

Novavax Initiates Phase 2 Portion of Phase 1/2 Clinical Trial of COVID-19 Vaccine

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GAITHERSBURG, Md., Aug. 24, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that the first volunteers have been enrolled in the Phase 2 portion of its ongoing clinical trial to evaluate the immunogenicity and safety of NVX-CoV2373, Novavax' COVID-19 vaccine candidate. The Phase 2 clinical trial expands on the age range of the Phase 1 portion by including older adults 60-84 years of age as approximately 50 percent of the trial's population. NVX-CoV2373 is a stable, prefusion protein made using Novavax' nanoparticle technology and includes Novavax' proprietary Matrix-M™ adjuvant.

"We expect this Phase 2 portion of the trial to expand on the encouraging Phase 1 safety and immunogenicity data for NVX-CoV2373, and we will now look for robust immune responses in older adults," said Gregory M. Glenn, M.D., President, Research and Development at Novavax. "Our Phase 3 trial of NanoFlu, which we reported in March of 2020, provided us with a deep understanding of the unique needs of older adults, who are particularly vulnerable to COVID-19. We know that the world is closely watching all of these trials, and we anticipate interim data from this trial in the fourth quarter of this year."

The Phase 2 portion of the ongoing Phase 1/2 clinical trial is a randomized, placebo-controlled, observer-blinded study to evaluate the safety and immunogenicity of NVX-CoV2373 with Matrix-M in subjects aged 18 to 84 years. The clinical trial will assess two dose sizes (5 and 25 µg), each with 50 µg of Matrix-M. Although the trial was designed to confirm immunogenicity and safety in adults, secondary objectives include preliminary evaluation of efficacy. The study is targeting enrollment of up to 1,500 healthy volunteers, with approximately 50 percent of participants ≥60 years of age, at up to 40 sites in the U.S. and Australia

The trial is supported by funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

In the Phase 1 portion of the Phase 1/2 clinical trial, conducted in Australia, NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. These data have been submitted for peer-review to a scientific journal and are posted online at the preprint server medRxiv.org.

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

About NVX-CoV2373

NVX-CoV2373 is a 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 contains Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. In preclinical trials, NVX-CoV2373 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 data of the Phase 1/2 clinical trial, NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. Phase 2 clinical trials began in August. 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.

NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera in its Phase 1 data of the Phase 1/2 clinical trial. 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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