

Novavax Submits Request to the U.S. FDA for Emergency Use Authorization of COVID-19 Vaccine

January 31, 2022

- NVX-CoV2373 demonstrated overall efficacy of ~90% in PREVENT-19 clinical trial conducted during the emergence of variant strains

GAITHERSBURG, Md., Jan. 31, 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 has submitted a request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) for NVX-CoV2373, its protein-based COVID-19 vaccine candidate for immunization of individuals 18 years of age and older against SARS-CoV-2.

The request for EUA is based on the totality of pre-clinical, clinical and manufacturing-related (CMC) data provided to the agency, including results of two large pivotal clinical trials that demonstrated an overall efficacy of approximately 90 percent and a reassuring safety profile.

"We're extremely proud of the work of our teams and we look forward to FDA's review of our EUA request. We believe our vaccine offers a differentiated option built on a well-understood protein-based vaccine platform that can be an alternative to the portfolio of available vaccines to help fight the COVID-19 pandemic," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "I'd like to also extend our thanks for the support of the U.S. Department of Health and Human Services and the U.S. Department of Defense for their partnership leading up to today's milestone of EUA request submission."

Novavax conducted two pivotal Phase 3 clinical trials: PREVENT-19 which enrolled approximately 30,000 participants in the U.S. and Mexico and published results in the [New England Journal of Medicine \(NEJM\)](#) and a trial with almost 15,000 participants in the U.K. which was also published in [NEJM](#). In both trials, the vaccine demonstrated efficacy 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 clinical studies (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed in authorized markets. As part of the PREVENT-19 trial, a booster study is ongoing to evaluate the safety and effectiveness of a third dose of the vaccine, as well as a study in adolescents aged 12-17.

NVX-CoV2373 has been granted conditional authorization by multiple regulatory agencies worldwide, including the European Commission, and emergency use listing (EUL) from the [World Health Organization \(WHO\)](#), with additional filings currently under review.

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. NVX-CoV2373 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. NVX-CoV2373 contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

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 (SII), 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 is being evaluated in two pivotal Phase 3 trials.

PREVENT-19, a trial in the U.S. and Mexico that enrolled almost 30,000 participants, achieved 90.4% efficacy overall. It was designed as a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 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%. The key secondary endpoint is 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. 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* \(NEJM\)](#).

A trial conducted in the U.K. with 14,039 participants 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 7 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*](#).

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 (NIAID), part of the National Institutes of Health (NIH) at HHS. BARDA is providing up to \$1.75 billion under a Department of Defense agreement.

About Matrix-M™ Adjuvant

Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and generally 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, received Conditional Marketing Authorization from the European Commission, Emergency Use Listing from the World Health Organization, Emergency Use Authorization in Indonesia and the Philippines, and has been submitted for regulatory authorization in multiple markets globally.

For more information, visit www.novavax.com and connect with us [LinkedIn](#).

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement authorizations with data from the additional manufacturing sites in Novavax' global supply chain, the potential impact of Novavax and NVX-CoV2373 in addressing vaccine access, offering an alternative to existing COVID-19 vaccines, controlling the pandemic and protecting populations, and the efficacy, safety and intended utilization 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 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 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, 2020 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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