Medicines and Healthcare Products Regulatory Agency Grants Conditional Marketing Authorization for Novavax COVID-19 Vaccine in Great Britain*

February 3, 2022

- *Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted)? is the first protein-based COVID-19 vaccine authorized in Great Britain*
- *Novavax and the U.K. Vaccines Taskforce previously announced an agreement for up to 60 million doses*
- *Authorization based on data including an ongoing pivotal Phase 3 trial conducted in the U.K. with almost 15,000 participants*

GAITHERSBURG, Md., Feb. 3, 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) has granted conditional marketing authorization (CMA) for Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older in Great Britain. The vaccine, also known as NVX-CoV2373, is the first protein-based vaccine to be authorized for use in Great Britain.

"We are proud that Nuvaxovid will be the first protein-based vaccine option authorized by MHRA as the United Kingdom tackles this next phase of the pandemic," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the agency for its thorough review process and are tremendously grateful to the clinical trial participants and trial sites in the U.K., as well as the Vaccines Taskforce, for their ongoing support and vital contributions to this program."

The MHRA decision was based on the totality of preclinical, clinical, and chemistry, manufacturing and controls (CMC) data reviewed by the agency. This includes two pivotal ongoing Phase 3 clinical trials: PREVENT-19 which enrolled approximately 30,000 participants in the U.S. and Mexico, the results of which were published in the*New England Journal of Medicine (NEJM)*[i]; and a trial with almost 15,000 participants in the U.K., the results of which were also published in *NEJM*[ii]. In both trials, the vaccine demonstrated efficacy with a reassuring safety profile. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups. The most common adverse reactions observed during clinical studies (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise. Novavax will continue to collect and analyze real-world data, including the monitoring of safety and the evaluation of variants, as the vaccine is distributed. The vaccine is stored at 2° - 8° Celsius and has a current assigned shelf life in Great Britain of 9 months.

Novavax previously announced an agreement with the U.K. Vaccines Taskforce for up to 60 million doses of Novavax' COVID-19 vaccine.

For more information on Nuvaxovid, including a full listing of where it has been authorized for use, please visit the following websites:

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

The brand name Nuvaxovid™ has not yet been authorized for use in the U.S. by the FDA.

Conditional Marketing Authorization of Nuvaxovid™ in Great Britain
The Medicines and Healthcare products Regulatory Agency (MHRA) has granted conditional marketing authorization for Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

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. A

second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Nuvaxovid.
- 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. 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 hemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
- The efficacy of Nuvaxovid may be lower in immunosuppressed individuals.
- The effects 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 (frequency category of very common ?1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

For additional information, please visit www.NovavaxCovidVaccine.com for the full Summary of Product Characteristics with Package Leaflet, Prescribing Information and Important Safety Information, adverse event reporting instructions, or to request additional information.

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. NVX-CoV2373 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.

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. The current assigned shelf life of the vaccine in Great Britain is 9 months. 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 (SII), 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 is being evaluated in two pivotal Phase 3 trials.

PREVENT-19, a trial in the U.S. and Mexico that enrolled almost 30,000 participants, achieved 90.4% efficacy overall. It was designed as a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 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%. The key secondary endpoint is 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. 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)*[i].

A trial conducted in the U.K. with 14,039 participants 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 7 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*[ii].

About Matrix-M™ Adjuvant
Novavax' patented saponin-based Matrix-M™ adjuvant has demonstrated a potent and generally 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 Conditional Marketing Authorization from the European Commission** and Emergency Use Listing from the World Health Organization. The vaccine is also under review by multiple regulatory agencies worldwide.

For more information, visit www.novavax.com and connect with us LinkedIn.

Forward-Looking Statements
Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the ongoing development of NVX-CoV2373, 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, the potential impact 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 integration of NVX-CoV2373 into the United Kingdom's broader COVID-19 vaccination program 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 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, 2020 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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[i] Dunkle L, Kotloff K, Gay C. Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico. N Engl J Med. 2021 Dec 15.
[ii] Heath P, Galiza E, Baxter D. Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine. N Engl J Med. 2021 June 30;385:1172-1183.

?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.
*Great Britain conditional marketing authorization includes England, Scotland and Wales
**European Commission conditional marketing authorization includes Northern Ireland

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