Novavax and European Commission Finalize Advance Purchase Agreement for up to 200 million doses of COVID-19 Vaccine

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GAITHERSBURG, Md., Aug. 4, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that it has reached an agreement with the European Commission (EC) for the purchase of up to 200 million doses of NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. The agreement covers the purchase of up to 100 million doses of the vaccine with the option for an additional 100 million doses through 2023.

Novavax is working to complete its rolling submission for NVX-CoV2373 to the European Medicines Agency (EMA) in the third quarter of 2021, with delivery of initial doses expected to begin following approval.

"We thank the European Commission for their partnership in this important step to expand vaccine options for the citizens of Europe and globally as we work to bring the first COVID-19 protein subunit vaccine to the market," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "With clinical data from our trials showing strong efficacy against Variants of Concern and Variants of Interest, we believe that our vaccine candidate will play a critical role in the effort to help control the pandemic in the EU and other regions in the world."

In a Phase 3 clinical trial with nearly 30,000 adults in the United States and Mexico, NVX-CoV2373 demonstrated 100% protection against moderate and severe disease and 90.4% overall efficacy. In a Phase 3 clinical trial conducted in the United Kingdom with approximately 15,000 adults, NVX-CoV2373 showed an overall efficacy of 89.7%, and more than 96% efficacy against the original strain of the virus.

"As new coronavirus variants are spreading in Europe and around the world, this new contract with a company that is already testing its vaccine successfully against these variants is an additional safeguard for the protection of our population. It further strengthens our broad vaccine portfolio, to the benefit of Europeans and our partners worldwide," said Ursula von der Leyen, President of the European Commission.

Novavax' global supply chain spans more than 10 countries, including facilities across the European Union from which it plans to ultimately supply doses.

About NVX-CoV2373

NVX-CoV2373 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. 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 efficacy of 96.4% against the original virus strain, 86.3% against the B.1.1.7 (Alpha) variant and 89.7% overall; and 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 is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 55% efficacy overall in HIV-negative participants and 48.6% efficacy against a newly emerging escape variant first described in South Africa, 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™ 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 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.

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.

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