Novavax and Serum Institute of India Announce First Emergency Use Authorization of Novavax' COVID-19 Vaccine in Adolescents ?12 to 18 in India

March 22, 2022

- *First authorization of Novavax' COVID-19 vaccine in adolescent population received*
- *Covovax™ (SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine) is the first protein-based COVID-19 vaccine authorized for adolescents ?12 to <18 in India*
- *Authorization highlights immunogenicity and reassuring safety profile of Covovax in Phase 2/3 study of Indian adolescents aged ?12 to <18 and data from an ongoing Phase 3 pediatric expansion trial of NVX-CoV2373 in adolescents aged ?12 to <18 in the U.S.*

GAITHERSBURG, Md. and PUNE, India, March 22, 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, announced that the Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) for Novavax' protein-based COVID-19 vaccine for adolescents aged ?12 to <18 years in India. The vaccine, also known as NVX-CoV2373, is manufactured and marketed in India by SII under the brand name Covovax™ and is the first protein-based vaccine authorized for use in this age group in India.

"We're proud of this first approval in adolescents given the efficacy and safety that our data show in this population, and that our COVID-19 vaccine will provide an alternative protein-based vaccine option for individuals 12 years of age and older in India," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We hope that this authorization of our COVID-19 vaccine in adolescents is the first of many worldwide so that families have an additional choice built on a well-understood platform used in other vaccines for decades."

A Phase 2/3, observer-blinded, randomized, controlled study in a total of 460 Indian adolescents aged ?12 to <18 years was conducted to evaluate the safety and immunogenicity of Covovax. The study demonstrated that Covovax was well-tolerated with a reassuring safety profile. Furthermore, the data indicated that Covovax is immunogenic in adolescents aged ?12 to <18 years. The authorization in India also references the ongoing PREVENT-19 pivotal Phase 3 pediatric expansion trial of NVX-CoV2373 in adolescents in the U.S. aged ?12 to <18, results of which were shared in February.

"The approval of Covovax for adolescents 12 and older in India marks another significant milestone in strengthening our immunization efforts across India and LMICs," said Adar Poonawalla, Chief Executive Officer, Serum Institute of India. "We are proud to deliver a protein-based COVID-19 vaccine with a favorable safety profile to the adolescents of our nation."

Covovax is the fourth vaccine to receive EUA from the DCGI for use among adolescents 12 and older. The safety and efficacy of Covovax in adolescents aged less than 12 years have not yet been established; however, studies evaluating the safety and immunogenicity of Covovax for the age groups of ?7 to <12 and ?2 to <7 years in India are underway.

DCGI initially granted EUA for Covovax for adults 18 years old and above in December. In addition, Covovax has received Emergency Use Listing (EUL) from the World Health Organization, as well as EUA in Indonesia, the Philippines, and Bangladesh. For additional information on Covovax, please visit the following websites:

- Serum Institute of India
- Central Drugs Standard Control Organization

Authorized Use of Novavax' COVID-19 Vaccine in India
The Drugs Controller General of India (DCGI) has issued a permission for restricted use in emergency situation for Covovax for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Authorization in the U.S.
NVX-CoV2373 has not yet been authorized for use in the U.S. by the U.S. FDA.

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.

About Serum Institute of India Pvt. Ltd.
Driven by the philanthropic philosophy of affordable vaccines, Serum Institute of India Pvt, 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; association with Zipline and government agencies to transform emergency medicine and critical care along with spearheading the race of vaccine development against the COVID-19 pandemic.

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, additional worldwide authorizations of NVX-CoV2373 for adolescents, 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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