Introductory Remarks for Nuvaxovid at September 2025 Advisory Committee on Immunization Practices (ACIP) Meeting

NUVAXOVID™ (COVID-19 Vaccine, Adjuvanted) is a recombinant protein COVID-19 vaccine, which is based on a well-established technology platform. It is the only non-mRNA protein-based vaccine available in the United States, providing Americans an important tool to protect themselves against COVID and ensure that they have choice in doing so.

In May, the FDA fully licensed Nuvaxovid based on pivotal Phase 3 clinical trial data that showed Nuvaxovid was safe and effective for the prevention of COVID-19. The product is indicated for adults 65 years and older and individuals ages 12 through 64 at higher risk for severe outcomes from COVID-19. The vaccine has also been fully approved by other regulatory authorities around the globe including the European Medicines Agency.

The ongoing safety and effectiveness of Nuvaxovid is our utmost priority. We continue to generate and share clinical and real-world evidence to support the ongoing use of Nuvaxovid. This data is shared with the scientific community, regulatory authorities, and the public in a variety of forums.

We have substantial post-marketing safety experience with Nuvaxovid with a database that includes over 5 million doses administered globally. There were no new safety signals identified for the 2023/2024 or 2024/2025 formula of Nuvaxovid. As with all our products, we continue to monitor and report to regulatory authorities any new or existing safety signals.

Starting this fall, Sanofi is responsible for the commercialization of Nuvaxovid. The product has a 6-month shelf life and has already begun shipping to healthcare providers and local retailers in the United States.

Sanofi looks forward to expanding awareness and access to Nuvaxovid to allow eligible individuals the availability of the nation's only protein-based, non-mRNA COVID-19 vaccine this fall.

NUVAXOVID is a vaccine to protect against COVID-19 for people who are:

- 65 years of age and older, or
- 12 years through 64 years of age at high risk for severe COVID-19

Vaccination with NUVAXOVID may not protect all people who receive the vaccine.

NUVAXOVID does not contain SARS-CoV-2, the virus that causes COVID-19.
NUVAXOVID cannot give you or your child COVID-19.

IMPORTANT SAFETY INFORMATION

You or your child should not get NUVAXOVID if you had a severe allergic reaction to a previous dose of NUVAXOVID or to any of its ingredients.

There is a remote chance that the vaccine could cause a severe allergic reaction, which would usually occur within a few minutes to one hour after getting a dose. For this reason, the vaccination provider may ask you or your child to stay at the place where you or your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include: difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body and/or dizziness and weakness.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received NUVAXOVID. The chance of having this occur is very low. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine: chest pain; shortness of breath; feelings of having a fast-beating, fluttering, or pounding heart.

Other side effects reported in clinical trials and/or post-approval use of NUVAXOVID include: Injection site reactions (pain/tenderness, swelling, redness and itching), fatigue or generally feeling unwell, muscle pain, headache, joint pain, nausea, vomiting, fever, chills, allergic reactions such as hives and swelling of the face, swollen lymph nodes, paresthesia (unusual feeling in the skin such as tingling or a crawling feeling), and hypoesthesia (decreased feeling or sensitivity, especially in the skin).

Please see full Prescribing Information for more details.

MAT-US-2511330-v1.0-09/2025