



Novavax Initiates Phase 3 Efficacy Trial of COVID-19 Vaccine in the United Kingdom

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Clinical trial to enroll up to 10,000 volunteers across the UK to assess whether NVX-CoV2373 is effective in the prevention of COVID-19

GAITHERSBURG, Md., Sept. 24, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that it has initiated its first Phase 3 study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373, Novavax' COVID-19 vaccine candidate. The trial is being conducted in the United Kingdom (UK), in partnership with the UK Government's Vaccines Taskforce, and is expected to enroll and immunize up to 10,000 individuals between 18-84 (inclusive) years of age, with and without relevant comorbidities, over the next four to six weeks.

"With a high level of SARS-CoV-2 transmission observed and expected to continue in the UK, we are optimistic that this pivotal Phase 3 clinical trial will enroll quickly and provide a near-term view of NVX-CoV2373's efficacy," said Gregory M. Glenn, M.D., President, Research and Development at Novavax. "The data from this trial is expected to support regulatory submissions for licensure in the UK, EU and other countries. We are grateful for the support of the UK Government, including from its Department of Health and Social Care and National Institute for Health Research, to advance this important research."

NVX-CoV2373 is a stable, prefusion protein made using Novavax' recombinant protein nanoparticle technology that includes Novavax' proprietary MatrixM™ adjuvant. The vaccine has a favorable product profile that will allow handling in an unfrozen, liquid formulation that can be stored at 2°C to 8°C, allowing for distribution using standard vaccine channels.

Novavax has continued to scale-up its manufacturing capacity, currently at up to 2 billion annualized doses, once all capacity has been brought online by mid-2021.

About the Phase 3 Study

Consistent with its long-standing commitment to transparency and in order to enhance information-sharing during the worldwide pandemic, Novavax will be publishing its UK study protocol in the coming days.

The UK Phase 3 clinical trial is a randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M in up to 10,000 subjects aged 18 to 84 years. Half the participants will receive two intramuscular injections of vaccine comprising 5 µg of protein antigen with 50 µg Matrix-M adjuvant, administered 21 days apart, while half of the trial participants will receive placebo.

The trial is designed to enroll at least 25 percent of participants over the age of 65 as well as to prioritize groups that are most affected by COVID-19, including racial and ethnic minorities. Additionally, up to 400 participants will also receive a licensed seasonal influenza vaccine as part of a co-administration sub-study.

The trial has two primary endpoints. The first primary endpoint is first occurrence of PCR-confirmed symptomatic COVID-19 with onset at least 7 days after the second study vaccination in volunteers who have not been previously infected with SARS-CoV-2. The second primary endpoint is first occurrence of PCR-confirmed symptomatic moderate or severe COVID-19 with onset at least 7 days after the second study vaccination in volunteers who have not been previously infected with SARS-CoV-2. The primary efficacy analysis will be an event-driven analysis based on the number of participants with symptomatic or moderate/severe COVID-19 disease. An interim analysis will be performed when 67% of the desired number of these cases has been reached.

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

About NVX-CoV2373

NVXCoV2373 is a vaccine candidate engineered from the genetic sequence of SARSCoV2, the virus that causes COVID-19 disease. NVXCoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and contains Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. NVX-CoV2373 contains purified protein antigens and cannot replicate, nor can it cause COVID-19. In preclinical trials, NVXCoV2373 demonstrated indication of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In its Phase 1 portion of its Phase 1/2 clinical trial, NVXCoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. NVX-CoV2373 is also being evaluated in two ongoing Phase 2 studies, which began in August; a Phase 2b trial in South Africa, and a Phase 1/2 continuation in the U.S. and Australia. Novavax has secured \$2 billion in funding for its global coronavirus vaccine program, including up to \$388 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

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. Novavax is undergoing 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. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

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 8-K for the period ended June 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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The logo for Novavax, featuring the word "NOVAVAX" in a bold, blue, sans-serif font.

Source: Novavax, Inc.