Novavax to Participate in OCTAVE-DUO Study to Evaluate Third Dose of Vaccine in Participants with Impaired Immune Systems

August 25, 2021

GAITHERSBURG, Md., Aug. 25, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that Novavax' recombinant nanoparticle protein vaccine candidate is being studied in OCTAVE-DUO, now underway in the UK to evaluate the safety and immunogenicity of a third COVID-19 vaccine dose in participants with impaired immune systems.

Funded by the UK government's Vaccines Taskforce and the UK Research and Innovation (UKRI), the study is being led by the University of Glasgow and University of Birmingham. It is a follow-on to OCTAVE (Observational Cohort Trial -T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2), which evaluated the immune response to COVID-19 vaccines in participants with impaired immune systems due to cancer, inflammatory arthritis, kidney or liver diseases, or a stem cell transplant.

As part of OCTAVE-DUO, 320 participants with lymphoid malignancies from OCTAVE and similar studies who demonstrated low or no response to two doses of a primary COVID-19 vaccine regimen will be randomly assigned to receive a third vaccine dose from one of three manufacturers at least 14 days after completing the initial 2-dose regime. The individuals may receive the same vaccine as the first two doses or one from another manufacturer. Of these participants, one third will be administered Novavax' recombinant nanoparticle protein-based COVID-19 vaccine, NVX-CoV2373.

"We expect the results of this study to be particularly helpful to better understanding how our vaccine might work as a heterologous third dose in immunocompromised individuals," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "As the pandemic continues to surge, the ability to have a flexible approach to vaccine regimens will be important for both medically vulnerable individuals as well as to achieving population-wide coverage."

Participants will be evaluated for changes in vaccine-specific immune responses and any adverse events, with findings expected later in 2021. The Medicines and Healthcare products Regulatory Agency (MHRA) and Joint Committee on Vaccination and Immunization (JCVI) will review the results to further inform the use of vaccination in immunocompromised populations.

About NVX-CoV2373
NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence of the first strain 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 formulated with 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 can neither replicate, nor can it cause COVID-19. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial in the U.K. that demonstrated efficacy of 96.4% against the original virus strain, 86.3% against the Alpha (B.1.1.7) variant and 89.7% efficacy overall; and the PREVENT-19 trial in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. It is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 55% efficacy overall in HIV-negative participants and 48.6% efficacy against a newly emerging escape variant first described in South Africa, and a Phase 1/2 continuation in the U.S. and Australia.

NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

About Matrix-M™ Adjuvant
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. Novavax is 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.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NVX-CoV2373 and its partnerships, and other Novavax vaccine product candidates, timing of future regulatory filings and actions, and the role that Novavax may play in helping control the COVID-19 pandemic are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax' Annual Report on Form 10-K for the year ended December 31, 2020 and subsequent Quarterly Reports on Form 10-Q, 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 www.sec.gov and www.novavax.com, 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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