Novavax Files for Emergency Use of COVID-19 Vaccine in the United Arab Emirates

December 13, 2021

GAITHERSBURG, Md., Dec. 13, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that it has submitted a regulatory filing to the Ministry of Health and Prevention (MoHaP) for emergency use of its COVID-19 vaccine in the United Arab Emirates (UAE).

"The rapid emergence and continued spread of variants is a stark reminder that no one is safe until everyone is safe in the fight against COVID-19," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We remain committed to delivering our vaccine, which is based on a proven, well understood platform, to countries around the world as we anticipate that ongoing vaccination will be necessary over the long term to end the pandemic."

Novavax made the submission for the regulatory evaluation by MoHaP of NVX-CoV2373, the company's recombinant nanoparticle protein-based COVID-19 vaccine with Matrix-M™ adjuvant. The filing includes clinical data from two pivotal Phase 3 clinical trials: PREVENT-19, which included 30,000 participants in the U.S. and Mexico and demonstrated 100% protection against moderate and severe disease, 93.2% efficacy against the predominantly circulating variants of concern and variants of interest, and 90.4% efficacy overall; and a trial of 15,000 participants 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. In both trials, NVX-CoV2373 demonstrated a reassuring safety and tolerability profile.

Novavax and Serum Institute of India Pvt. Ltd. (SII) recently received Emergency Use Authorization (EUA) for the vaccine in Indonesia and the Philippines, and the companies have filed for EUA 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, the European Union,Singapore 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 chemistry, manufacturing and controls (CMC) data package submitted to MoHaP and other global regulatory agencies leverages Novavax' manufacturing partnership with 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.

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, 93.2% efficacy against the predominantly circulating variants of concern and variants of interest, 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 mcg antigen and 50 mcg 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 harnesses the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. NVX-CoV2373, the company's COVID-19 vaccine, received Emergency Use Authorization in Indonesia and the Philippines and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. These 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, LinkedIn, Instagram and Facebook.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, the scope, timing and outcome of future regulatory filings and actions, Novavax' plans to submit a complete package to the U.S. FDA by the end of the year, and Novavax' plan to supplement the CMC data submitted to the MoHaP with data from the 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; 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.

Contacts:

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

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

Media
Alison Chartan | 240-720-7804
Laura Keenan Lindsey | 202-709-7521
media@novavax.com

SOURCE Novavax, Inc.