Novavax Statement on CDC Guidance Update for COVID-19 Clinical Trial Participants

August 30, 2021

GAITHERSBURG, Md., Aug. 30, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that the U.S. Centers for Disease Control and Prevention (CDC) has provided updated guidance for those who have been vaccinated as part of a clinical trial in the U.S. The CDC guidance states that participants in the Novavax PREVENT-19 Phase 3 clinical trial meet the criteria to be considered fully vaccinated two weeks after they have completed the vaccine series.

"Novavax commends the CDC for its continued support for COVID-19 clinical trial volunteers, with this update providing clarity and guidance for participants in our PREVENT-19 Phase 3 clinical trial," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "We are grateful to all of our clinical trial participants who have helped create a safer future for all."

As part of its overall guidance regarding COVID-19 vaccines, the CDC's website has been updated to include the following section, which specifically addresses participants in the Novavax PREVENT-19 trial:

> ***"People vaccinated for COVID-19 as part of a clinical trial in the United States***
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> *Some people in the United States have completed a COVID-19 vaccination series as part of a U.S.-based clinical trial involving a COVID-19 vaccine that is not currently authorized by FDA.*
>
> ***People who received the full series of an active COVID-19 vaccine candidate as part of a U.S.-based clinical trial of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by WHO***
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> *If a participant in a U.S.-based clinical trial has been documented to have received the full series of an "active" (not placebo) COVID-19 vaccine candidate, and vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board), the participant can be considered fully vaccinated 2 weeks after they completed the vaccine series. Currently, the Novavax COVID-19 vaccine meets these criteria.* ***This does not imply that the vaccine has been authorized by FDA or is recommended by CDC or ACIP.***
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> *Novavax clinical trial participants who did not receive the full 2-dose series of the active COVID-19 vaccine candidate should be counseled by trial investigators to follow current prevention measures to protect themselves against COVID-19 and offered an FDA-authorized COVID-19 vaccine series."*

PREVENT-19, Novavax' study to assess the safety and efficacy of the company's recombinant nanoparticle protein vaccine, NVX-CoV2373 with Matrix-M™ adjuvant, demonstrated 90% overall efficacy and 100% protection against moderate and severe disease.

For more information, please visit the CDC's 'Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States' page here or Novavax.com.

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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