Novavax Nuvaxovid™ COVID-19 Vaccine? Authorized in the United Kingdom for Use as a Booster in Adults

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GAITHERSBURG, Md., Nov. 9, 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 Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (U.K.) has expanded the conditional marketing authorization (CMA)[i] for Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine? as a homologous and heterologous booster dose after the primary series of Nuvaxovid (six months) or of an mRNA or adenoviral vector vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults aged 18 and older.

"Our protein-based vaccine, developed using an innovative approach to traditional technology, may have a prominent role to play in COVID-19 boosting," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "As we continue to explore best practices for managing COVID-19 long term, we have ongoing trials further exploring Nuvaxovid's immunogenicity as a booster dose. Currently available clinical and preclinical data indicate that our vaccine induces robust immune responses against Omicron variants, including BA.4/5."

The MHRA decision was based on data from Novavax' Phase 2 trial conducted in the U.S. and Australia (1,283 participants), from a separate Phase 2 trial conducted in South Africa (4,404 participants), and from the U.K.-sponsored COV-BOOST trial (2,878 participants).[1,2] As part of the Phase 2 trials, a single booster dose of Nuvaxovid was administered to healthy adult participants approximately six months after their primary two-dose vaccination series of Nuvaxovid.[1,2] The third dose produced increased immune responses against the original ancestral strain of SARS-CoV-2 comparable to or exceeding levels associated with protection in Phase 3 clinical trials.[1,2] In the COV-BOOST trial, Nuvaxovid increased antibody titers when used as a heterologous third booster dose after a primary two-dose vaccination series of an mRNA vaccine or adenoviral vector vaccine.[2]

In the Novavax-sponsored trials, following the booster, local and systemic reactions had a median duration of approximately two days.[1,2] Adverse reactions were usually mild to moderate in severity.[1,2] Safety reporting of reactogenicity events showed an increasing incidence across all three doses of Nuvaxovid. Medically attended adverse events (AE), potentially immune-mediated medical conditions, and severe AEs occurred infrequently following the booster dose and were balanced between vaccine and placebo groups.[1,2]

Nuvaxovid is also available for use as a booster in adults aged 18 and older in the U.S., 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.

The MHRA previously granted CMA for Nuvaxovid as a primary series in adults aged 18 and older in February 2022, and in adolescents aged 12 through 17 in August 2022.

?This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you are concerned about an adverse event, it should be reported on a Yellow Card. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting please include the vaccine brand and batch/Lot number if available.

i. Additional efficacy and safety data are being collected.

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: UK

- 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 Nuvaxovid. 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 Nuvaxovid.

- There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.
- 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 (adverse reactions described in section 4.8 of the SPC) with Nuvaxovid may temporarily affect the ability to drive or use machines.
- Individuals may not be fully protected until 7 days after their second dose. As with all vaccines, vaccination with Nuvaxovid may not protect all vaccine recipients.
- The most common adverse reactions observed during clinical studies were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

For more information on Nuvaxovid, including the Summary of Product Characteristics with Package Leaflet, adverse event reporting instructions, or to request additional information, please visit the following websites:

- **MHRA Regulatory approval of COVID-19 vaccine Nuvaxovid**
- **Novavax global authorization website**

About Nuvaxovid™ (NVX-CoV2373)
Nuvaxovid (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. 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 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 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 the Novavax COVID-19 vaccine (NVX-CoV2373) Phase 3 Trials
The Novavax COVID-19 vaccine (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 the Novavax COVID-19 vaccine 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, the Novavax COVID-19 vaccine 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 the Novavax COVID-19 vaccine 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 WHO. 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 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, including NVX-CoV2515 and bivalent Omicron-based / original strain based vaccine, a COVID-seasonal influenza investigational vaccine candidate, its quadrivalent influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including any potential recommendations and authorizations from JVCI, MHRA or any other regulatory authority, 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 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; 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
Erika Schultz | 240-268-2022
ir@novavax.com

Media
Ali Chartan or Giovanna Chandler | 202-709-5563
media@novavax.com

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2. Munro APS, Janani L, Cornelius V, et al. Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial [published correction appears in Lancet. 2021 Dec 18;398(10318):2246]. Lancet. 2021;398(10318):2258-2276. doi:10.1016/S0140-6736(21)02717-3.

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