

Novavax Announces Initiation of PREVENT-19 Pivotal Phase 3 Efficacy Trial of COVID-19 Vaccine in the United States and Mexico

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GAITHERSBURG, Md., Dec. 28, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced initiation of PREVENT-19, its pivotal Phase 3 study in the United States and Mexico to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373, the Company's COVID-19 vaccine candidate. The trial builds on research from Phase 1/2 studies demonstrating that the vaccine provoked a robust immune response, generated highly neutralizing antibodies against the virus and was generally well-tolerated.

"With the COVID-19 pandemic raging around the globe, this trial is a critical step in building the global portfolio of safe and effective vaccines to protect the world's population," said Stanley C. Erck, president and chief executive officer, Novavax. "We thank our colleagues and partners who continue to work with us to urgently advance our commercial-scale manufacturing processes, and we are grateful for the hard work and assistance from Operation Warp Speed, the U.S. FDA and the government of Mexico on this program."

NVX-CoV2373 contains a full-length, prefusion spike protein made using Novavax' recombinant nanoparticle technology and the company's proprietary saponin-based Matrix-M™ adjuvant. The purified protein is encoded by the genetic sequence of the SARS-CoV-2 spike (S) protein and is produced in insect cells. It can neither cause COVID-19 nor can it replicate, is stable at 2°C to 8°C and is shipped in a ready-to-use liquid formulation that permits distribution using standard vaccine supply chain channels.

PREVENT-19 is being conducted with support from [Operation Warp Speed](#) partners, including the Department of Defense and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response. BARDA is also providing up to \$1.6 billion under a Department of Defense agreement (identifier MCDC OTA agreement number W15QKN-16-9-1002).

The [company is also](#) currently conducting a large pivotal Phase 3 clinical study in the United Kingdom (U.K.), a Phase 2b safety and efficacy study in South Africa, and an ongoing Phase 1/2 trial in the U.S. and Australia. Data from these trials are expected as soon as early first quarter 2021, although timing depends on transmission rates in the regions.

About the PREVENT-19 Phase 3 Study

PREVENT-19 (the PRE-fusion protein subunit Vaccine Efficacy Novavax Trial | COVID-19) is a randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M in up to 30,000 subjects 18 years of age and older compared with placebo. The trial design has been harmonized to align with other Phase 3 trials conducted under the auspices of Operation Warp Speed, including the use of a single external independent Data and Safety Monitoring Board to evaluate safety and conduct an unblinded review when predetermined interim analysis events are reached.

The trial's primary endpoint is the prevention of PCR-confirmed, symptomatic COVID-19. The key secondary endpoint is the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints will be assessed at least seven days after the second study vaccination in volunteers who have not been previously infected with SARS-CoV-2.

Two thirds of the participants will be assigned to randomly receive two intramuscular injections of the vaccine, administered 21 days apart, while one third of the trial participants will receive placebo. Trial sites were selected in locations where transmission rates are currently high, to accelerate the accumulation of positive cases that could show efficacy.

The primary efficacy analysis is event-driven, based on the number of participants with symptomatic mild, moderate or severe COVID-19 disease. Participants will be followed for 24 months following the second injection.

Enrollment and Study Population

Information about the trial and how to enroll in PREVENT-19 is available on clinicaltrials.gov under trial identifier NCT04611802 and www.Novavax.com/PREVENT-19.

Novavax plans to recruit, enroll, and study a diverse population with an emphasis on communities and demographic groups most impacted by the disease as well as to maximize participation of older adults and those living with co-morbid conditions (e.g., obesity, hypertension and diabetes) that place them at higher risk of complications from COVID-19. Enrollment goals are:

- ? 25 percent of the study population is intended to be in the 65 years of age or older group
- ? 15 percent black/African American
- 10-20 percent LatinX
- 1-2 percent American Indian

“We are encouraged by the data generated to-date on NVX-CoV2373 and are optimistic about our ability to positively build on the body of evidence with this trial,” said Gregory M. Glenn, M.D, president of research and development, Novavax. “We recognize that volunteers considering our trial may have questions about the potential impact on their ability to receive an authorized vaccine when it becomes available to them. We wish to reassure participants that we are working to ensure that their involvement in our trial does not negatively impact their ability to be vaccinated at the appropriate time.”

Many of the trial sites participating in PREVENT-19 are part of the NIAID-supported COVID-19 Prevention Network (CoVPN), which includes existing NIAID-supported clinical research networks with infectious disease expertise and was designed for rapid and thorough evaluation of vaccine candidates and monoclonal antibodies for preventing COVID-19.

“This trial underscores the importance of private/public partnerships in solving the need for globally available vaccines to interrupt the ongoing COVID-19 epidemic,” said Larry Corey, M.D., virologist at the Fred Hutchinson Cancer Research Center and co-leader of the CoVPN.

In the interest of transparency and scientific exchange and to demonstrate the rigor with which the study is being executed, Novavax has posted the Phase 3 trial protocol on its website at novavax.com/resources.

For further information, including media-ready images, b-roll, downloadable resources and more, click [here](#).

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence 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. It 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 block binding of spike protein to cellular receptors and provided protection from infection and disease. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing.

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 late-stage 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 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, 2019, and Quarterly Report on Form 10-Q for the period ended September 30, 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, 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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