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

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GAITHERSBURG, Md. and PUNE, India, Nov. 17, 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 Philippine Food and Drug Administration (FDA) 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 the Philippines by SII under the brand name COVOVAX™.

"With less than a third of the Philippine population fully immunized, we expect the option for a protein vaccine, built on a well-understood technology platform, to contribute substantially to increased vaccination rates," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Novavax looks forward to SII's delivery of the vaccine to the Philippines, and with additional authorizations expected elsewhere soon, to helping control the COVID-19 pandemic around the globe."

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 the Philippines is another step forward in the global fight against the coronavirus," said Adar Poonawalla, Chief Executive Officer, Serum Institute of India. "We are proud to deliver the first protein-based COVID-19 vaccine to the Philippines."

The Novavax/SII vaccine has recently received EUA in Indonesia and the companies have also filed for emergency authorization in India and for Emergency Use Listing (EUL) with the World Health Organization (WHO). Novavax also announced regulatory filings for its vaccine in the United Kingdom, Australia, New Zealand, Canada and with the WHO, as well as the complete submission of all data and modules in the European Union to support the final regulatory review of its dossier by the European Medicines Agency. Additionally, Novavax and SK bioscience announced a Biologics License Application (BLA) in South Korea. Novavax expects to submit the complete package to the U.S. FDA by the end of the year.

For additional information on COVOVAX, including the Summary of Product Characteristics, Prescribing Information and Important Safety Information, please visit the following websites:

- Food and Drug Administration Philippines
- Serum Institute of India

Authorized Use of Novavax' Covid-19 Vaccine in the Philippines
The Philippines Food and Drug Administration has issued Emergency Use Authorization (EUA) for Covovax /Recombinant Spike Protein of SARS-CoV-2 Virus 5 mcg for active immunization of individual 18 years of age and older for the prevention of coronavirus disease 2019 caused by SARS-CoV-2

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: 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. It is also being evaluated in 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.

About NVX-CoV2373
NVX-CoV2373, Novavax' Covid-19 vaccine, 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. 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.

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, its partnerships, the ongoing development of NVX-CoV2373 and other Novavax vaccine product candidates, the scope, timing and outcome of future regulatory filings and actions, the role that COVAVAX may play in increasing vaccination rates in the Philippines, the expected timing of vaccine shipments, and the role that Novavax may play in helping control the COVID-19 pandemic around the globe 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
Novavax
Laura Keenan Lindsey | 202-709-7521
Ali Chartan | 240-720-7804
media@novavax.com

Serum Institute of India
Mayank Sen | +919867974055
mayank.sen@seruminstitute.com

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