

# Novavax Initiates Pediatric Expansion for Phase 3 Clinical Trial of COVID-19 Vaccine

May 3, 2021

GAITHERSBURG, Md., May 3, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that it has initiated a pediatric expansion of its Phase 3 clinical trial for NVX-CoV2373, the company's recombinant protein vaccine candidate against COVID-19. The additional arm of the ongoing PREVENT-19 pivotal trial will evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 in up to 3,000 adolescents aged 12-17 across up to 75 sites in the United States.

Participants will randomly receive either the vaccine candidate or placebo in two doses, administered 21 days apart. Two-thirds of volunteers will receive intramuscular injections of the vaccine and one-third will receive placebo. A blinded crossover is planned to take place six months after the initial set of vaccinations to ensure that all trial participants receive active vaccine. Participants will be monitored for safety for up to two years following the final dose.

"Through the expansion of our PREVENT-19 clinical trial, we hope to build upon the encouraging safety and efficacy data generated to-date in adults for our vaccine candidate and to play a significant global role in offering vaccination to as many people as possible across age groups to end the suffering caused by the pandemic," said Gregory M. Glenn, M.D., President, Research and Development, Novavax.

Dr. Glenn will share an update regarding this arm of the PREVENT-19 trial during the 21<sup>st</sup> annual World Vaccine Congress taking place online, May 4-6. He will participate in two sessions during the congress, including a presentation and a panel discussion. Details are as follows:

## Morning Plenary:

**Date:** Tuesday, May 4

**Time:** 9:10am – 10:40am EST

**Title:** Safety, efficacy, and uptake of COVID-19 vaccines

**Moderator:** Jakob Cramer, M.D., Head of Clinical Development, CEPI

## Afternoon Session: COVID-19: Vaccine Response & Approaches

**Date:** Tuesday, May 4

**Time:** 3:30pm – 3:45pm EST

**Title:** Novavax COVID-19 Program Update

To register, please visit the World Vaccine Congress website [here](#). Dr. Glenn's presentation slides will be posted to the company's website following the presentation [here](#).

## **About NVX-CoV2373**

NVX-CoV2373 is a protein-based vaccine candidate 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 adjuvanted with Novavax' patented saponin-based Matrix-M™ 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. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial in the U.K. that demonstrated 100% protection against severe disease, efficacy of 96.4% against the original virus strain, 86.3% against the B.1.1.7/501Y.V1 variant and 89.7% overall; and the PREVENT-19 trial in the U.S. and Mexico that began in December 2020. It is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 100% protection against severe disease and 48.6% efficacy against a newly emerging escape variant first described in South Africa, and a Phase 1/2 continuation in the U.S. and Australia.

NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

#### **About Matrix-M™**

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 combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax?is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults and will be advanced for regulatory submission. Both 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](#) and [LinkedIn](#).

#### **Novavax Forward Looking Statements**

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2020, 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 [sec.gov](http://sec.gov), 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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