Novavax Completes Enrollment of PREVENT-19, COVID-19 Vaccine Pivotal Phase 3 Trial in the United States and Mexico

PREVENT-19 enrolls 30,000 volunteers across 118 sites in the U.S. and Mexico

GAITHERSBURG, Md., Feb. 22, 2021 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the complete enrollment of PREVENT-19, its pivotal Phase 3 study in the United States and Mexico to evaluate the efficacy, safety and immunogenicity of the company's COVID-19 vaccine. Novavax has previously reported positive interim efficacy results of NVX-CoV2373, its recombinant protein-based vaccine candidate, in an ongoing Phase 3 clinical trial taking place in the United Kingdom.

"The full enrollment of PREVENT-19 is another important step in building a body of evidence to demonstrate that NVX-CoV2373 will be safe and effective across diverse, representative populations," said Gregory M. Glenn, President of Research and Development, Novavax. "We thank the thousands of volunteers and individuals, including our partners at NIH, the COVID-19 Prevention Network and trial sites in the U.S. and Mexico, who enabled rapid recruitment and enrollment in the trial, which we believe is a critical aspect to building vaccine trust and uptake across the globe."

PREVENT-19 was planned with specific recruitment diversity and representation goals and enrolled 30,000 volunteers. Location of trial sites emphasized communities and demographic groups most impacted by the disease, including those living with co-morbid conditions that place them at higher risk of complications from COVID-19. The trial largely reached its demographic goals amid the concurrent rollout of vaccines authorized for emergency use.

The trial enrolled diverse participants as follows:

- LatinX: 20%
- African American: 13%
- Native American: 6%
- Asian American: 5%
- Older adults (65 years and older): 13%

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

PREVENT-19 is being conducted with support from the U.S. government partnership (formerly Operation Warp Speed), which includes the Department of Defense, 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, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS. BARDA is also providing up to $1.75 billion under a Department of Defense agreement.

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 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 block binding of the spike protein to cellular

receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing. NVX-CoV2373 is currently being evaluated in two pivotal Phase 3 trials: a trial in the U.K that demonstrated 89.3 percent overall efficacy and 95.6 percent against the original strain in a post-hoc analysis, and the PREVENT-19 trial in the U.S. and Mexico that began in December. It is also being tested in two ongoing Phase 2 studies that began in August: A Phase 2b trial in South Africa that demonstrated 50-60 percent efficacy against newly emerging escape variants, and a Phase 1/2 continuation in the U.S. and Australia.

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. Novavaxis 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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