U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted for Individuals Aged 18 and Over

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- *Novavax' vaccine is the first protein-based COVID-19 vaccine authorized in the U.S.*
- *Immunizations with the Novavax COVID-19 Vaccine, Adjuvanted as a primary series will begin upon product release and once a policy recommendation from the CDC is received*

GAITHERSBURG, Md., July 13, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that the Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and over.

"Today's FDA emergency use authorization of our COVID-19 vaccine provides the U.S. with access to the first protein-based COVID-19 vaccine," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "This authorization reflects the strength of our COVID-19 vaccine's efficacy and safety data, and it underscores the critical need to offer another vaccine option for the U.S. population while the pandemic continues."

"Patients and providers in the U.S. now have access to a protein-based COVID-19 vaccine backed by data that have demonstrated efficacy, safety, and tolerability," said Karen Kotloff, M.D., Professor of Pediatrics, University of Maryland School of Medicine, Associate Director of Clinical Studies at the Center for Vaccine Development and Global Health, COVID-19 Prevention Network co-lead for the PREVENT-19 trial. "Offering more vaccine technologies and options in our vaccination portfolio, including those built upon technologies that have been successfully used for years, will hopefully help to increase our country's vaccination rate."

The FDA EUA was based on data from the pivotal Phase 3 clinical trial, PREVENT-19, which enrolled approximately 30,000 participants aged 18 years and over in the U.S. and Mexico. In the trial, the Novavax COVID-19 Vaccine, Adjuvanted demonstrated 90.4% efficacy (95% confidence interval [CI], 83.8% to 94.3%; P<0.001) with a reassuring safety profile. Among participants 18 through 64 years of age, solicited adverse reactions (AR) following administration of any dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (82.2%), fatigue/malaise (62.0%), muscle pain (54.1%), headache (52.9%), joint pain (25.4%), nausea/vomiting (15.6%), injection site redness (7.0%), injection site swelling (6.3%), and fever (6.0%). In participants 65 years of age or over, solicited ARs following administration of any dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (63.4%), fatigue/malaise (39.2%), muscle pain (30.2%), headache (29.2%), joint pain (15.4%), nausea/vomiting (7.3%), injection site swelling (5.3%), injection site redness (4.8%), and fever (2.0%).

Doses of the Novavax COVID-19 Vaccine, Adjuvanted were shipped from the Serum Institute of India Pvt. Ltd., the world's largest vaccine manufacturer by volume, and are now in the U.S. The next step for the vaccine is a policy recommendation for use from the Centers for Disease Control and Prevention (CDC).

Earlier this week, the U.S. Department of Health and Human Services (HHS), in collaboration with the Department of Defense, announced an agreement to secure an initial 3.2 million doses of the Novavax' COVID-19 Vaccine, Adjuvanted. These vaccine doses will be made available for free to states, jurisdictions, federal pharmacy partners, and federally qualified health centers.

In addition to the FDA EUA, the Novavax COVID-19 vaccine has received conditional authorization for use in individuals aged 18 and over from multiple regulatory agencies worldwide, including the European Commission (EC), and emergency use listing from the World Health Organization (WHO).

This project has been supported in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), through the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) under contract #MCDC2011-001.

Use of the Novavax COVID-19 Vaccine, Adjuvanted in the U.S.
The Novavax COVID-19 Vaccine, Adjuvanted has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to provide a two-dose primary series to individuals 18 years of age and older to prevent Coronavirus Disease 2019 (COVID-19).

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Authorized Use
The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) to provide a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications
Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted.

Warnings and Precautions
Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted. Monitor the Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control (CDC) and Prevention guidelines.

Myocarditis and Pericarditis: Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of the Novavax COVID-19 Vaccine, Adjuvanted *(see Full EUA Prescribing Information)*.

Syncope (fainting): May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.

Limitations of Vaccine Effectiveness: The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

Adverse Reactions
Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis.

Myocarditis, pericarditis, and anaphylaxis have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

Reporting Adverse Events and Vaccine Administration Errors
The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events (irrespective of attribution to vaccination),
- cases of Multisystem Inflammatory Syndrome (MIS), and
- cases of COVID-19 that results in hospitalization or death.

Complete and submit reports to VAERS online: https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Novavax COVID-19 Vaccine, Adjuvanted EUA" in the description section of the report.

To the extent feasible, report adverse events to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: www.NovavaxMedInfo.com, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

Please click to see the Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and EUA Full Prescribing Information.

About NVX-CoV2373 (Novavax' COVID-19 Vaccine, Adjuvanted)
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 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.

NVX-CoV2373 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.

The PREVENT-19 trial of NVX-CoV2373 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 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. Novavax intends to pursue additional U.S. procurement of both NVX-CoV2373 doses and other potential formulations.?

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 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 authorization from multiple regulatory authorities globally, including the U.S., EC and the WHO. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional indications and populations such as 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 timing of clinical trial results, the ongoing development of NVX-CoV2373, including an Omicron strain based vaccine and bivalent Omicron-based / original strain based vaccine, a COVID-seasonal influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including a potential policy recommendation from the Centers for Disease Control and Prevention, 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, 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; unanticipated challenges or delays in conducting clinical trials; 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

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