U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted as a Booster for Adults

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GAITHERSBURG, Md., Oct. 19, 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 first booster dose at least six months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

"The U.S. now has access to the Novavax COVID-19 Vaccine, Adjuvanted, the first protein-based option, as a booster," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "According to CDC data, almost 50 percent of adults who received their primary series have yet to receive their first booster dose. Offering another vaccine choice may help increase COVID-19 booster vaccination rates for these adults."

The FDA EUA decision was based on data from the Phase 3 Prevent-19 clinical trial and from the U.K.-sponsored COV-BOOST trial. In the Phase 3 trial, a single booster dose of the Novavax COVID-19 Vaccine, Adjuvanted was administered to healthy adult participants aged 18 and older approximately eight or 11 months after their primary series. Following a booster dose, antibody levels increased significantly relative to pre-boost levels, rising above levels associated with protection in the Phase 3 trials. Neutralizing antibodies also increased by 34- to 27-fold compared to pre-boost levels when boosted at eight or 11 months. In the COV-BOOST trial, the Novavax COVID-19 Vaccine, Adjuvanted increased antibody titers when used as a third dose following initial dosing with another authorized COVID-19 vaccine (heterologous boosting).

In the trial, following the booster, local and systemic reactions had a median duration of approximately two days. The incidence of Grade 3 or higher events remained relatively low. Safety reporting of reactogenicity events showed an increasing incidence across all three doses of the Novavax COVID-19 Vaccine, Adjuvanted, often seen with increased immunogenicity. Among participants 18 years of age and older, solicited adverse reactions following administration of a booster dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (81.1%), fatigue/malaise (63.4%), muscle pain (63.0%), headache (52.9%), joint pain (30.3%), nausea/vomiting (14.7%), injection site swelling (8.4%), injection site redness (6.3%), and fever (6.3%).

The next step for the vaccine is a policy recommendation for use as a first booster from the Centers for Disease Control and Prevention (CDC). Doses of the Novavax COVID-19 Vaccine, Adjuvanted are available for use in the U.S. pending this final step and can be located on Vaccines.gov.

Novavax' vaccine is also available for use as a booster in adults aged 18 and older in the European Union, Japan, Australia, New Zealand, Switzerland, and Israel. In addition, a number of countries have policy recommendations allowing use of the vaccine as a heterologous or homologous booster dose. In the U.S., the FDA granted EUA for a two-dose primary series in adults aged 18 and older in July and for adolescents aged 12 through 17 in August. Following these EUA's, the CDC recommended the vaccine for use as a primary series for both age groups.

This project has been supported in part with federal funds from the Department of Health and Human Services (HHS); the Administration for Strategic 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 Number W15QKN-16-9-1002, Project Number MCDC2011-001.

Use of the Novavax COVID-19 Vaccine, Adjuvanted in the U.S.
The Novavax COVID-19 Vaccine, Adjuvanted vaccine 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 prevent Coronavirus Disease 2019 (COVID-19) as a primary series in individuals 12 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted vaccine is also authorized to provide a first booster dose at least 6 months after completion

of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

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 12 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted vaccine is also authorized to provide a first booster dose at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

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)*. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis).
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, anaphylaxis, paresthesia, and hypoesthesia 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 myocarditis,

- cases of pericarditis,
- cases of Multisystem Inflammatory Syndrome (MIS), in adults and children, and
- cases of COVID-19 that results in hospitalization or death.

Complete and submit reports to VAERS online: 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 (Vaccination Providers) and EUA Full Prescribing Information.

***Please click to see the* Fact Sheet for Recipients and Caregivers.**

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, BARDA, part of the Administration for Strategic Preparedness and Response, 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 (number MCDC2011-001). JPEO-CBRND 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. 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 are being 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. The Novavax COVID-19 vaccine has received authorization from multiple regulatory authorities globally, including the U.S. FDA, the European Commission, and the World Health Organization. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional populations and indications such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its COVID-19-Influenza Combination (CIC) vaccine candidate in a Phase 1/2 clinical trial, its quadrivalent influenza investigational vaccine candidate, and an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent format 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**.

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, NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, a CIC investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including potential recommendations and authorizations from the CDC, 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 evolving COVID-19 pandemic, 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, 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; unanticipated challenges or delays in conducting clinical trials; 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.

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