Novavax COVID-19 Vaccine Granted Fast Track Designation by U.S. FDA

November 9, 2020

GAITHERSBURG, Md., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for NVX-CoV2373, the Company's COVID-19 vaccine candidate. Currently in late-phase clinical development, NVXCoV2373 is a stable, prefusion protein made using Novavax' nanoparticle technology and includes its proprietary MatrixM™ adjuvant.

"The FDA's decision to grant Fast Track Designation for NVX-CoV2373 reflects the urgent need for a safe and effective vaccine to prevent COVID-19, and we look forward to working closely with the agency to accelerate access to this vaccine," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "While the regulatory review of this clinical program will be expedited, Novavax remains committed to a data-driven and scientifically rigorous approach in demonstrating safety and efficacy, which we believe will support confidence in the vaccine in the U.S. and globally."

Novavax expects to begin its pivotal Phase 3 clinical trial in the United States and Mexico by the end of November. Data from the event-driven trial could support global authorization and approval, including in the U.S. The Company's ongoing Phase 3 clinical trial in the UK to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 is expected to be fully enrolled by the end of November. Depending on the overall COVID-19 attack rate, interim data in the UK trial, which is also event-driven, are expected as soon as early first quarter 2021.

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. NVX-CoV2373 contains purified protein antigen and cannot replicate, nor can it cause COVID-19. In preclinical trials, NVX-CoV2373 demonstrated induction of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In the Phase 1 portion of its 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. NVX-CoV2373 is also being evaluated in a Phase 3 trial in the UK and two ongoing Phase 2 studies that 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 $399 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI) and almost $1.7 billion from the U.S. government.

About Fast Track Designation

Fast Track Designation by the U.S. FDA is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need, with the intent of getting important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. Specifically, Fast Track Designation facilitates meetings with FDA to discuss all aspects of development to support licensure and provides the opportunity to submit sections of a BLA on a rolling basis as data become available.

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 undertaking 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 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 10-Q 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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