

U.S. Government Secures 3.2 Million Doses of Novavax COVID-19 Vaccine

July 11, 2022

- *Agreement will provide the first protein-based vaccine option in the U.S., pending FDA Emergency Use Authorization and CDC recommendation*

GAITHERSBURG, Md., July 11, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced an agreement with the U.S. Department of Health and Human Services (HHS), in collaboration with the Department of Defense, to secure an initial 3.2 million doses of Novavax' COVID-19 vaccine (NVX-CoV2373) should it receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and a recommendation from the Centers for Disease Control and Prevention (CDC). Novavax' protein-based vaccine will be made available for free to states, jurisdictions, federal pharmacy partners, and federally qualified health centers.

"We are pleased to come one step closer to potentially offering our vaccine to physicians, healthcare organizations, and consumers who have been awaiting a protein-based vaccine option," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We are grateful for the U.S. government's ongoing support and partnership to bring Novavax' COVID-19 vaccine to the U.S., and we look forward to the FDA's decision on an emergency use authorization."

The Novavax COVID-19 vaccine 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. The Novavax COVID-19 vaccine contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

On June 7, 2022, the FDA's Vaccines and Related Biological Products Advisory Committee [voted to recommend](#) that the FDA grant an EUA for the Novavax COVID-19 vaccine for individuals aged 18 and over. The FDA is currently reviewing Novavax' application for EUA. If EUA is granted, a potential policy recommendation from the CDC would be the final step before immunizations with the Novavax COVID-19 vaccine could begin.

Authorization in the U.S.

NVX-CoV2373 has not yet been authorized for use in the U.S.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine engineered from the genetic sequence of the first strain of SARS-CoV-2, the virus that causes COVID-19 disease. The vaccine was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus 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.

The 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. Use of the vaccine should be in accordance with official recommendations.

Novavax has established partnerships for the manufacture, commercialization, and distribution of NVX-CoV2373 worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India, the world's largest vaccine manufacturer by volume. They will later be supplemented with data from additional manufacturing sites throughout Novavax' global supply chain.

About the NVX-CoV2373 Phase 3 Trials

NVX-CoV2373 continues being evaluated in two pivotal Phase 3 trials.

PREVENT-19 (the **PRE**-fusion protein subunit **V**accine **E**fficacy **N**ovavax **T**rial | COVID-19) is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the efficacy, safety, and immunogenicity of NVX-CoV2373 with Matrix-M adjuvant in 29,960 participants 18 years of age and over in 119 locations in the U.S. and Mexico. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19

with onset at least seven days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%. A secondary endpoint was the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints were assessed at least seven days after the second study vaccination in volunteers who had not been previously infected with SARS-CoV-2. In the trial, NVX-CoV2373 achieved 90.4% efficacy overall. It was generally well-tolerated and elicited a robust antibody response after the second dose in both studies. Full results of the trial were published in the [*New England Journal of Medicine*](#) (NEJM).

The pediatric expansion of PREVENT-19 is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the safety, effectiveness, and efficacy of NVX-CoV2373 with Matrix-M adjuvant in 2,247 adolescent participants 12 to 17 years of age in 73 locations in the United States, compared with placebo. In the pediatric trial, NVX-CoV2373 achieved its primary effectiveness endpoint (non-inferiority of the neutralizing antibody response compared to young adult participants 18 through 25 years of age from PREVENT-19) and demonstrated 80% efficacy overall at a time when the Delta variant of concern was the predominant circulating strain in the U.S. Additionally, immune responses were about two-to-three-fold higher in adolescents than in adults against all variants studied.

PREVENT-19 is being conducted with support from the U.S. government, including the Department of Defense, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the HHS, and the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health at HHS. BARDA is providing up to \$1.75 billion under a Department of Defense agreement (# MCDC2011-001). The Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense is also providing funding of up to \$45.7 million under a separate agreement. To date, the U.S. government has agreed to order 3.2 million doses of NVX-CoV2373 under these existing agreements should NVX-CoV2373 receive FDA EUA and a recommendation from the CDC. Novavax and the U.S. government will determine the timing, pricing, and amounts for delivery of any additional NVX-CoV2373 doses upon FDA EUA. Novavax intends to pursue additional U.S. procurement of both NVX-CoV2373 doses and other potential formulations.

Additionally, a trial conducted in the U.K. with 14,039 participants aged 18 years and over was designed as a randomized, placebo-controlled, observer-blinded study and achieved overall efficacy of 89.7%. The primary endpoint was based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least seven days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline. Full results of the trial were published in [*NEJM*](#).

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, has received conditional authorization from multiple regulatory authorities globally, including the European Commission and the World Health Organization. The vaccine is currently under review by multiple regulatory agencies worldwide and will soon be under review in the U.S. for use in adults, adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating a COVID-seasonal influenza combination vaccine candidate in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and NanoFlu*, its quadrivalent influenza investigational vaccine candidate, and is also evaluating an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent Omicron-based / original strain-based vaccine. 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 [LinkedIn](#).

*NanoFlu identifies a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate produced by Novavax. This investigational candidate was evaluated during a controlled phase 3 trial conducted during the 2019-2020 influenza season.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the potential for subsequent orders from the U.S. government for additional doses of NVX-CoV2373 and other potential formulations, the timing of clinical trial results, the ongoing development of NVX-CoV2373, a COVID-seasonal influenza investigational

vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including with respect to an FDA EUA decision and potential CDC recommendation for NVX-CoV2373, Novavax' plans to supplement existing authorizations with data from the additional manufacturing sites in Novavax' global supply chain, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents and as a booster, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, and the efficacy, safety and intended utilization of NVX-CoV2373 and expected administration of NVX-CoV2373 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, without limitation, 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, 2021 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

Alex Delacroix | 240-268-2022

ir@novavax.com

Media

Ali Chartan or Giovanna Chandler | 202-709-5563

media@novavax.com

SOURCE Novavax, Inc.

Image not found or type unknown