Novavax Nuvaxovid™ COVID-19 Vaccine Receives Expanded Emergency Use Authorization in Taiwan for Use in Adolescents Aged 12 Through 17

September 16, 2022

GAITHERSBURG, Md., Sept. 16, 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 Taiwan Food and Drug Administration (TFDA) has granted expanded emergency use authorization (EUA) for Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adolescents aged 12 through 17.

"In Taiwan, we have seen strong use of our protein-based COVID-19 vaccine in adults and are pleased to expand availability to adolescents aged 12 through 17 as we prepare for more time spent indoors during the fall and winter months and possible COVID-19 surges," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We believe that our vaccine, developed using an innovative approach to traditional technology, may help increase adolescent vaccination rates."

The EUA is based on data from the ongoing pediatric expansion of the Phase 3 PREVENT-19 trial of 2,247 adolescents aged 12 through 17 years across 75 sites in the U.S., to evaluate the safety and effectiveness of Nuvaxovid. In the pediatric expansion, Nuvaxovid achieved its primary efficacy endpoint with clinical efficacy of 78.29% (95% CI: 37.55%, 92.45%) overall at a time when the Delta variant was the predominant circulating SARS-CoV-2 strain in the U.S. The efficacy analysis was supported by assessment of antibody titers that were shown to be higher in adolescents than in young adults.

Preliminary safety data from the pediatric expansion showed the vaccine to be generally well-tolerated. Serious and severe adverse reactions (AR) were low in number and balanced between vaccine and placebo groups, and not considered related to the vaccine. Local and systemic reactogenicity was generally lower than or similar to adults, after the first and second dose. Among participants 12 through 17 years of age, solicited ARs following administration of any dose of the vaccine were injection site pain/tenderness (75.0%), headache (56.9%), fatigue/malaise (57.9%), muscle pain (49.0%), nausea/vomiting (19.9%), joint pain (16.2%), fever (16.9%), injection site swelling (8.0%), and injection site redness (7.5%). Most were mild-to-moderate in severity and lasted less than two days. No new safety signal was observed through the placebo-controlled portion of the pediatric expansion.

In the 12 through 17-year-old population, the vaccine has been authorized in more than 10 markets including the U.S., the European Union, and the United Kingdom (U.K.).

The TFDA previously granted EUA for Nuvaxovid to prevent COVID-19 in adults aged 18 and older in June 2022.

Trade Name in the U.S.

The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration (FDA).

Important Safety Information

- Nuvaxovid is contraindicated in persons who have a hypersensitivity to the active substance, or to any of the excipients.
- Events of anaphylaxis have been reported with administration of COVID-19 vaccines. Appropriate medical treatment and supervision should be available in case of an anaphylactic reaction following the administration of the vaccine. Close observation for at least 15 minutes is recommended and a second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of the vaccine.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress?related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.
- Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- Nuvaxovid should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

- The efficacy of Nuvaxovid may be lower in immunosuppressed individuals.
- Administration of Nuvaxovid in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.
- The effects with Nuvaxovid may temporarily affect the ability to drive or use machines.
- Individuals may not be fully protected until seven days after their second dose. As with all vaccines, vaccination with Nuvaxovid may not protect all vaccine recipients.
- The most frequent adverse reactions in adolescents 12 to 17 years of age were injection site tenderness, injection site pain, headache, myalgia, fatigue, malaise, nausea or vomiting, arthralgia, injection site swelling, pyrexia, and injection site redness.

For more information on NVX-CoV2373 please visit the following website:

- **Novavax global authorization website**

About Nuvaxovid™ (NVX-CoV2373)

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

Nuvaxovid is packaged as a ready-to-use liquid formulation in a vial containing 10 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 Nuvaxovid 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 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 U.S., compared with placebo. In the pediatric trial, the vaccine 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.

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. 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 indications and populations such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its COVID-19-Influenza Combination 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 timing of clinical trial results, the ongoing development of NVX-CoV2373, NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, a COVID-seasonal influenza combination investigational vaccine candidate, a quadrivalent influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including 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 intended utilization, and the 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; 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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