Novavax and Serum Institute of India Announce Submission to Regulatory Agencies in India, Indonesia, Philippines for Emergency Use Authorization of Novavax' Recombinant Nanoparticle COVID-19 Vaccine

August 5, 2021

- Novavax and Serum Institute of India file regulatory submissions to the Drugs Controller General of India and to regulatory agencies in Indonesia and Philippines for Novavax' recombinant nanoparticle COVID-19 vaccine

- Filing for World Health Organization Emergency Use Listing expected in August 2021

GAITHERSBURG, Md., Aug. 5, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, with its partner, Serum Institute of India Pvt. Ltd. (SII), today announced that the companies have filed regulatory submissions for emergency use authorization of Novavax' recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. The submissions were made to the Drugs Controller General of India (DCGI) and regulatory agencies in Indonesia and the Philippines.

"Today's submission of our recombinant nanoparticle COVID-19 vaccine, the first protein-based option filed with any regulatory agency, represents a major milestone in Novavax' transformation into a commercial global vaccine company," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "This important step toward access to millions of doses of a safe and effective vaccine for countries with an urgent need to control the pandemic was made possible through our strategic partnership with Serum Institute of India, and it demonstrates the power of global collaboration."

SII and Novavax have now completed the submission of all 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 data. A Good Manufacturing Practice joint site inspection of SII was successfully completed by DCGI in May 2021.

A submission to the World Health Organization (WHO) for emergency use listing (EUL) based on the DCGI submission is expected to be filed in August. 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.

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.

SII is manufacturing, and developing, and is responsible for commercializing the vaccine in India. Novavax and SII have cumulative commitments to provide more than 1.1 billion doses to the COVAX Facility.

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. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

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 is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 55% efficacy overall in HIV-negative participants and 48.6% efficacy against a newly emerging escape variant first described in South Africa, and a Phase 1/2 continuation in the U.S. and Australia.

NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials.

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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