

All modules required for regulatory review of Novavax vaccine, including CMC data, are now complete for WHO

GAITHERSBURG, Md., Nov. 4, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced the completion of its rolling submission to the World Health Organization (WHO) for emergency use listing (EUL) of NVX-CoV2373, its COVID-19 vaccine candidate.

"Today's submission reflects our continued focus on accelerating access and equitable distribution as we work to bring our vaccine to people in need around the globe," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We continue to work with urgency to deliver our COVID-19 vaccine, built on a proven, well-understood vaccine platform, because no one is safe until everyone is safe."

Novavax has now completed the submission to WHO of all modules required for the regulatory evaluation of NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. The chemistry, manufacturing and controls (CMC) module submitted to WHO, as well as other regulatory agencies worldwide, leverages Novavax' manufacturing partnership with the Serum Institute of India Pvt. Ltd. (SII), the world's largest vaccine manufacturer by volume. Novavax will make further submissions to enable vaccine supply from additional manufacturing sites in Novavax' global supply chain. Today's filing by Novavax is in addition to a previous filing to WHO by Novavax and SII.

The submission also includes clinical data from PREVENT-19, a pivotal Phase 3 trial of 30,000 participants in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. Clinical data from a pivotal Phase 3 trial of 15,000 participants in the U.K. were also previously submitted to WHO, in which NVX-CoV2373 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. In both trials, NVX-CoV2373 demonstrated a favorable safety and tolerability profile.

Novavax recently announced authorization of its vaccine in Indonesia. The company also announced regulatory filings for its vaccine in the [United Kingdom](#), [Australia](#), [New Zealand](#) and Canada, as well as the complete submission of all data and modules in the [European Union](#) to support the final regulatory review of its dossier by the European Medicines Agency. Novavax expects to submit the complete package to the U.S. FDA by the end of the year.

The grant of WHO EUL is a prerequisite for exports to numerous countries participating in the COVAX Facility, which was established to allocate and distribute vaccines equitably to participating countries and economies. Novavax continues to work closely with governments, regulatory authorities and non-governmental organizations (NGOs) in its commitment to ensuring equitable global access to its COVID-19 vaccine.

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.

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 us on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373 and other Novavax vaccine product candidates, the scope, timing and outcome of future regulatory filings and actions and Novavax' plans to deliver a COVID-19 vaccine to people around the globe 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.

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