofi Forward-Looking Statements

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