

# FDA Advisory Committee Recommends Emergency Use Authorization of Novavax COVID-19 Vaccine for People Aged 18 Years and Older

June 7, 2022

- *Novavax COVID-19 vaccine receives positive vote from U.S. Food and Drug Administration Vaccines and Related Biological Products Advisory Committee*
- *If Emergency Use Authorization is granted by the FDA, the Novavax COVID-19 vaccine would become the first protein-based COVID-19 vaccine available in the U.S.*

GAITHERSBURG, Md., June 7, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced the U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 21 to 0, with one abstention, to recommend that the FDA grant Emergency Use Authorization (EUA) for the Novavax COVID-19 vaccine (NVX-CoV2373) for individuals aged 18 years and over.

"The advisory committee's positive recommendation acknowledges the strength of our data and the importance of a protein-based COVID-19 vaccine developed using an innovative approach to traditional vaccine technology," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "In today's VRBPAC meeting, we heard the overwhelming support for our vaccine from physicians, healthcare organizations, and consumers who are eagerly anticipating a protein-based vaccine option. Consistent with submissions to regulatory authorities worldwide, we have already submitted an amendment with updated manufacturing information for the EUA to the FDA for review. We look forward to collaborating with the FDA as it makes its final decision."

The VRBPAC considered data from the pivotal Phase 3 clinical trial, PREVENT-19, which enrolled approximately 30,000 participants aged 18 years and older in the U.S. and Mexico and was published in the [New England Journal of Medicine](#). In the trial, the Novavax COVID-19 vaccine demonstrated 90.4% efficacy (95% confidence interval [CI], 82.9 to 94.6;  $P < 0.001$ ) with a reassuring safety profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups. The most common adverse reactions observed during the trial (frequency category of very common  $\geq 1/10$ ) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise. The data showed that overall the rate of myocarditis was balanced between the vaccine and placebo arms (0.007% and 0.005%) and in the post-crossover portions of Novavax trials the observed cases were all within the expected rate.

The FDA considers the recommendations of VRBPAC when making decisions on EUA.

The Novavax COVID-19 vaccine has received authorization for use in individuals aged 18 and over from more than 40 countries in addition to [Emergency Use Listing](#) from the World Health Organization.

## Authorization in the U.S.

The Novavax COVID-19 vaccine (NVX-CoV2373) has not yet been authorized for use in the U.S.

## About NVX-CoV2373

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<sup>TM</sup> adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

The Novavax COVID-19 vaccine 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 NVX-CoV2373 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 NVX-CoV2373 Phase 3 Trials**

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 NVX-CoV2373 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, NVX-CoV2373 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 NVX-CoV2373 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, NVX-CoV2373 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.

PREVENT-19 is being conducted with support from the U.S. government, including the Department of Defense, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (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 (# MCDC2011-001).

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. NVX-CoV2373, the company's COVID-19 vaccine, has received conditional authorization from multiple regulatory authorities globally, including the European Commission and the World Health Organization. The vaccine is currently under review by multiple regulatory agencies worldwide and will soon be under review in the U.S. for use in adults, 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 NVX-CoV2373 and NanoFlu\*, its quadrivalent influenza investigational vaccine candidate, and is also evaluating an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent 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 timing of clinical trial results, the ongoing development of NVX-CoV2373, including an Omicron strain based vaccine, a COVID-seasonal influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including the FDA's upcoming decision regarding EUA for Novavax' COVID-19 vaccine candidate, and Novavax' subsequent discussions with 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 potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, the efficacy, safety and intended utilization of NVX-CoV2373, and 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; 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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