

Novavax and Serum Institute of India Receive Emergency Use Authorization for COVID-19 Vaccine in India

December 28, 2021

GAITHERSBURG, Md. and PUNE, India, Dec. 28, 2021 /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 Drugs Controller General of India (DCGI) has granted emergency use authorization (EUA) for Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. The vaccine will be manufactured and marketed in India by SII under the brand name Covovax™.

"No one is safe until everyone is safe, and today's authorization marks a vital step for India, where additional vaccine options and millions of doses are needed in the country's ongoing efforts to control the pandemic," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Novavax and SII will not rest in our partnership to deliver our vaccine to those in India and across the globe, as we work to protect the health of people everywhere."

Because the vaccine is stored with standard refrigeration at 2° to 8° Celsius, it may be transported and stored using existing vaccine supply chain, potentially increasing access in hard-to-reach areas.

"The approval of Covovax in India marks a 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, based on Phase 3 clinical data demonstrating more than 90% efficacy and a favorable safety profile, to our nation."

The Novavax/SII vaccine recently received EUA in [Indonesia](#) and the [Philippines](#), as well as Emergency Use Listing (EUL) with the [World Health Organization](#) (WHO). Novavax was also granted Conditional Marketing Authorization by the European Commission and EUL with the WHO for its vaccine, which will be marketed by Novavax as Nuvaxovid™. Novavax has also announced regulatory filings for its vaccine in multiple countries worldwide, while partners SK bioscience and Takeda have submitted regulatory filings in [South Korea](#) and Japan, respectively. Novavax expects to submit the complete package to the U.S. FDA by the end of the year.

For additional information on Covovax, please visit the following websites in the coming days:

- [Central Drugs Standard Control Organization \(India\)](#)
- [Serum Institute of India](#)

Authorized Use of Novavax' Covid-19 Vaccine in India

The Drugs Controller General of India (DCGI) has issued Emergency Use Authorization (EUA) for Covovax /Recombinant Spike Protein of SARS-CoV-2 Virus 5 mcg to induce immunity against SARS-CoV-2 to prevent COVID-19 for adults 18 years old and above.

Authorization in the U.S.

NVX-CoV2373 has not yet been authorized for use in the U.S. and the trade name Nuvaxovid has not yet been approved by the U.S. FDA.

Important Safety Information

Covovax is contraindicated in persons who have hypersensitivity to the active substance or to any of the excipients of this vaccine.

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.

About the NVX-CoV2373 Phase 3 trials

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

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 the [*New England Journal of Medicine* \(NEJM\)](#).

PREVENT-19, a trial in the U.S. and Mexico, with 25,452 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 [*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 India, 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 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, the ongoing development of NVX-CoV2373 and its partnerships, the scope, timing and outcome of future regulatory filings and actions, the role that

COVOVAX may play in helping to increase vaccination rates and to control the COVID-19 pandemic in India and across the globe, Novavax' and SII's continued efforts to deliver COVOVAX to those in India and across the globe, and COVOVAX's potential to increase vaccination access in hard-to-reach areas 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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