Novavax Announces Participation in Two Booster Studies Using its COVID-19 Vaccine

March 25, 2022

- *U.S. NIAID-sponsored trial will evaluate heterologous booster regimens, including NVX-CoV2373, after primary series with current FDA approved or emergency use authorized-vaccines*
- *NVX-CoV2373 will be evaluated in a head-to-head boosting trial in the United Arab Emirates to assess boosting options for a large number of the world's population that have previously been vaccinated with inactivated COVID-19 vaccine*

GAITHERSBURG, Md., March 25, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that NVX-CoV2373, its protein-based COVID-19 vaccine, is included in two trials now underway to evaluate its vaccine's safety, immunogenicity, and reactogenicity as a booster amidst the ongoing COVID-19 pandemic. Both studies have initiated participant enrollment and will help to extend knowledge of how a range of vaccines, including Novavax' COVID-19 vaccine, can be used as boosters following primary immunization.

"Additional COVID-19 booster studies are important to support vaccine choice for individuals, healthcare providers, and public health authorities," said Filip Dubovsky, M.D., Chief Medical Officer, Novavax. "Our COVID-19 vaccine has already been recommended by multiple national policy bodies for both primary vaccination and booster settings in individuals 18 years of age and older. We look forward to adding to this body of evidence to support the expanded use of our protein-based vaccine."

Novavax is participating in an ongoing Phase 1/2 trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) to assess homologous and heterologous boosting regimens in participants who received a primary series of a COVID-19 vaccine which has received full approval or Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). Participants will be given a third dose (≥ 12 weeks later) of either NVX-CoV2373 or one of the three COVID-19 vaccines that have already received EUA or full authorization from the FDA. The study is enrolling approximately 1,130 healthy individuals aged 18 years or older, about 180 of whom will receive NVX-CoV2373 as a heterologous booster. The trial is being conducted at approximately 10 clinical research sites and its primary objectives are to evaluate safety, reactogenicity, and immunogenicity of delayed heterologous or homologous vaccine doses after EUA dosed vaccines. Participants will be followed for 12 months, with topline results expected later this year and full results expected in 2023.

Novavax' COVID-19 vaccine is also being evaluated in an observer-blinded Phase 3 study in the United Arab Emirates (UAE) to assess homologous versus heterologous boosting of participants who have already been immunized with Sinopharm's COVID-19 vaccine. The safety and immunogenicity of a single booster dose of Novavax' COVID-19 vaccine in adults previously vaccinated with Sinopharm's COVID-19 vaccine will be evaluated. The study is enrolling approximately 1,000 participants aged 18 years or older at two centers in Abu Dhabi with the goal of providing data to support boosting with NVX-CoV2373 in the large number of individuals who have been vaccinated with inactivated vaccines globally. Participants will be followed for six months, with full results expected during the fourth quarter of 2022. The Ministry of Health and Prevention approved NVX-CoV2373 for emergency use in the UAE in December.

For more information about the NIAID-sponsored study, read here on clinicaltrials.gov. For more information about the study in the UAE, read here on clinicaltrials.gov. NVX-CoV2373 has not yet been authorized for use by the FDA, nor has it received heterologous or homologous booster approval in all the countries where it's been authorized.

Important Safety Information

- NVX-CoV2373 is contraindicated in persons who have a hypersensitivity to the active substance, or to any of the excipients.
- Events of anaphylaxis have been reported with administration of COVID-19 vaccines. Appropriate medical treatment and supervision should be available in case of an anaphylactic reaction following the administration of the vaccine. Close observation for at least 15 minutes is recommended and a second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of NVX-CoV2373.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress?related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that

precautions are in place to avoid injury from fainting.
- Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- NVX-CoV2373 should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
- The efficacy of NVX-CoV2373 may be lower in immunosuppressed individuals.
- Administration of NVX-CoV2373 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.
- The effects with NVX-CoV2373 may temporarily affect the ability to drive or use machines.
- Individuals may not be fully protected until 7 days after their second dose. As with all vaccines, vaccination with NVX-CoV2373 may not protect all vaccine recipients.
- The most common adverse reactions observed during clinical studies were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine 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.

Novavax' COVID-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 mcg antigen and 50 mcg Matrix-M adjuvant) given intramuscularly 21 days apart. The vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels. Use of the vaccine should be in accordance with official recommendations.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume. They will later be supplemented with data from additional manufacturing sites throughout Novavax' global supply chain.

About the NVX-CoV2373 Phase 3 trials

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

PREVENT-19, a trial in the U.S. and Mexico that enrolled almost 30,000 participants aged 18 years and older, achieved 90.4% efficacy overall. It was designed as a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%. A secondary endpoint was the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints were assessed at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2. It was generally well-tolerated and elicited a robust antibody response after the second dose in both studies. Full results of the trial were published in the *New England Journal of Medicine (NEJM).*

A trial conducted in the U.K. with 14,039 participants aged 18 years and older was designed as a randomized, placebo-controlled, observer-blinded study and achieved overall efficacy of 89.7%. The primary endpoint was based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline. Full results of the trial were published in *NEJM*.

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 harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. NVX-CoV2373, the company's COVID-19 vaccine, has received conditional authorization from multiple regulatory authorities globally, including the European Commission and the World Health Organization. The vaccine is also under review by multiple regulatory agencies worldwide. In addition to its COVID-19 vaccine, Novavax is also currently evaluating a COVID-seasonal influenza combination vaccine in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and NanoFlu, its quadrivalent influenza investigational vaccine candidate. These 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, LinkedIn, Instagram and Facebook.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the timing of clinical trial results, the ongoing development of NVX-CoV2373 and NanoFlu, its COVID-seasonal influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, and the efficacy, safety and intended utilization of NVX-CoV2373 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, without limitation, 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, 2021, 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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