

VidPrevtyn Beta COVID-19 booster vaccine, developed by Sanofi and GSK, approved for use in Great Britain

 PUBLISHED DEC 21, 2022
BY [GSK](#)

For media and investors only

- SARS-CoV-2 spike protein (B.1.351 strain) vaccine is the first and only protein-based variant COVID-19 booster vaccine approved in Great Britain and the European Union
- Results show the SARS-CoV-2 spike protein (B.1.351 strain) vaccine demonstrated an immune response against all tested variants of concern¹

GSK plc (LSE/NYSE: GSK) has today announced the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) authorised Sanofi's SARS-CoV-2 spike protein (B.1.351 strain) vaccine for the prevention of COVID-19 disease in adults aged 18 and above in Great Britain, following the European Commission licence last month, which included Northern Ireland. This SARS-CoV-2 spike protein (B.1.351 strain) vaccine is indicated as a booster for active immunisation to prevent COVID-19 in adults who have previously received a mRNA or adenoviral COVID-19 vaccine, and the use of this vaccine should be in accordance with official recommendations¹.

The approval is based on results from two separate immunogenicity trials, including one comparative trial with an approved mRNA booster as a comparator^{1,2,3}. In these registrational immunogenicity trials, carried out at times when the Omicron variant was predominantly circulating, the vaccine induced a neutralising antibody response against all tested variants of concern.^{1,2,3} This vaccine is based on the Beta variant spike antigen and includes GSK's adjuvant. Across the registrational trials, the vaccine candidate was generally well-

tolerated, with an acceptable safety profile.¹

This booster vaccine was developed jointly by Sanofi and GSK.

Rebecca Catterick, General Manager, Sanofi Vaccines, UK & Ireland:

Today's approval validates our research in developing a novel solution for the COVID-19 pandemic. VidPrevtyn Beta will be an important new option to help protect populations against COVID-19.

Phil Dormitzer, Global Head of Vaccines R&D, GSK:

The approval from MHRA of our protein-based, adjuvanted vaccine is a vital step for providing further vaccine solutions to Great Britain this winter. Boosters have an important role in protecting people from COVID-19

COVID-19 continues to circulate in the UK and remains a public health concern. According to the Office for National Statistics, COVID-19 was the eighth-leading cause of death in England and the seventh leading cause in Wales as of October 2022⁴. Epidemiological analysis from the UK Health Security Agency indicates that Omicron BA.5 has become the dominant SARS-CoV-2 variant in the UK. As of November 2022, variant BA.5, including all sub-lineages, was found in more than 75% of all sequenced samples in the UK⁵.

The UK Health Security Agency reports increasing prevalence of COVID-19 this winter and recommends a booster for those at high risk of complications of COVID-19 infection⁶.

VidPrevtyn Beta is a monovalent, recombinant-protein COVID-19 vaccine developed by Sanofi, modelled on the Beta variant spike antigen and includes GSK's pandemic adjuvant. The same recombinant-protein technology is used in Sanofi's approved seasonal flu vaccines. The approval by the MHRA is valid in Great Britain only. This SARS-CoV-2 spike protein (B.1.351 strain) vaccine was approved via the European Commission (EC) Decision Reliance Route. The EU licence includes the territory of Northern Ireland.

About VAT00013 (COVIBOOST) Immunogenicity & Safety Study ^{1,2}

The independent COVIBOOST (VAT00013) study conducted by the

Assistance Publique – Hôpitaux de Paris (AP-HP) investigated Sanofi's SARS-CoV-2 spike protein (B.1.351 strain) vaccine following primary vaccination with two doses of COVID-19 mRNA vaccine (tozinameran). The SARS-CoV-2 spike protein (B.1.351 strain) vaccine generated a higher immune response (as measured by neutralising antibody titres) than the COVID-19 mRNA vaccine (tozinameran) booster or the Sanofi original vaccine candidate, both of which target the original D614 parent strain. In this study, which assessed 247 adult participants 18 years of age and older, all three vaccines elicited neutralising antibodies against the Omicron BA.1 variant, with highest responses generated by the SARS-CoV-2 spike protein (B.1.351 strain) Sanofi vaccine, one month after injection.

About the VAT00002 Immunogenicity & Safety Study 1,3

The Phase 3 VAT00002 Cohort 2 study included 543 participants 18 years of age or older boosted with Sanofi's SARS-CoV-2 spike protein (B.1.351 strain) vaccine following previous priming with mRNA or adenovector COVID-19 vaccines. Sanofi's SARS-CoV-2 spike protein (B.1.351 strain) vaccine induced (at day 15 following booster vaccination) a significant boost in neutralizing antibody titres as compared to pre-booster against multiple variants of concern (with Geometric Mean Titres Ratio (GMTR, fold increase) against the B.1.351 strain ranging from 38.5 to 72.3, and from 14.5 to 28.6 for the D614G strain in adults previously primed with mRNA or adenovector COVID-19 vaccines, respectively). In the VAT00002 cohort 2 study, adverse reactions were mostly mild to moderate, transient, and self-resolutive.

Research and development for Sanofi's SARS-CoV-2 spike protein (B.1.351 strain) vaccine 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 is the marketing authorisation holder. GSK contributes with its pandemic adjuvant.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2021, GSK's Q3 Results for 2022 and any impacts of the COVID-19 pandemic.

VidPrevtyl Beta – Summary of Product Characteristics (SmPC)
Available at: <https://www.ema.europa.eu/en/documents/product-information/vid...> Last accessed: December 2022 Assistance Publique – Hôpitaux de Paris (AP-HP). Randomized, Single-blinded, Multicenter Trial Comparing the Immune Response to a 2nd Booster Dose of COVID-19 mRNA Vaccine (Pfizer-BioNTech) or Sanofi /GSK B.1.351 Adjuvanted Vaccine in Adults (COVIBOOST) (VAT013). Data on File. Sanofi. Study of Recombinant Protein Vaccines With Adjuvant as a Primary Series and as a Booster Dose Against COVID-19 in Adults 18 Years of Age and Older (VAT00002) Cohort 2 Study. Data on File. Office for National Statistics (ONS). 23 November 2022. Monthly mortality analysis, England and Wales: October 2022. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeat...> Last accessed: December 2022 UK Health Security Agency (UKHSA). 25 November 2022. SARS-CoV-2 variants of concern and variants under investigation in England - Technical briefing 48. Available at: <https://assets.publishing.service.gov.uk/government/uploads/sy...> Last accessed: December 2022 National flu and COVID-19 surveillance reports, COVID-19 surveillance up until end of week 47. Available at: <https://www.gov.uk/government/news/national-flu-and-covid-19-s...> Last accessed: December 2022

Press release distributed by Wire Association on behalf of GSK, on Dec 21, 2022. For more information subscribe and [follow](#) us.

Media Assets

Embedded Media

Visit the [online press release](#) to interact with the embedded media.

<https://wireassociation.eu/newsroom/gsk/releases/en/vidprevtyn-beta-covid-19-booster-vaccine-developed-by-sanofi-and-gsk-approved-for-use-in-great-britain-1786>

GSK

Newsroom: <https://wireassociation.eu/newsroom/gsk>

Website: <https://www.gsk.com/>

Primary Email: corporate.media@gsk.com

Social Media

Facebook - <https://www.facebook.com/GSK>

Twitter - <http://twitter.com/GSK>

Youtube - <http://www.youtube.com/GSK>

Linkedin - <http://www.linkedin.com/company/glaxosmithkline>

Instagram - <https://www.instagram.com/gsk/>
