

# Novavax Receives Positive European Medicines Agency Recommendation for Conditional Marketing Authorization of its COVID-19 Vaccine

December 20, 2021

- *European Commission decision on conditional marketing authorization expected imminently*
- *Upon authorization, Nuvaxovid™ (also known as NVX-CoV2373) will be the first protein-based COVID-19 vaccine available in Europe*

GAITHERSBURG, Md., Dec. 20, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that the European Medicines Agency (EMA) [has recommended](#) granting a conditional marketing authorization for Novavax' COVID-19 vaccine (also known as NVX-CoV2373) to prevent COVID-19 in people from 18 years of age and older. Upon authorization, NVX-CoV2373 will be marketed in the European Union (E.U.) as Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted).

"Novavax appreciates the CHMP's positive opinion concerning our vaccine, and we look forward to a decision from the European Commission," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "An authorization from the Commission would deliver the first protein-based vaccine to the E.U. during a critical time when we believe having choice among vaccines will lead to increased immunization."

The EMA recommendation follows a positive CHMP opinion based on an expedited review of the totality of manufacturing, preclinical, and clinical trial data submitted by the company, with the conclusion that the vaccine meets the stringent criteria set by the E.U. for efficacy, safety and quality. This included data from two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled almost 30,000 participants in the U.S. and Mexico, and achieved an overall efficacy of 90.4%, the results of which were published in the [New England Journal of Medicine \(NEJM\)](#); and a trial with more than 14,000 participants in the U.K. that achieved an overall efficacy of 89.7%, the results of which were also published in [NEJM](#). In both trials, NVX-CoV2373 demonstrated high efficacy and a reassuring safety and tolerability profile.

Novavax and the European Commission [announced](#) an advance purchase agreement (APA) for up to 200 million doses of Novavax' COVID-19 vaccine in August 2021. This filing leverages Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, which will supply initial doses for the E.U. It will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.

Novavax and SII recently received emergency use authorization (EUA) in [Indonesia](#) and the [Philippines](#), where it will be commercialized by SII under the trade name Covovax™. The companies also received emergency use listing for Covovax from the [World Health Organization](#). The vaccine is also currently under review by multiple regulatory agencies worldwide, and the company expects to submit its complete chemistry, manufacturing and controls (CMC) data package to the U.S. Food and Drug Administration (FDA) by the end of the year.

The brand name Nuvaxovid™ has not yet been authorized for use in the U.S. by the FDA.

## **Authorization in the U.S.**

NVX-CoV2373 has not been authorized for use in the U.S. and the trade name Nuvaxovid has not yet been approved by the U.S. FDA.

## **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.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide.

### **About the NVX-CoV2373 Phase 3 trials**

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

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.

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 in both studies.

### **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, received Emergency Use Authorization in Indonesia and the Philippines and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial. 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 [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

### **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 potential for conditional marketing authorization of NVX-CoV2373 to increase immunization and the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement the conditional marketing authorization submitted to the EMA and, by the end of the year, to submit a complete CMC data package to the U.S. FDA 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](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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