

# Novavax Submits Application to the U.S. FDA for Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted as a Booster in Adults Aged 18 and Older

August 15, 2022

- *If authorized, Novavax' vaccine would be the first protein-based COVID-19 booster for adults*
- *If authorized, the Novavax COVID-19 Vaccine, Adjuvanted could be used as a booster dose for adults aged 18 and older vaccinated with any other currently available COVID-19 vaccine*

GAITHERSBURG, Md., Aug. 15, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that it submitted an application to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of its protein-based COVID-19 Vaccine, Adjuvanted for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as a homologous and heterologous booster in adults aged 18 and older.

"It's important for people to have a choice as they evaluate how to stay protected against COVID-19, and boosters are an invaluable tool to build upon immunity obtained from previous vaccinations," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Based on the data presented to the FDA's VRBPAC and the CDC ACIP, we believe our vaccine offers a broad, long-lasting immune response against a range of variants."

This application for EUA is supported by data from Novavax' [Phase 3 PREVENT-19 trial](#) conducted in the United States and Mexico, and from the UK-sponsored COV-BOOST Phase 2 trial. As part of an open-label booster phase of the PREVENT-19 trial, a single booster dose of the Novavax COVID-19 Vaccine, Adjuvanted was administered to healthy adult participants at least six months after their primary two-dose vaccination series of the Novavax COVID-19 Vaccine, Adjuvanted. The third dose produced robust antibody responses comparable to or exceeding levels associated with the efficacy data in the primary series Phase 3 clinical trials. In the COV-BOOST trial, the Novavax COVID-19 Vaccine, Adjuvanted induced a significant antibody response when used as a heterologous third booster dose.

In the PREVENT-19 trial, following the booster, local and systemic reactions had a median duration of approximately two days. Safety reporting of reactogenicity events showed an increasing incidence across all three doses of the Novavax COVID-19 Vaccine, Adjuvanted, reflecting the increased immunogenicity seen with a third dose. Medically attended adverse events, potentially immune-mediated medical conditions, and severe adverse events occurred infrequently following the booster dose.

In the U.S., the FDA [granted EUA](#), followed by a [positive recommendation](#) from the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), and [endorsement](#) from the CDC for a two-dose primary series in adults aged 18 and older in [July](#). Doses of the Novavax COVID-19 Vaccine, Adjuvanted have been available for use in the U.S. since [July](#).

This project has been supported in part with federal funds from the Department of Health and Human Services (HHS); the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), through the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) under contract number MCDC2011-001.

## **Use of the Novavax COVID-19 Vaccine, Adjuvanted in the U.S.**

The Novavax COVID-19 Vaccine, Adjuvanted has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to provide a two-dose primary series to individuals 18 years of age and older to prevent Coronavirus Disease 2019 (COVID-19).

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.

## Authorized Use

The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) to provide a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

## IMPORTANT SAFETY INFORMATION

### Contraindications

Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted.

### Warnings and Precautions

**Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted. Monitor the Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to [the Centers for Disease Control \(CDC\) and Prevention guidelines](#).

**Myocarditis and Pericarditis:** Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of the Novavax COVID-19 Vaccine, Adjuvanted (*see Full EUA Prescribing Information*).

**Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

**Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.

**Limitations of Vaccine Effectiveness:** The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

### Adverse Reactions

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis.

Myocarditis, pericarditis, and anaphylaxis have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

### Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events (irrespective of attribution to vaccination),
- cases of Multisystem Inflammatory Syndrome (MIS), and
- cases of COVID-19 that results in hospitalization or death.

Complete and submit reports to VAERS online: <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Novavax COVID-19 Vaccine, Adjuvanted EUA" in the description section of the report.

To the extent feasible, report adverse events to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: [www.NovavaxMedInfo.com](http://www.NovavaxMedInfo.com), Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

***Please click to see the [Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccine Providers\) and EUA Full Prescribing Information](#).***

### **About the Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373)**

The Novavax COVID-19 Vaccine, Adjuvanted 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. The Novavax COVID-19 Vaccine, Adjuvanted contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

The Novavax COVID-19 Vaccine, Adjuvanted 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.

The PREVENT-19 trial is being conducted with support from the U.S. government, including the Department of Defense, BARDA, part of the Office of the Assistant Secretary for Preparedness and Response at the HHS, and the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health at HHS. BARDA is providing up to \$1.75 billion under a Department of Defense agreement (number MCDC2011-001). JPEO-CBRND is also providing funding of up to \$45.7 million under a separate agreement. To date, the U.S. government has agreed to order 3.2 million doses of the Novavax COVID-19 Vaccine, Adjuvanted. Novavax and the U.S. government will determine the timing, pricing, and amounts for delivery of any additional doses. Novavax intends to pursue additional U.S. procurement of both the Novavax COVID-19 Vaccine, Adjuvanted doses and other potential formulations.

Novavax has established partnerships for the manufacture, commercialization, and distribution of the Novavax COVID-19 Vaccine, Adjuvanted 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 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, Adjuvanted, the company's COVID-19 vaccine, has received authorization from multiple regulatory authorities globally, including in the U.S., European Union and with the World Health Organization. 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 a COVID-seasonal influenza combination vaccine candidate in a Phase 1/2 clinical trial, which combines the Novavax COVID-19 Vaccine, Adjuvanted and NanoFlu\*, its quadrivalent influenza investigational vaccine candidate, and is also evaluating 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](http://www.novavax.com) and connect with us on [LinkedIn](#).

\*NanoFlu identifies a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate produced by Novavax. This investigational candidate was evaluated during a controlled phase 3 trial conducted during the 2019-2020 influenza season.

### **Forward-Looking Statements**

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the potential for subsequent orders from the U.S. government for additional doses of NVX-CoV2373 and other potential formulations, the timing of clinical trial results, the ongoing development of NVX-CoV2373, NVX-CoV2515, a bivalent vaccine candidate and a COVID-seasonal influenza investigational combination vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including potential recommendations and authorizations from the CDC, Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents, and as a booster, the evolving

COVID-19 pandemic, 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 expected administration of NVX-CoV2373 and Novavax' other vaccine candidates 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; 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 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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