

Novavax Makes One Million Doses of Nuvaxovid™ Available for Use in the United Kingdom

September 27, 2022

GAITHERSBURG, Md., Sept. 27, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that an initial one million doses of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine are now available for use in the United Kingdom (U.K.). Nuvaxovid is the first protein-based COVID-19 vaccine granted authorization from the Medicines and Healthcare products Regulatory Agency (MHRA) and will be offered per the Joint Committee on Vaccination and Immunisation (JCVI) [advice](#).

"With U.K. data showing that people infected with both COVID-19 and the flu are more than five times as likely to die compared to someone with no infection¹, it is more important than ever to consider any vaccine offered to you by the National Health Service," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We continue to believe in the importance of a diversified national vaccine portfolio to reduce winter pressures on the health service."

Nuvaxovid was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike protein and is formulated with Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response. Nuvaxovid contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

The MHRA granted Conditional Marketing Authorization (CMA) for Nuvaxovid's use as a two-dose primary series vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults aged 18 and older in [February 2022](#), and in adolescents aged 12 through 17 in [August 2022](#). Novavax submitted a request to the MHRA for expanded CMA of Nuvaxovid as a booster in adults aged 18 and older on [June 1, 2022](#) and is awaiting a decision from the agency.

?This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you are concerned about an adverse event, it should be reported on a Yellow Card. Reporting forms and information can be found at <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting please include the vaccine brand and batch/Lot number if available.

Trade Name in the U.S.

The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration.

Important Safety Information: UK

- 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 following the administration of the vaccine. Close observation for at least 15 minutes is recommended and a second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Nuvaxovid.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress-related reactions may occur in association with vaccination as a psychogenic 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. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- Nuvaxovid should be given 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.
- Administration of Nuvaxovid in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.
- The effects with Nuvaxovid may temporarily affect the ability to drive or use machines.
- 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 were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

For more information on Nuvaxovid, including the Summary of Product Characteristics with Package Leaflet, adverse event reporting instructions, or to request additional information, please visit the following websites:

- [MHRA Regulatory approval of COVID-19 vaccine Nuvaxovid](#)
- [Novavax global authorization website](#)

About Nuvaxovid™ (NVX-CoV2373)

Nuvaxovid (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. The vaccine 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. Nuvaxovid contains purified protein antigen and can neither replicate, nor can it cause COVID-19.??

Nuvaxovid 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. Use of the vaccine should be in accordance with official recommendations.??

Novavax has established partnerships for the manufacture, commercialization, and distribution of Nuvaxovid worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India, the world's largest vaccine manufacturer by volume. They will later be supplemented with data from additional manufacturing sites throughout Novavax' global supply chain.

About the Novavax COVID-19 vaccine (NVX-CoV2373) Phase 3 Trials?

The Novavax COVID-19 vaccine (NVX-CoV2373) continues being evaluated in two pivotal Phase 3 trials.

PREVENT-19 (the?PRE-fusion protein subunit?Vaccine?Efficacy?Novavax?Trial | COVID-19) is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the efficacy, safety and immunogenicity of the Novavax COVID-19 vaccine with Matrix-M adjuvant in 29,960 participants 18 years of age and over in 119 locations in?the U.S.?and?Mexico. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least seven 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%. A secondary endpoint was 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. In the trial, the Novavax COVID-19 vaccine achieved 90.4% efficacy overall. It was generally well-tolerated and elicited a robust antibody response after the second dose in both studies. Full results of the trial were published in the?[New England Journal of Medicine](#)?(NEJM).?

The pediatric expansion of PREVENT-19 is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the safety, effectiveness, and efficacy of the Novavax COVID-19 vaccine with Matrix-M adjuvant in 2,247 adolescent participants 12 to 17 years of age in 73 locations in the United States, compared with placebo. In the pediatric trial, the vaccine achieved its primary effectiveness endpoint (non-inferiority of the neutralizing antibody response compared to young adult participants 18 through 25 years of age from PREVENT-19) and demonstrated 80% efficacy overall at a time when the Delta variant of concern was the predominant circulating strain in the U.S.?Additionally, immune responses were about two-to-three-fold higher in adolescents than in adults against all variants studied.?

Additionally, a trial conducted in the U.K. with 14,039 participants aged 18 years and over 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 seven days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline. Full results of the trial were published in?[NEJM](#).??

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. The Novavax COVID-19 vaccine, has received authorization from multiple regulatory authorities globally, including the U.S. Food and Drug Administration, the European Commission, and the WHO. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional indications and populations such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its COVID-19-Influenza Combination vaccine candidate in a Phase 1/2 clinical trial, its quadrivalent influenza investigational vaccine candidate, and an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent format Omicron-based / original strain-based vaccine. 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 and connect with us on [LinkedIn](#).

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NVX-CoV2373, NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, a COVID-seasonal influenza combination investigational vaccine candidate, its quadrivalent influenza investigational vaccine candidate, Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, the scope, timing and outcome of future regulatory filings and actions, including potential recommendations and authorizations from the MHRA, JCVI or any other regulatory authority, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents, and as a booster, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, the efficacy, safety intended utilization, and the expected administration 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, without limitation, 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; unanticipated challenges or delays in conducting clinical trials; 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; the emergence of variants of the SARS-CoV-2 virus that may negatively impact market acceptance or anticipated sales of NVX-CoV-2373; 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, 2021 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 statement. You are encouraged to read our filings with the SEC, available at www.sec.gov and www.novavax.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this statement 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.

References

1. Stowe J, et al. Interactions between SARS-CoV-2 and influenza and the impact of coinfection on disease severity: a test-negative design. International Journal of Epidemiology. 2021 Aug 30;50(4):1124-1133.

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