

# Novavax's Updated Nuvaxovid™ COVID-19 Vaccine Receives Positive CHMP Opinion in the EU

October 31, 2023

- *Pending a European Commission decision, Novavax's vaccine will be the only updated protein-based non-mRNA COVID-19 vaccine available in Europe for individuals aged 12 and older*

GAITHERSBURG, Md., Oct. 31, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a global company advancing protein-based vaccines with its Matrix-M™ adjuvant, today announced that the Nuvaxovid™ XBB.1.5 dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted) (NVX-CoV2601) has been recommended for approval for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged 12 and older in the European Union by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency. The European Commission will review the CHMP recommendation and is expected to make a final decision in the coming days.

"Following the positive CHMP opinion and pending European Commission decision, Novavax will work closely with EU member states on our shared goal of delivering an updated protein-based non-mRNA COVID-19 vaccine in Europe," said John C. Jacobs, President and Chief Executive Officer, Novavax.

The CHMP positive opinion was [based on non-clinical data](#) showing that Novavax's updated COVID-19 vaccine induced functional immune responses against 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 newly emerging subvariants 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 may 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.

Novavax's vaccine is authorized for use in the [U.S.](#) and is currently under review in other markets.

## **NOVAVAX COVID-19 VACCINE, ADJUVANTED (2023-2024 FORMULA) AUTHORIZED USES**

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. Refer to the full Fact Sheet for information about the Novavax COVID-19 Vaccine, Adjuvanted.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

## **IMPORTANT SAFETY INFORMATION**

### **What should you mention to your vaccination provider before you or your child get the Novavax COVID-19 Vaccine, Adjuvanted?**

Tell your vaccination provider about all of your or your child's medical conditions, including if you or your child:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

### **Who should not get the Novavax COVID-19 Vaccine, Adjuvanted?**

A person should not get the Novavax COVID-19 Vaccine, Adjuvanted if they had:

- a severe allergic reaction after a previous dose of any Novavax COVID-19 Vaccine, Adjuvanted
- a severe allergic reaction to any ingredient of these vaccines

### **What are the risks of the Novavax COVID-19 Vaccine, Adjuvanted?**

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction 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 your body
- 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 the vaccine. In most of these people, symptoms began within 10 days following vaccination. 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

Side effects that have been reported in clinical trials with the Novavax COVID-19 Vaccine, Adjuvanted include:

- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site reactions: pain/tenderness, swelling, redness and itching
- General side effects: 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

Side effects that have been reported in post-authorization use with the Novavax COVID-19 Vaccine, Adjuvanted include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Paresthesia (unusual feeling in the skin such as tingling or a crawling feeling)
- Hypoesthesia (decreased feeling or sensitivity, especially in the skin)

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

### **What should I do about side effects?**

If you or your child experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider for any side effects that bother you or your child or do not go away.

Report vaccine side effects to the FDA and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 18008227967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Novavax, Inc., using the following contact information: Website: [www.NovavaxMedInfo.com](http://www.NovavaxMedInfo.com), Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

## **What about pregnancy or breastfeeding?**

If you or your child are pregnant or breastfeeding, discuss the options with your healthcare provider.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the Novavax COVID-19 Vaccine, Adjuvanted during pregnancy. Women who are vaccinated with the Novavax COVID-19 Vaccine, Adjuvanted during pregnancy are encouraged to enroll in the registry by visiting <https://c-viper.pregistry.com>.

## **Please see the [Fact Sheet for Recipients and Caregivers](#) for more information. [Reporting Adverse Events and Vaccine Administration Errors](#)**

- Adverse events can also be reported to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: <https://www.novavaxmedinfo.com/>, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

## **About Nuvaxovid™ XBB.1.5 2023-2024 Formula (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. 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](http://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 Novavax COVID-19 Vaccine, recombinant, adjuvanted (2023-2024 Formula) (NVX-CoV2601), its coordination with certain countries 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 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 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 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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