European Commission Grants Conditional Marketing Authorization for Novavax COVID-19 Vaccine

December 20, 2021

- *Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) is the first protein-based COVID-19 vaccine authorized for use in Europe*
- *Novavax and the European Commission previously announced an advance purchase agreement for up to 200 million doses through 2023*
- *Authorization follows positive recommendation by European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP)*

GAITHERSBURG, Md., Dec. 20, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that the European Commission (EC) has granted Novavax 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. The authorization follows the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommendation today to authorize the vaccine (also known as NVX-CoV2373) and is applicable in all 27 European Union (E.U.) member states.

"We welcome today's European Commission decision reflecting the first authorization of a protein-based COVID-19 vaccine for the people of the E.U.," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the European Medicines Agency, the Committee for Medicinal Products for Human Use reviewers and the European Commission for their thorough assessment as we look forward to playing a critical role in helping to address the continued threat of COVID-19. We also thank the thousands of clinical trial participants, our partners and Novavax employees worldwide who have contributed to this historic milestone."

Click here to view multimedia content that accompanies this press release.

The EMA opinion and related EC decision is based on the totality of preclinical, manufacturing and clinical trial data submitted for review. This includes two pivotal Phase 3 clinical trials: PREVENT-19 which included 30,000 participants in the U.S. and Mexico, the results of which were published in *The New England Journal of Medicine (NEJM)*; and a trial with 15,000 participants in the U.K., the results of which were also published in *NEJM*. In both trials, NVX-CoV2373 demonstrated high efficacy and an acceptable safety and tolerability profile. 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.

Novavax and the EC announced an advance purchase agreement (APA) for up to 200 million doses of Novavax' COVID-19 vaccine in August 2021. Initial doses are expected to arrive in Europe in January. Novavax is working with EMA and its partners to expedite local release testing.

This authorization leverages Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, which will supply initial doses for the E.U. It will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.

Novavax and SII recently received emergency use authorization (EUA) in Indonesia and the Philippines, where it will be commercialized by SII under the trade name Covovax™. The companies also received emergency use listing for Covovax from the World Health Organization. The vaccine is also currently under review by multiple regulatory agencies worldwide, and the company expects to submit its complete chemistry, manufacturing and controls (CMC) data package to the U.S. Food and Drug Administration (FDA) by the end of the year.

Authorized Use of Nuvaxovid™ in the European Union
European Commission 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
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation, or stress–related reactions may occur in association with vaccination as a 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
- Give Nuvaxovid 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
- The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials
- 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

Please visit https://www.novavaxcovidvaccine.com for the full leaflet and adverse reaction reporting instructions.

Detailed information on this medicine is also available on the European Medicines Agency web site: http://www.ema.europa.eu

Authorization in the U.S.
NVX-CoV2373 has not yet been authorized for use in the U.S. and the trade name Nuvaxovid has not yet been approved by the U.S. FDA.

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.

Novavax has established partnerships for the manufacture, commercialization and distribution of NVX-CoV2373 worldwide.

About the NVX-CoV2373 Phase 3 trials
NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials.

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.

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 in both studies.

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, received Emergency Use Authorization in Indonesia and the Philippines and has been submitted for regulatory authorization in multiple markets globally. NanoFlu™, the company's quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Novavax is currently evaluating a COVID-NanoFlu combination vaccine in a Phase 1/2 clinical trial. 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 Twitter, LinkedIn, Instagram and Facebook.

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 the CMA submitted to the EMA and, by the end of the year, to submit a complete CMC data package to the U.S. FDA, the timing of the arrival of doses, and Novavax' role in helping to address COVID-19 and control the pandemic globally 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.

Contacts:

Investors
Novavax, Inc.
Erika Schultz | 240-268-2022
ir@novavax.com

Solebury Trout
Alexandra Roy | 617-221-9197
aroy@soleburytrout.com

Media
Ali Chartan | 240-720-7804
Laura Keenan Lindsey | 202-709-7521
media@novavax.com

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