Novavax and Gavi Execute Advance Purchase Agreement for COVID-19 Vaccine for COVAX Facility

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- Novavax to deliver 350 million doses beginning Q3 2021
- 1.1 billion doses of Novavax vaccine to be available to countries participating in COVAX
- Serum Institute of India to provide balance of doses for LMICs
- Underscores commitment to global equitable access to Novavax vaccine

GAITHERSBURG, Md., May 6, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that it has finalized an advance purchase agreement (APA) with Gavi, the Vaccine Alliance (Gavi) for supply of its recombinant protein-based COVID-19 vaccine candidate to the COVAX Facility. Under the APA, Novavax is expected to manufacture and distribute 350 million doses of NVX-CoV2373 to countries participating under the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies. Under a separate purchase agreement with Gavi, the Serum Institute of India (Serum Institute) is expected to manufacture and deliver the balance of the 1.1 billion doses of Novavax' vaccine.

"This is a tremendous opportunity to partner with global organizations focused on accelerating equitable access to safe and effective COVID-19 vaccines, particularly in countries where vaccination rates are currently low," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "This arrangement is the culmination of a collaboration among CEPI, Gavi, Serum Institute and Novavax, who are partnering in our urgent mission to deliver significant amounts of vaccines to all countries, regardless of income level. Novavax thanks CEPI for its longstanding support and tireless work with Gavi as the curators of the COVAX Facility."

Under the APA, Novavax expects to deliver doses with antigen and adjuvant manufactured at facilities directly funded by the investments Novavax received from the Coalition for Epidemic Preparedness Innovations (CEPI). CEPI invested nearly $400 million in Novavax in the spring of 2020 to advance preclinical and early clinical development, manufacturing scale-up, technology transfer, and manufacturing capacity reservation for NVX-CoV2373.

"CEPI's investments to accelerate the clinical development and manufacturing of this vaccine candidate have been critical to enabling equitable access to the vaccine through COVAX," said Dr. Richard Hatchett, CEO of CEPI. "With this agreement in place, the Novavax vaccine candidate will play a vital role in our mission to protect those most at risk from COVID-19, wherever they are in the world."

"Today's agreement with Novavax marks a major step towards COVAX's objective of building the world's largest and most diverse portfolio of COVID-19 vaccines, and a major step towards our goal of delivering 2 billion doses of safe and effective vaccines in 2021," said Dr Seth Berkley, CEO of Gavi. "Novavax' commitment not only to support COVAX directly, but also through technology transfer via other manufacturers, shines a light on the end-to-end nature of COVAX and the kind of collaboration needed to bring this pandemic under control."

Together, Novavax and Serum Institute expect to initiate delivery of the cumulative 1.1 billion doses in the third quarter of 2021, pending receipt of appropriate regulatory authorizations. Under the APA, Novavax will receive an upfront payment from Gavi later this month and an additional payment after it secures Emergency Use Listing for its vaccine by the WHO. In addition, Novavax has agreed to provide additional doses in the event that Serum Institute cannot materially deliver expected vaccine doses to the COVAX Facility.

Vaccine dose allocation will be determined by Gavi across the AMC-eligible and self-financing participants under a tiered pricing schedule.

"CEPI's early support served as a catapult for Novavax to create a global supply network that we expect could provide a significant percent of the world's vaccine supply via COVAX," Erck continued. "We look forward to the ongoing collaboration with Serum Institute to deliver on our manufacturing capacity and to working with WHO to secure authorization as rapidly as possible for NVX-CoV2373."

About the COVAX Facility
The COVAX Facility is a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines that currently includes more than 190 participating economies, designed and administered by Gavi, the Vaccine Alliance. It is part of COVAX, co-led by CEPI, Gavi and the World Health Organization (WHO), which are working in partnership with developed and developing country vaccine manufacturers, UNICEF, PAHO, the World Bank, civil society organizations and others to guarantee fair and equitable access to the vaccine.

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 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 100% protection against severe disease, efficacy of 96.4% against the original virus strain and 89.7% overall, and the PREVENT-19 trial in the U.S. and Mexico that began in December 2020. 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 100% protection against severe disease and 48.6% efficacy against a newly emerging escape variant, 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™
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, 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.

Contacts:

Investors
Novavax, Inc.
Erika Schultz | 240-268-2022
ir@novavax.com

Solebury Trout
Alexandra Roy | 617-221-9197
aroy@soleburytrout.com

Novavax Media
Laura Keenan | 202-709-7521
media@novavax.com

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