Novavax Confirms European Medicines Agency Review of COVID-19 Vaccine Filing for Conditional Marketing Authorization

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GAITHERSBURG, Md., Nov. 17, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that European Medicines Agency (EMA) has begun its evaluation of an application for conditional marketing authorization (CMA) for Novavax' COVID-19 vaccine, which will be marketed in the European Union under the brand name Nuvaxovid™. EMA's statement may be found here.

"Today's announcement from EMA brings Novavax another step closer to our goal of ensuring broad global access to our protein-based COVID-19 vaccine across Europe," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Novavax looks forward to providing an additional vaccine option in Europe, built on a proven, well-understood technology platform, and thanks the European Commission for its ongoing partnership and confidence in our COVID-19 program."

The company announced earlier this month that it had completed the submission of all data and modules required by EMA for regulatory evaluation of NVX-CoV2373, Novavax' recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. EMA has indicated that its assessment will proceed under an accelerated timeline, with an opinion issued potentially within weeks.

The chemistry, manufacturing and controls (CMC) data package submitted to EMA and other global regulatory agencies leverages Novavax' manufacturing partnership with the Serum Institute of India Pvt. Ltd. (SII), the world's largest vaccine manufacturer by volume. It will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.

The Novavax/SII vaccine has recently received Emergency Use Authorization (EUA) in Indonesia and the Philippines, and the companies have also filed for emergency authorization in India and for Emergency Use Listing (EUL) with the World Health Organization (WHO). Novavax also announced regulatory filings for its vaccine in the United Kingdom, Australia, New Zealand, Canada and with the WHO. Additionally, Novavax and SK bioscience announced a Biologics License Application (BLA) submission to MFDS in South Korea. Novavax expects to submit the complete package to the U.S. FDA by the end of the year. The brand name Nuvaxovid™ has not been authorized by the U.S. FDA.

About the NVX-CoV2373 Phase 3 Trials
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 Alpha (B.1.1.7) variant and 89.7% efficacy 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 was generally well-tolerated and elicited a robust antibody response.

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.

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 on Twitter and LinkedIn.

Forward-Looking Statements
Statements herein relating to the future of Novavax, including Novavax' plans to supplement its CMC data package submitted to EMA with data from additional manufacturing sites in Novavax' global supply chain, 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; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; 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 statement. 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 statement 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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