

Novavax Receives Full Marketing Authorization for Prototype COVID-19 Vaccine Nuvaxovid™ ? in United Kingdom

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- *Full authorization of prototype enables rapid authorization of updated Novavax COVID-19 vaccines in future*

GAITHERSBURG, Md., Oct. 18, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (U.K.) has granted full marketing authorization for its prototype COVID-19 vaccine Nuvaxovid™ ? (NVX-CoV2373) for individuals aged 12 and older for active immunization to help prevent COVID-19.

"Full marketing authorization of our prototype COVID-19 vaccine in the U.K. is a stepping stone to enable authorization of updated strains of our vaccine in the future," said John C. Jacobs, President and Chief Executive Officer, Novavax. "We are working with the MHRA to provide the information needed for the rapid review of our updated protein-based non-mRNA COVID-19 vaccine as an important step to ensuring access to vaccine options in the U.K. this coming vaccination season."

Authorization was based on two Phase 3 trials, PREVENT-19 conducted in the U.S. and Mexico and a Phase 3 trial in the U.K., as well as a Phase 2a/b trial in South Africa. In these trials, Novavax demonstrated the efficacy and safety of its prototype vaccine as a primary series in individuals aged 12 and older, and the immunogenicity and safety of the vaccine as a booster in individuals aged 18 and older.

?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.

i. Additional efficacy and safety data are being collected.

Trade Name in the U.S.

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

Important Safety Information: U.K.

- 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 Nuvaxovid. 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.
- There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.
- 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 (adverse reactions described in section 4.8 of the SPC) 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)

NVX-CoV2373 is a protein-based vaccine made by creating copies of the surface spike protein of SARS-CoV-2 that causes COVID-19. With Novavax's unique recombinant nanoparticle technology, the non-infectious spike protein serves as the antigen that primes the immune system to recognize the virus, while Novavax's Matrix-M adjuvant enhances and broadens the immune response. The vaccine is packaged as a ready-to-use liquid formulation and is stored at 2° to 8°C, enabling the use of existing vaccine supply and cold chain channels.

About the PREVENT-19 Phase 3 Trial

The PRE-fusion protein subunit Vaccine Efficacy Novavax Trial COVID-19 (PREVENT-19) was a randomized, placebo-controlled, observer-blinded Phase 3 trial conducted in the U.S. and Mexico to evaluate the efficacy and safety of NVX-CoV2373 as a primary series and as a booster in adults and adolescents to prevent SARS-CoV-2 infection. As a primary series, the primary endpoint was the first occurrence of polymerase chain reaction (PCR)-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least seven days after the second dose in 29,960 adult participants aged 18 and older at baseline without protocol violations prior to illness. A secondary endpoint was the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Full results of the trial were published in *the [New England Journal of Medicine](#)*

About the NVX-CoV2373 U.K. Phase 3 Trial

The primary endpoint in this phase 3, randomized, observer-blinded, placebo-controlled trial conducted in the United Kingdom (U.K.), was first occurrence of confirmed COVID-19 with onset at least seven days after the second vaccination. The trial enrolled 14,039 adult participants aged 18 and older. Full results were published in the *[New England Journal of Medicine](#)*.

About Matrix-M™ Adjuvant

When added to vaccines, Novavax's patented saponin-based Matrix-M adjuvant enhances the immune system response, making it broader and more durable. The Matrix-M adjuvant stimulates the entry of antigen-presenting cells at the injection site and enhances antigen presentation in local lymph nodes.

About Novavax

Novavax, Inc. (Nasdaq: NVAX) promotes improved health by discovering, developing and commercializing innovative vaccines to help protect against serious infectious diseases. Novavax, a global company based in Gaithersburg, Md., U.S., offers a differentiated vaccine platform that combines a recombinant protein approach, innovative nanoparticle technology and Novavax's patented Matrix-M adjuvant to enhance the immune response. Focused on the world's most urgent health challenges, Novavax is currently evaluating vaccines for COVID-19, influenza and COVID-19 and influenza combined. Please visit novavax.com and [LinkedIn](#) for more information.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the scope, timing and outcome of future regulatory filings and actions. 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; 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 or delays in obtaining regulatory authorization for its product candidates, including future COVID-19 variant strain changes; challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; 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's Annual Report on Form 10-K for the year ended December 31, 2022 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 and 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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