Novavax Initiates Efficacy Trial of COVID-19 Vaccine in South Africa

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GAITHERSBURG, Md., Aug. 17, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the beginning of a Phase 2b clinical trial in South Africa to evaluate the efficacy of NVX-CoV2373, Novavax' COVID-19 vaccine candidate. Dr. Shabir Madhi, Professor of Vaccinology at Wits University, will lead the clinical trial, which is supported in part by a $15 million grant from the Bill & Melinda Gates Foundation. NVX?CoV2373 is a stable, prefusion protein made using Novavax' proprietary nanoparticle technology and includes Novavax' proprietary Matrix?M™ adjuvant.

"Because South Africa is experiencing a winter surge of COVID-19 disease, this important Phase 2b clinical trial has the potential to provide an early indication of efficacy, along with additional safety and immunogenicity data for NVX-CoV2373," said Gregory M. Glenn, M.D., President, Research and Development at Novavax. "We appreciate the continued support of the Bill & Melinda Gates Foundation and CEPI, and our strong ongoing collaboration with Wits University, all of whom are united with us in our commitment to produce and deliver a safe, effective vaccine across the globe."

The randomized, observer-blinded, placebo-controlled Phase 2b clinical trial of NVX-CoV2373 will include two cohorts. One cohort will evaluate efficacy, safety and immunogenicity in approximately 2,665 healthy adults. The second cohort will evaluate safety and immunogenicity in approximately 240 medically stable, HIV-positive adults. This allows for evaluation of the vaccine across a diverse, representative study population. Novavax expects that, if approved in South Africa, its COVID-19 vaccine would ultimately be supplied to South Africa through Novavax' recently announced collaboration with the Serum Institute of India.

"The major motivation for the COVID-19 vaccines being evaluated at an early stage in South Africa is to generate evidence in the African context on how well these vaccines work in settings such as our own," said Shabir Madhi, M.B.B.C.H., FCPaeds, Ph.D. "I am pleased to work with Novavax as the principal investigator in this clinical trial, following Novavax' COVID-19 vaccine's positive Phase 1 data, which provides strong rationale for moving development forward in a larger subset of adults."

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 to the U.S. Food and Drug Administration (FDA) and an independent safety monitoring committee, and have also been submitted for peer-review to a scientific journal and are posted online at the preprint server medRxiv.org. Novavax intends to initiate the Phase 2 portion of this trial in the U.S. and Australia in the near future. This trial will include approximately 1,500 subjects and will include older adults.

The Coalition for Epidemic Preparedness Innovations (CEPI) is funding the manufacturing of doses of NVX-CoV2373 for this Phase 2b clinical trial.

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 will begin 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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