Novavax and Serum Institute of India Announce Full Product Registration in South Africa of Novavax COVID-19 Vaccine as a Primary Series for Adults Aged 18 and Older

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GAITHERSBURG, Md., Sept. 13, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases and Serum Institute of India Pvt. Ltd. (SII), the world's largest vaccine manufacturer by volume, today announced that the South African Health Products Regulatory Authority has granted full product registration with conditions for Novavax' protein-based vaccine, NVX-CoV2373, as a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults aged 18 and older. The Novavax vaccine is marketed in South Africa under the brand name Covovax™.

"We are pleased to work with the Serum Institute to offer our protein-based vaccine to the people of South Africa and to support expanded access to an area of the world where vaccination rates are well below public health targets," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "As COVID-19 continues to evolve, having a choice of vaccines is critical to improving vaccination rates."

The product registration was based on the totality of preclinical, manufacturing, and clinical trial data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled 29,960 participants aged 18 years and older in the U.S. and?Mexico?and was published in the *New England Journal of Medicine?(NEJM)*; and a UK-based trial with almost 15,000 adult participants, also published in?*NEJM*.

In both trials, the vaccine demonstrated efficacy with a reassuring safety and tolerability profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups. The most common adverse reactions observed during clinical studies (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

NVX-CoV2373 has received authorization for use in adults aged 18 and older from more than 43 countries, including the U.S., and from the World Health Organization (WHO).

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 seven 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.

For more information on NVX-CoV2373 please visit the following website:

- **Novavax global authorization website**

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. The vaccine 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.

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

PREVENT-19 (the **PRE**-fusion protein subunit **V**accine **E**fficacy **N**ovavax **T**rial | COVID-**19**) is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373 with Matrix-M adjuvant in 29,960 participants 18 years of age and over in 119 locations in the U.S. and Mexico. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least seven 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. In the trial, NVX-CoV2373 achieved 90.4% efficacy overall. 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 ***NEJM***.

The pediatric expansion of PREVENT-19 is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the safety, effectiveness, and efficacy of NVX-CoV2373 with Matrix-M adjuvant in 2,247 adolescent participants 12 to 17 years of age in 73 locations in the U.S., compared with placebo. In the pediatric trial, the vaccine achieved its primary effectiveness endpoint (non-inferiority of the neutralizing antibody response compared to young adult participants 18 through 25 years of age from PREVENT-19) and demonstrated 80% efficacy overall at a time when the Delta variant of concern was the predominant circulating strain in the U.S. Additionally, immune responses were about two-to-three-fold higher in adolescents than in adults against all variants studied.

Additionally, a trial conducted in the U.K. with 14,039 participants aged 18 years and over 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 seven 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. The Novavax COVID-19 vaccine, has

received authorization from multiple regulatory authorities globally, including the U.S. Food and Drug Administration, the European Commission, and the WHO. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional indications and populations such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its COVID-19-Influenza Combination vaccine candidate in a Phase 1/2 clinical trial, its quadrivalent influenza investigational vaccine candidate, and an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent format Omicron-based / original strain-based vaccine. 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 **LinkedIn**.

About Serum Institute of India
Driven by the philanthropic philosophy of affordable vaccines, Serum Institute of IndiaPvt, Ltd. is the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.5 billion doses), supplying the world's least expensive and WHO-accredited vaccines to as many as 170 countries. It was founded in 1966 with the aim of manufacturing lifesaving immunobiological drugs including vaccines worldwide. With a strong commitment towards global health, the institute's objective has been proliferated by bringing down the prices of newer vaccines such as such as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines. SII is credited with bringing world-class technology to India, through its state-of-the-art equipped multifunctional production facility in Manjari, Pune and government agencies to transform emergency medicine and critical care along with spearheading the race of vaccine development against the COVID-19 pandemic. Serum Life Sciences Ltd is a subsidiary company of Serum Institute of India, with a global sales office in London to market COVID-19 vaccines manufactured by Serum Institute of India.

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, NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, a COVID-seasonal influenza combination 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, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents, and as a booster, the evolving COVID-19 pandemic, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, the efficacy, safety intended utilization, and the expected administration 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; unanticipated challenges or delays in conducting clinical trials; 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 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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