

Sanofi-GSK next-generation COVID-19 booster delivers strong immune response against variants of concern, including Omicron

- Next-generation booster vaccine candidate delivers immune boost in adults primed with mRNA vaccines; with a stronger immune response compared to Pfizer-BioNTech's Comirnaty booster vaccine
- Next-generation booster vaccine candidate demonstrates potential to protect against COVID-19 variants of concern, including Omicron BA.1 and BA.2, with a favorable safety and tolerability profile

Paris – June 13, 2022 – Sanofi today reports data from two trials, VAT02 Cohort 2 and COVIBOOST VAT013, conducted with its new next-generation COVID-19 **booster vaccine candidate modelled on the Beta variant** antigen and including GSK's pandemic adjuvant.

In the Phase 3 VAT02 Cohort 2 study, the **Sanofi-GSK next-generation vaccine candidate induced** (at day 15 post-immunization) **a significant boost in antibody titers above baseline against multiple variants of concern** (15-fold increase against D614 parent virus, 30-fold increase against Beta strain) **in adults previously primed with mRNA COVID-19 vaccines**. In particular against Omicron, preliminary data show a 40-fold increase against BA.1. The **Sanofi-GSK next-generation booster candidate generated double the number of neutralizing antibodies against Omicron BA.1 and BA.2** compared to the D614-based (original parent virus) booster.

In parallel, the independent COVIBOOST (VAT013) study conducted by the Assistance Publique – Hôpitaux de Paris (AP-HP) demonstrated that, following primary vaccination with two doses of Pfizer-BioNTech's *Comirnaty* vaccine, the **Sanofi-GSK next-generation booster candidate 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. The proportion of participants with at least a 10-fold increase in neutralizing antibody titers for the original D614 SARS-CoV-2 strain between day 0 and day 15 was:

- 76.1% (95% CI 64.5–85.4) for the Sanofi-GSK next-generation booster, vs
- 63.2% (95% CI 51.3–73.9) for the Pfizer BioNTech D614 booster, and
- 55.3% (95% CI 43.4–66.7) for the Sanofi-GSK D614 (first-generation parent booster candidate).

In this study, which included 247 subjects, all the three vaccines also elicited neutralizing antibodies against the Omicron BA.1 variant, with highest responses generated by the Sanofi-GSK next-generation candidate. Results of COVIBOOST study are available on a [pre-print server](#), pending publication in a peer-reviewed journal.

Across both studies, the Sanofi-GSK next-generation vaccine candidate was well-tolerated, with a favorable safety profile. In the VAT02 cohort 2 study, low numbers (less than 4%) of Grade 3 reactions were reported, all transient and non-severe.

Thomas Triomphe

Executive Vice President, Sanofi Vaccines

“COVID-19 keeps evolving and the combination of emergence of variants and waning immunity is likely to lead to the need for additional booster shots, at least in some populations. The Beta variant expresses similar mutations across multiple variants of concern, including Omicron,

making it a strong vaccine candidate to confer broad protection against multiple strains of COVID-19. Seeing the cross-neutralization data from the independent AP-HP study, we believe this next-generation booster could have an important role to play for public health vaccination campaigns. We look forward to submitting these data to global regulatory authorities.”

Sanofi and GSK have developed their next-generation booster candidate in parallel to ongoing regulatory reviews of their first-generation vaccine candidate. The totality of data supporting this next-generation booster vaccine will be submitted to regulatory authorities in the upcoming weeks, with the aim of making it available later this year.

About VATo2

The VAT02 booster study is an extension of the company’s phase 3 safety and immunogenicity study. In Cohort 1 of this study, participants previously vaccinated with the primary series of an authorized COVID-19 vaccine received a booster dose of the Sanofi-GSK adjuvanted recombinant vaccine candidate, using SARS-CoV-2 (D614) antigen. These data confirmed the vaccine candidate’s universal potential to boost neutralizing antibodies 18- to 30-fold across all vaccine platforms (mRNA, protein, adenovirus). Cohort 2 included 1,500 participants. VAT02 results will be published in a peer-reviewed journal at a later date.

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 COVIBOOST (VATo13) study

COVIBOOST is an independent study conducted by the Assistance Publique – Hôpitaux de Paris (AP-HP). It is a randomized, single-blinded, multicenter trial across 11 centers in France, which studies the immune response of the Sanofi-GSK first- and next-generation booster vaccine candidates (adjuvanted, recombinant protein) and that of a 3rd dose of the Pfizer-BioNTech vaccine Comirnaty, following two doses of Comirnaty received as primary vaccination. The study was funded by the French Ministry of Solidarity and Health and Sanofi.

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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