

# Novavax's Updated COVID-19 Vaccine? Authorized in the United Kingdom

January 24, 2024

GAITHERSBURG, Md., January 24, 2024 – Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that the United Kingdom's (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for Nuvaxovid XBB.1.5 dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted) (NVX-CoV2601) for active immunization to prevent COVID-19 in individuals aged 12 and older.

"Today's MHRA authorization is recognition of the role our vaccine can have in protecting the British public against COVID-19 this year," said John C. Jacobs, President and Chief Executive Officer, Novavax. "We are in ongoing conversations with additional U.K. partners to identify potential opportunities to offer our protein-based non-mRNA COVID-19 vaccine to all eligible individuals who want one. We believe this is critical to supporting long-term, broad uptake of a seasonal COVID-19 vaccine in the U.K."

Authorization was [based on non-clinical data](#) showing that Novavax's updated COVID-19 vaccine induced functional immune responses for XBB.1.5, XBB.1.16 and XBB.2.3 variants. Additional non-clinical data demonstrated that Novavax's vaccine induced neutralizing antibody responses to subvariants JN.1, BA.2.86, EG.5.1, FL.1.5.1 and XBB.1.16.6 as well as CD4+ polyfunctional cellular (T-cell) responses against EG.5.1 and XBB.1.16.6. These data indicate Novavax's vaccine can stimulate both arms of the immune system and induce a broad response against circulating variants.<sup>1,2</sup>

In clinical trials, the most common adverse reactions associated with Novavax's prototype COVID-19 vaccine (NVX-CoV2373) included headache, nausea or vomiting, muscle pain, joint pain, injection site tenderness, injection site pain, fatigue and malaise.

*i. Additional efficacy and safety data are being collected.*

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 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™ XBB.1.5 dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted) (NVX-CoV2601)**

NVX-CoV2601 is an updated version of Novavax's prototype COVID-19 vaccine (NVX-CoV2373) formulated to target the Omicron XBB.1.5 subvariant. It 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 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](https://www.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, including the availability of its updated XBB version of its Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) (NVX-CoV2601) and the timing of delivery and distribution of its vaccine 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 characterisation 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 authorisation for its product candidates, including its updated XBB version of its COVID-19 vaccine in time for the fall 2023 vaccination season or for future COVID-19 variant strain changes; challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of India Pvt. Ltd. for co-formulation and filling and the impact of any delays or disruptions in

their operations on the delivery of customer orders; challenges in obtaining commercial adoption of our updated protein-based non-mRNA XBB COVID-19 vaccine, NVX-CoV2373 or any COVID-19 variant strain-containing formulation; 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'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](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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**References:**

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2. Markov PV, Ghafari M, Beer M, et al. The evolution of SARS-CoV-2. *Nat Rev Microbiol*. 2023;21(6):361-379. doi:10.1038/s41579-023-00878-2.