



Serum Institute of India and Novavax Receive Emergency Use Authorization in India for COVOVAX™

PUNE, India – December 28, 2021 – Serum Institute of India Pvt. Ltd. (SII), the world's largest vaccine manufacturer by volume, and Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, receive **emergency use authorization (EUA)** for Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with **Matrix-M™** adjuvant by the **Drugs Controller General of India (DCGI)**. The vaccine will be manufactured and marketed in India by SII under the brand name **COVOVAX™**.

Sharing his views, **Adar Poonawalla, Chief Executive Officer, Serum Institute of India (SII)**, said, *"The approval of COVOVAX by DCGI is a significant milestone in strengthening our immunization efforts across India and LMICs. We are proud to deliver a highly-effective protein-based COVID-19 vaccine of more than 90% efficacy rate, based on clinical data demonstrating a favorable safety profile. We are certain that as the repertoire of the COVID-19 vaccine increases, we will be poised strongly to save the lives of millions of people against the pandemic."*

"We expect the authorization of our vaccine to serve a vital need in India, helping to increase the vaccination rate in a country where a significant number of doses is needed to control the pandemic," said **Stanley C. Erck, President and Chief Executive Officer, Novavax**. *"Novavax and our partner, Serum Institute of India, continue to increase our forward momentum, and we will not rest in our work to deliver our vaccine to those in India and across the globe, as we work to protect the health of people everywhere."*

The Novavax/SII vaccine recently received Emergency Use Listing (EUL) with the [World Health Organization \(WHO\)](#), EUA in [Indonesia](#) and the [Philippines](#). Novavax also announced regulatory filings for its vaccine in [Australia](#), [Canada](#), the [European Union](#), [New Zealand](#), the [United Kingdom](#), and with the [WHO](#). Additionally, Novavax and SK bioscience announced a Biologics License Application (BLA) submission in [South Korea](#). Novavax expects to submit the complete package to the U.S. FDA by the end of the year.

Authorized Use of Novavax' Covid-19 Vaccine in India

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.

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 the NVX-CoV2373 Phase 3 Trials

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial in the U.K. that demonstrated efficacy of 96.4% against the original virus strain, 86.3% against the Alpha (B.1.1.7) variant and 89.7% efficacy overall; and the PREVENT-19 trial in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. It was generally well-tolerated and elicited a robust antibody response.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate 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 microgram antigen and 50 microgram Matrix-M adjuvant) given intramuscularly 21 days apart. The vaccine is stored at 2° to 8° Celsius, enabling the use of existing vaccine supply and cold chain channels.

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 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.

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 combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both 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](#), [Facebook](#), [LinkedIn](#) and [Instagram](#).

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