# Novavax and Serum Institute of India Announce Submission to World Health Organization for Emergency Use Listing of Novavax' COVID-19 Vaccine

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- Novavax and Serum Institute of India file regulatory submission for World Health Organization Emergency Use Listing of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine

GAITHERSBURG, Md., Sept. 23, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, with its partner, Serum Institute of India Pvt. Ltd. (SII), today announced a regulatory submission to the World Health Organization (WHO) for emergency use listing (EUL) of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. The submission to WHO is based on the companies' previous regulatory submission to the Drugs Controller General of India(DCGI).

"Today's submission of our protein-based COVID-19 vaccine to WHO for emergency use listing is a significant step on the path to accelerating access and more equitable distribution to countries in great need around the world," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "It represents another major milestone in Novavax' transformation into a commercial global vaccine company and reinforces the value of global collaboration and need for multiple approaches to help control the pandemic."

The grant of EUL by the WHO is a prerequisite for exports to numerous countries participating in the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies. In addition to the submission for WHO EUL, SII and Novavax last month completed the submission of modules required by regulatory agencies in India, Indonesia and the Philippines for the initiation of review of the vaccine, including preclinical, clinical, and chemistry, manufacturing and controls (CMC) data.

**About NVX-CoV2373**
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.

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°- 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 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 and will be advanced for regulatory submission. 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 and LinkedIn.

**Forward-Looking Statements**
Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NVX-CoV2373 and other Novavax vaccine product candidates, timing of future regulatory filings and actions, and the role that Novavax may play in helping control the COVID-19 pandemic 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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