

# World Health Organization SAGE Issues Interim Recommendations for Novavax COVID-19 Vaccine

December 21, 2021

- WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommends primary two-dose vaccination series of NVX-CoV2373 in persons aged 18 and older

- SAGE recommends additional third dose of NVX-CoV2373 administered to immunocompromised persons

- Recommendation follows grant of WHO Emergency Use Listing for Novavax' vaccine

GAITHERSBURG, Md., Dec. 21, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that the World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) has published its interim [recommendations](#) for use of NVX-CoV2373, Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. The recommendations follow Emergency Use Listing (EUL) of the vaccine by WHO, which will be manufactured and marketed as Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) by Novavax in Europe and other markets, and as COVOVAX™ in India and licensed territories by the Serum Institute of India Pvt. Limited (SII).

"This interim recommendation from WHO provides helpful guidance for the use of our COVID-19 vaccine as countries that rely on EUL begin their own assessment and underscores the critical role that we expect the vaccine will play in the global fight against the coronavirus," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We look forward to delivering our recombinant protein-based vaccine to hundreds of millions of people around the world in partnership with our partner, Serum Institute of India."

WHO recommends the following:

- A 2-dose primary vaccination series of NVX-CoV2373 in persons aged 18 years and older administered 3-4 weeks apart, as well as administration of an additional dose of NVX-CoV2373 to immunocompromised persons between one and three months after dose 2 of the primary series;
- Use of the vaccine in specific populations, including persons with comorbidities, breastfeeding women, and those living with human immunodeficiency virus (HIV);
- Use of NVX-CoV2373 vaccine in pregnant women if the benefits of vaccination to the pregnant woman outweigh the potential risks; and
- Coadministration of an inactivated seasonal influenza vaccine and any dose of NVX-CoV2373 is acceptable.

The SAGE recommendation is based on the totality of preclinical and clinical trial data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19 which included 30,000 participants in the U.S. and Mexico, the results of which were published in [The New England Journal of Medicine \(NEJM\)](#); and a trial with 15,000 participants in the U.K., the results of which were also published in [NEJM](#). In both trials, NVX-CoV2373 demonstrated high efficacy and an acceptable safety and tolerability profile. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

The WHO EULs for Nuvaxovid and COVOVAX leverage Novavax' manufacturing partnership with SII, the world's largest vaccine manufacturer by volume, which will supply initial doses for the COVAX Facility. The EUL application for Nuvaxovid will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.

Novavax recently received [conditional marketing authorization](#) (CMA) for Nuvaxovid in the European Union, and Novavax and SII recently received emergency use authorization (EUA) for COVOVAX in [Indonesia](#) and the [Philippines](#). The vaccine is also currently under review by multiple regulatory agencies worldwide. The company expects to submit its complete chemistry, manufacturing and controls (CMC) data package to the U.S. FDA for review by the end of 2021. The brand name Nuvaxovid has not yet been authorized for use in the U.S. by the U.S. FDA.

Novavax' COVID-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 mcg antigen and 50 mcg Matrix-M adjuvant) given intramuscularly 21 days apart. The

vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels. The current assigned shelf-life of the vaccine is 9 months.

For more information on Nuvaxovid and COVOVAX, including the Summary of Product Characteristics, Prescribing Information and Important Safety Information, or to request additional information please visit the following websites:

- Novavax [global authorization website](#)
- [World Health Organization](#)
- [Serum Institute of India](#)

### **Emergency Use Listing of Nuvaxovid™ and COVOVAX™ by the World Health Organization**

The World Health Organization (WHO) has issued Emergency Use Listing for Nuvaxovid™ (SARS-CoV-2 rS vaccine [Recombinant, adjuvanted]), and COVOVAX/Recombinant Spike Protein of SARS-CoV-2 Virus 5 mcg for active immunization of individual 18 years of age and older for the prevention of coronavirus disease 2019 caused by SARS-CoV-2.

### **Important Safety Information**

- Nuvaxovid™ is contraindicated in persons who have a hypersensitivity to the active substance or to any of the excipients
- Events of anaphylaxis have been reported with administration of COVID-19 vaccines. Appropriate medical treatment and supervision should be available in case of an anaphylactic reaction
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress-related reactions may occur in association with vaccination as a response to the needle injection. It is important that precautions are in place to avoid injury from fainting
- Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection
- Give Nuvaxovid with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals
- The efficacy of Nuvaxovid may be lower in immunosuppressed individuals
- The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials
- Individuals may not be fully protected until 7 days after their second dose. As with all vaccines, vaccination with Nuvaxovid may not protect all vaccine recipients
- The most common adverse reactions observed during clinical studies (frequency category of very common ? 1/10), were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue and malaise

Please visit <https://www.novavaxcovidvaccine.com> for the full leaflet and adverse reaction reporting instructions.

### **Authorization in the U.S.**

NVX-CoV2373 has not yet been authorized for use in the U.S. and the trade name Nuvaxovid has not yet been approved by the U.S. FDA.

### **About NVX-CoV2373**

NVX-CoV2373 is a protein-based vaccine engineered from the genetic sequence of the first strain of SARS-CoV-2, the virus that causes COVID-19 disease. NVX-CoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and is formulated with Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

Novavax' COVID-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 mcg antigen and 50 mcg Matrix-M adjuvant) given intramuscularly 21 days apart. The vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide.

### **About the NVX-CoV2373 Phase 3 trials**

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

A trial conducted in the U.K. with 14,039 participants was designed as a randomized, placebo-controlled, observer-blinded study and achieved overall efficacy of 89.7%. The primary endpoint was based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

PREVENT-19, a trial in the U.S. and Mexico that enrolled almost 30,000 participants, achieved 90.4% efficacy overall. It was designed as a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%. The key secondary endpoint is the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints were assessed at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2. It was generally well-tolerated and elicited a robust antibody response in both studies.

### **About Matrix-M™ Adjuvant**

Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in local lymph nodes, boosting immune response.

### **About Novavax**

Novavax, Inc. (Nasdaq: NVAX) is a biotechnology company that promotes improved health globally through the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. The company's proprietary recombinant technology platform harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. NVX-CoV2373, the company's COVID-19 vaccine, received Conditional Marketing Authorization from the European Commission, Emergency Use Listing from the World Health Organization, Emergency Use Authorization in Indonesia and the Philippines, and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. These vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies.

For more information, visit [www.novavax.com](http://www.novavax.com) and connect with us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

### **Forward-Looking Statements**

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement the EUL application submitted to the WHO and, by the end of the year, to submit a complete CMC data package to the U.S. FDA, the potential impact of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, and Novavax' expected global delivery of NVX-CoV2373 are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax' Annual Report on Form 10-K for the year ended December 31, 2020 and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at [www.sec.gov](http://www.sec.gov) and [www.novavax.com](http://www.novavax.com), for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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