

Novavax and Serum Institute of India File for Emergency Use Authorization of Novavax' COVID-19 Vaccine in South Africa

January 10, 2022

GAITHERSBURG, Md. and PUNE, India, Jan. 10, 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 a regulatory submission to the South African Health Products Regulatory Agency (SAHPRA) for emergency use authorization (EUA) of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. If authorized, the vaccine (known as NVX-CoV2373) will be manufactured by and commercialized by SII in South Africa under the brand name Covovax™.

"Novavax is thankful for our long-standing history of partnership in South Africa to advance much-needed vaccines. This is exemplified by the country's vital role in the Phase 2b clinical trial and booster study of our protein-based COVID-19 vaccine," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Novavax and Serum Institute remain focused on delivering the COVID-19 vaccine - built on well-understood technology - where it is needed most. We look forward to SAHPRA's review and, if authorized, delivering the vaccine to help South Africa control the pandemic."

The submission for the regulatory evaluation by SAHPRA of NVX-CoV2373 includes data from two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants in the U.S. and Mexico and was published in the [New England Journal of Medicine \(NEJM\)](#); and a trial with almost 15,000 participants in the U.K. which was also published in [NEJM](#). In both trials, the vaccine demonstrated high efficacy with a reassuring safety 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. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

Novavax' vaccine has received conditional marketing authorization (CMA) for its vaccine in the [European Union](#) and emergency use listing (EUL) from the [World Health Organization \(WHO\)](#). The Novavax/SII vaccine (Covovax) recently received EUA in [India](#), [Indonesia](#) and the [Philippines](#), as well as [WHO](#) EUL. With WHO EUL, there is the opportunity for authorization in over 170 countries with a potential reach of over six billion lives and Novavax expects to receive additional authorizations in the first half of 2022. The vaccine is also currently under review by multiple other regulatory agencies worldwide. This includes the submission of its complete chemistry, manufacturing and controls (CMC) data package to the U.S. Food and Drug Administration (FDA) at the end of 2021. The company expects to submit a request for EUA for the vaccine in the U.S. after one month in accordance with [guidance](#) from the FDA regarding submission of all EUA vaccines.

For more information on NVX-CoV2373, including a full listing of where it has been authorized for use, please visit Novavax' [global authorization website](#).

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. 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.
- NVX-CoV2373 should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as hemophilia) 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 fetus.
- 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 (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

For additional information, please visit www.NovavaxCovidVaccine.com for the full Summary of Product Characteristics with Package Leaflet, Prescribing Information and Important Safety Information, adverse event reporting instructions, or to request additional information.

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. The current assigned shelf life of the vaccine is 9 months.

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, 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%. The key secondary endpoint is 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 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 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, received Conditional Marketing Authorization from the European Commission, Emergency Use Listing from the World Health Organization, Emergency Use Authorization in Indonesia and the Philippines, and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a

COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. 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 facilities at 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 ongoing development of NVX-CoV2373, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to submit an EUA application to the U.S. FDA after one month, the potential impact of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, the efficacy, safety and intended utilization of NVX-CoV2373, and the expected delivery 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 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.

Contacts:

Investors

Novavax, Inc.

Erika Schultz | 240-268-2022

ir@novavax.com

Solebury Trout

Alexandra Roy | 617-221-9197

aroy@soleburytrout.com

Media

Ali Chartan | 240-720-7804

Laura Keenan Lindsey | 202-709-7521

media@novavax.com

Serum Institute of India

Mayank Sen | +91-986-797-4055

mayank.sen@seruminstitute.com

SOURCE Novavax, Inc.

Image not found or type unknown