

Two combination vaccine candidates for prevention of influenza and COVID-19 granted Fast Track designation in the US

- First non-mRNA combination vaccine candidates that include two already licensed vaccines to prevent influenza and COVID-19 infections
- Two phase 1/2 clinical studies are ongoing to evaluate the safety profile and immune response induced by the combination vaccine candidates

Paris, December 11, 2024. The US Food and Drug Administration has granted Fast Track designation to two Sanofi combination vaccine candidates to prevent influenza and COVID-19 infections in individuals 50 years of age and older. Both candidates combine two already licensed and authorized vaccines with proven efficacy through randomized controlled studies, and with favorable tolerability.

The first combination vaccine candidate (NCT06695117) consists of the influenza protein-based trivalent vaccine Fluzone High-Dose combined with the adjuvanted recombinant Novavax COVID-19 vaccine. The second candidate (NCT06695130) combines the influenza recombinant protein-based trivalent vaccine Flublok with the Novavax COVID-19 vaccine.

Both Fluzone High-Dose and Flublok have been proven to prevent more influenza infections in older adults than standard-dose influenza vaccines in pivotal randomized clinical studies. Additionally, in real-world evidence studies they have demonstrated significant and consistent reductions in flu-related hospitalizations. The Novavax COVID-19 vaccine has been shown to have a better tolerability profile than currently available mRNA COVID-19 vaccines when administered as a booster dose. It has also demonstrated high efficacy against COVID-19 as primary vaccination in two pivotal phase 3 studies.

Thomas Triomphe

Executive Vice President, Vaccines, Sanofi

“Building on our immunology expertise and on 12 years of robust clinical and real-world data, we aim to continue leading the way in protection against flu and its severe outcomes. Our goal is to develop a combined flu and COVID-19 vaccine that offers simpler scheduling and fewer injections without compromising on the industry leading levels of efficacy, safety and tolerability of the standalone vaccines included in our combination vaccine.”

Fast Track designation was granted based on the potential for the combination vaccine candidates to address the significant individual and healthcare system burden of two serious illnesses that can result in hospitalization and death, particularly among older adults.

Sanofi has initiated two separate phase 1/2 parallel, randomized, modified double-blind, multi-arm studies (NCT06695117 and NCT06695130) to evaluate the safety and immune response induced by the two combination vaccine candidates.

About NCT06695117 and NCT06695130

The two combination vaccine candidates consist of:

- NCT06695117: TIV-HD (FLUZONE High-Dose) combined with NVXC19 (Novavax COVID-19 vaccine) to prevent Influenza subtype A, influenza subtype B and coronavirus (SARS CoV-2) infections in individuals 50 years of age or older.
- NCT06695130: RIV3 (FLUBLOK) combined with NVXC19 (Novavax COVID-19 vaccine) to prevent Influenza subtype A, influenza subtype B and coronavirus (SARS CoV-2) infection in individuals 50 years of age or older.

One recent systematic review and meta-analysis suggests a combination booster vaccine could increase the uptake of COVID-19 vaccines among the 50 years and above age group by 56%.

Combination vaccines may also be attractive to healthcare professionals conducting immunization programs as they may be easier and quicker to administer with fewer injections to protect against multiple diseases, less errors and decreased syringe and vial disposal requirements.

Influenza (flu) is a contagious, acute viral respiratory disease. Every year, there are an estimated 290,000 to 650,000 influenza-related respiratory deaths globally. In developed countries most deaths associated with flu occur in people aged 65 years or older.

Adults aged 65 or older account for most hospitalizations from flu. Among this population there is a higher hospitalization rate for flu with 2-fold longer average length of hospital stay than with younger adults. One quarter of patients are readmitted to hospital within 90-days post-discharge.

Flu can wreak havoc across major organ systems. It can lead to an 8-fold increased risk of stroke and pneumonia, a 10-fold increased risk of heart attack and among older adults hospitalized for flu, 1 in 5 experience a decline in their ability to independently undertake simple daily tasks, such as bathing, and dressing themselves.

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus. Most people infected with the virus will experience mild to moderate respiratory illness and recover without requiring special treatment. However, some will become seriously ill resulting in hospitalization and death.

Many individuals continue to experience long-term sequelae following COVID-19, also referred to as "long COVID". Long COVID symptoms can vary from mild to severe, potentially necessitating extensive medical attention, and may even lead to disability. A meta-analysis of 12 studies shows that 30% of COVID-19 patients have persistent symptoms two years after infection, the most common of which are fatigue, cognitive problems, and pain.

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 the world, 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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