Novavax Announces Memorandum of Understanding with Gavi for Cumulative Supply to COVAX Facility of 1.1 Billion Doses of COVID-19 Vaccine

February 18, 2021

GAITHERSBURG, Md., Feb. 18, 2021 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced a Memorandum of Understanding (MOU) with Gavi, the Vaccine Alliance (Gavi), to provide 1.1 billion cumulative doses of NVX-CoV2373, Novavax' recombinant protein-based COVID-19 vaccine candidate, for the COVAX Facility. The vaccine doses will be manufactured and distributed globally by Novavax and Serum Institute of India (SII), the latter under an existing agreement between Gavi and SII. NVX-CoV2373 is being studied in two ongoing pivotal Phase 3 clinical trials: in the United States and Mexico, as well as in the United Kingdom (U.K.), for the prevention of COVID-19. Novavax has previously reported positive interim efficacy results from its U.K. trial.

COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, which is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, and the World Health Organization (WHO), who are working in partnership with developed and developing country vaccine manufacturers, UNICEF, the World Bank, civil society organisations and others to guarantee fair and equitable access to the vaccine for every country in the world. COVAX currently includes more than 190 participating economies.

"We are proud to partner with all the COVAX collaborators and Serum Institute of India to provide global public health leadership and ensure that all countries have broad access to NVX-CoV2373," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "Novavax will play a critical role in the worldwide effort to provide access to safe and effective vaccines to end the pandemic."

Gavi leads the design and implementation of the COVAX Facility and will work with Novavax to finalize an advance purchase agreement (APA) for vaccine supply and global distribution allocation via the COVAX Facility and its partners.

"This agreement brings the COVAX Facility one step closer to its goal of supplying vaccines globally and ending the acute phase of the pandemic," said Dr. Seth Berkley, CEO of Gavi. "It helps us close in on our goal of delivering two billion doses in 2021 and increases the range of vaccines available to us as we build a portfolio suitable for all settings and contexts."

CEPI has provided critical support to Novavax, including the commitment of approximately $400 million to advance early clinical development and manufacturing scale-up in multiple facilities around the globe. Novavax has created a global supply network to ensure there can be adequate and equitable supply of NVX-CoV2373 across the globe. Consistent with its mission to increase global manufacturing capacity and ensure broad, equitable supply distribution, Novavax licensed its NVX-CoV2373 technology to SII with no upfront, milestone or technology transfer payments. With this strategic partnership in place, Novavax and SII are jointly committed to deliver 1.1 billion doses to the COVAX Facility. For supply of NVX-CoV2373 to COVAX, Novavax is expected to supply doses primarily to high-income countries (HICs), with SII providing the majority of supply for low-, middle, and upper-middle-income countries, (LMICs, UMICs), utilizing a tiered pricing schedule.

"With this MOU in place, the vaccine candidate developed by our partners at Novavax is poised to play a significant role in combatting COVID-19 around the world," said Dr. Richard Hatchett, CEO of CEPI. "CEPI's investments in this vaccine have been pivotal to enabling equitable access to a significant volume of this vaccine through COVAX."

"We are pleased to deepen our partnership with Novavax and COVAX to increase the doses of vaccine available to benefit humanity," said Adar Poonawalla, Chief Executive Officer, Serum Institute of India." This global collaboration is vital to ensure that the largest possible amount of vaccine is available to reach individuals across the broadest segment of countries.

NVX-CoV2373 was the first vaccine to demonstrate clinical efficacy against the original strain of COVID-19 and both of the rapidly emerging variants in the United Kingdom and South Africa. NVX-CoV2373 can neither cause COVID-19 nor can it replicate. It is shipped in a ready-to-use liquid formulation. Because it is stable at 2°C to 8°C (refrigerated), existing vaccine supply chain channels can be used for its distribution.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate engineered from the genetic sequence 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 adjuvanted with Novavax' patented saponin-based Matrix-M™ 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 block binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing. NVX-CoV2373 is currently being evaluated in two pivotal Phase 3 trials: a trial in the U.K that demonstrated 89.3 percent overall efficacy and 95.6 percent against the original strain in a post-hoc analysis, and the PREVENT-19 trial in the U.S. and Mexico that began in December. It is also being tested in two ongoing Phase 2 studies that began in August: A Phase 2b trial in South Africa that demonstrated up to 60 percent efficacy against newly emerging escape variants, and a Phase 1/2 continuation in the U.S. and Australia.

About Matrix-M™

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.

Novavax Forward Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2019, and Quarterly Report on Form 10-Q for the period ended September 30, 2020, 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 sec.gov, 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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