Novavax and Serum Institute of India Announce World Health Organization Grants Emergency Use Listing for NVX-CoV2373 COVID-19 Vaccine

December 17, 2021

- *First EUL granted by WHO for a protein-based COVID-19 vaccine*
- *EUL vaccine manufactured and marketed by SII as COVOVAX™*
- *WHO EUL for Nuvaxovid™ currently under assessment; will be completed following European Medicines Agency (EMA) review*

GAITHERSBURG, Md. and PUNE, India, Dec. 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 World Health Organization (WHO) has granted Emergency Use Listing (EUL) for NVX-CoV2373, Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant, for active immunization of individuals 18 years of age and older for the prevention of coronavirus disease 2019 caused by SARS-CoV-2. Today's EUL pertains to vaccine manufactured and marketed by SII as COVOVAX™, a novel recombinant, adjuvanted SARS-CoV-2 rS Vaccine, in India and licensed territories. An additional EUL filing is under review by the WHO for vaccine to be marketed by Novavax under the brand name Nuvaxovid™.

The EUL prequalifies Novavax' COVID-19 vaccine as meeting the established WHO standards for quality, safety and efficacy. EUL is a prerequisite for exports to numerous countries, including those participating in the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies.

"Today's decision from the World Health Organization is vital to ensuring global access to a protein-based COVID-19 vaccine for hundreds of millions of people around the world," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the World Health Organization for its thorough assessment. We believe this vaccine will help overcome barriers to vaccine access in many regions of the world by leveraging the traditional refrigeration used in existing vaccine supply channels, while also offering an option based on a familiar and well-understood technology."

"The EUL by the World Health Organization is a great encouragement towards making COVID-19 vaccines more accessible. Our partnership with Novavax has been successful in providing global public health leadership and ensuring that all countries have broad access to a viable vaccine," said Adar Poonawalla, Chief Executive Officer, Serum Institute of India. "COVOVAX is the first protein-based COVID-19 vaccine option, with demonstrated efficacy and a well-tolerated safety profile, to be made available through the COVAX Facility. We thank the WHO and seek to help the world control the spread of the pandemic."

"It is very welcome news that the world now has a new weapon in its arsenal of tools to fight COVID-19," said Dr Richard Hatchett, Chief Executive Officer, Coalition for Epidemic Preparedness Innovations (CEPI). "CEPI's investments to accelerate the clinical development and manufacturing of Novavax' vaccine have been critical to enabling equitable access to the vaccine through COVAX."

"We welcome the news that the COVOVAX vaccine has received WHO Emergency Use Listing, providing the world – and COVAX participants – with another promising class of vaccine as well as yet another tool in the battle against COVID-19," said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance. "With data on safety and efficacy against several variants, strong potential in mix and match and booster regimens, and standard storage temperatures, this vaccine will provide countries with another critical option in the quest to help protect their populations."

The grant of EUL was based on the totality of preclinical, manufacturing and clinical trial data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19, which enrolled approximately 30,000 participants in the U.S. and Mexico, the results of which were published December 15, 2021 in the*New England Journal of Medicine (NEJM)*; and a trial that evaluated the vaccine in more than 14,000 participants in the U.K., the results of which were published June 30, 2021 in *NEJM*. In both trials, NVX-CoV2373 demonstrated high efficacy and a reassuring safety and tolerability profile. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed.

Novavax and SII recently received emergency use authorization (EUA) for COVOVAX in Indonesia and the Philippines. The vaccine is also currently under review by multiple regulatory agencies worldwide. The company expects to submit its complete chemistry, manufacturing and controls (CMC) data package to the U.S. FDA by the end of the year.

For additional information on today's announcement and COVOVAX, please visit the following websites:

- World Health Organization
- Serum Institute of India

Emergency Use Listing of COVOVAX™ by the World Health Organization
The World Health Organization (WHO) has issued Emergency Use Listing 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.

About NVX-CoV2373
NVX-CoV2373 is a protein-based vaccine 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 mcg antigen and 50 mcg 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.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide.

About the NVX-CoV2373 Phase 3 trials
NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

A trial conducted in the U.K. with 14,039 participants was designed as a randomized, placebo-controlled, observer-blinded study and achieved overall efficacy of 89.7%. The primary endpoint was based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

PREVENT-19, a trial in the U.S. and Mexico, with 25,452 participants, achieved 90.4% efficacy overall. It was designed as a is a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%. The key secondary endpoint is the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints were assessed at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2. It was generally well-tolerated and elicited a robust antibody response in both studies.

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 harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. NVX-CoV2373, the company's COVID-19 vaccine, received Emergency Use Authorization in Indonesia and the Philippines and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. These 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, LinkedIn, Instagram and Facebook.

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, the scope, timing and outcome of future regulatory filings and actions, the belief that COVOVAX will help overcome barriers to vaccine access in many regions of the world by leveraging the traditional refrigeration used in existing vaccine supply channels, the role that Novavax may play in helping to control the COVID-19 pandemic, Novavax' plans to deliver a COVID-19 vaccine to hundreds of millions of people around the world, the potential to mix and match booster regimens, and Novavax' plans to submit a complete CMC data package to the U.S. FDA by the end of the year 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
Ali Chartan | 240-720-7804
Laura Keenan Lindsey | 202-709-7521
media@novavax.com

SOURCE Novavax, Inc.