

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

November 1, 2021

GAITHERSBURG, Md. and PUNE, India, Nov. 1, 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 National Agency of Drug and Food Control of the Republic of Indonesia, or Badan Pengawas Obat dan Makanan (Badan POM), has granted emergency use authorization (EUA) for Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. It will be manufactured by SII in India and marketed by SII in Indonesia under the brand name COVOVAX™.

"The first authorization of Novavax' COVID-19 vaccine exemplifies our commitment to equitable global access and will fill a vital need for Indonesia, which despite being the fourth most populous nation on earth, continues to work to procure sufficient vaccine for its population," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "This also marks the first regulatory authorization worldwide of a protein-based COVID-19 vaccine based on Phase 3 clinical data demonstrating efficacy and a favorable safety profile. This is a landmark moment for Novavax and our partner, Serum Institute of India, and it is the first of many authorizations that Novavax expects in the coming weeks and months for our vaccine globally."

Because the vaccine is stored at 2° to 8° Celsius, the use of existing vaccine supply channels with more traditional cold chain capabilities is possible, potentially increasing access in hard-to-reach areas and vaccination rates across the nation. Initial shipments into Indonesia are expected to begin imminently.

"Access to supply of a safe and highly effective vaccine, coupled with the ease of its distribution, should be a critical enabler to help Indonesia control the current coronavirus outbreak," said Adar Poonawalla, Chief Executive Officer, Serum Institute of India. "We continue to work with urgency to ensure the first protein-based COVID-19 vaccine option in Indonesia is available for all awaiting its arrival."

Novavax and SII have already filed for authorization of Novavax' COVID-19 vaccine in India and the Philippines, as well as for Emergency Use Listing (EUL) with the World Health Organization (WHO). Novavax recently also completed rolling submissions for authorization of the Novavax vaccine with regulatory agencies in the United Kingdom, European Union, Canada and Australia. Novavax expects to submit additional regulatory filings for its vaccine around the world as well as an additional supplemental filing for its vaccine for EUL with the WHO, shortly. Novavax expects to submit its complete package to the U.S. FDA by the end of the year.

Indonesia is a member of the [Pharmaceutical Inspection Co-operation Scheme](#) (PIC/S), a non-binding co-operative arrangement between more than 50 regulatory authorities, including those in the U.S., United Kingdom, European Union, Australia and Canada, in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. PIC/S aims at harmonizing inspection procedures worldwide through the development of common standards in the field of GMP and at facilitating cooperation and networking between competent authorities, regional and international organizations, thus increasing mutual confidence.

For additional information on COVOVAX, including the Summary of Product Characteristics, Prescribing Information and Important Safety Information, please visit: [Indonesia National Agency of Drug and Food Control \(Badan POM\)](#). This information will be posted in the coming days.

Authorized Use of Novavax' Covid-19 Vaccine in Indonesia

Badan POM 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: 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.

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, the ongoing development of NVX-CoV2373 and its partnerships, and other Novavax vaccine product candidates, the scope, timing and outcome of future regulatory filings and subsequent regulatory approvals, the expected timing of vaccine shipments and the role that Novavax may play in helping control the COVID-19 pandemic in Indonesia 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

Laura Keenan Lindsey | 202-709-7521

Ali Chartan | 240-720-7804

media@novavax.com

SOURCE Novavax, Inc.

Image not found or type unknown