

# Novavax Announces Initiation of COVID-19 Vaccine Booster Study in Adolescents in Phase 3 PREVENT-19 Trial

April 22, 2022

- *PREVENT-19 trial participants aged 12 through 17 receive third dose of NVX-CoV2373*
- *Continuation of pediatric expansion in adolescents of PREVENT-19 Phase 3 trial will evaluate safety and immunogenicity of a booster dose*

GAITHERSBURG, Md., April 22, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, has initiated administration of the first booster doses of NVX-CoV2373, the company's protein-based COVID-19 vaccine, in the pediatric expansion of the PREVENT-19 pivotal Phase 3 clinical trial. The study will evaluate the safety and immunogenicity of a third dose of NVX-CoV2373 among trial participants aged 12 through 17.

"We see the ongoing need for alternative vaccine options because we are continuing to monitor spikes in COVID-19," said Gregory M. Glenn, M.D., President, Research and Development, Novavax. "The expansion of our PREVENT-19 booster trial into the pediatric population reinforces our commitment to seek to make our vaccine available to a broader population."

All PREVENT-19 trial participants aged 12 through 17 are now eligible to receive a third booster dose of NVX-CoV2373. The booster dose is identical to the active vaccine previously administered to the participants in a two-dose regimen (5 micrograms of recombinant spike protein plus 50 micrograms of Matrix-M™ adjuvant) and may be administered at least five months after receipt of active vaccine. Post-booster objectives include the assessment of the humoral immune response 28 days after the administration of the booster dose, as well as describing COVID-19 disease. Initial results are expected during the second half of 2022.

Findings from the pediatric expansion of the PREVENT-19 pivotal Phase 3 trial were announced in [February](#).

## Authorization in the U.S.

NVX-CoV2373 has not yet been authorized for use in the U.S. by the U.S. Food and Drug Administration.

## 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, 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 (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 older 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 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%. 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\* \(NEJM\)](#).

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.

Additionally, a trial conducted in the U.K. with 14,039 participants aged 18 years and older 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\*](#).

### **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 also under review by multiple regulatory agencies worldwide. In addition to its COVID-19 vaccine, Novavax is evaluating a COVID-seasonal influenza combination vaccine in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and its quadrivalent influenza investigational vaccine candidate previously known as NanoFlu\*. 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, including the PREVENT-19 booster study in adolescents results expected during the second half of 2022, the ongoing development of NVX-CoV2373, including its COVID-19-influenza combination vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, additional worldwide authorizations of NVX-CoV2373, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, 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, 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; 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, 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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