Novavax Submits Request to Expand Conditional Marketing Authorization of COVID-19 Vaccine in the European Union to Adolescents (Ages 12-17)

March 31, 2022

- *If granted, Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) would be the first protein-based option for adolescents aged 12-17 years in Europe*

GAITHERSBURG, Md., March 31, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced submission of its request to expand the conditional marketing authorization (CMA) of Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) in the European Union (EU) to adolescents aged 12 through 17 years.

"We are continuing to see spikes in COVID-19 across Europe and recognize the need to improve vaccination rates, particularly in the pediatric population," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We look forward to a decision from the European Medicines Agency and firmly believe in the benefit of diversified vaccine options."

The submission includes clinical data from the ongoing pediatric expansion of PREVENT-19, a pivotal Phase 3 trial of 2,247 adolescents aged 12 through 17 years across 73 sites in the U.S., to evaluate the safety, effectiveness (immunogenicity), and efficacy of Novavax' COVID-19 vaccine. The vaccine, also known as NVX-CoV2373, achieved its primary effectiveness endpoint in the trial and demonstrated 80% efficacy overall at a time when the Delta variant was the predominant circulating strain in the U.S.

Additionally, preliminary safety data from the pediatric expansion of PREVENT-19 showed the vaccine to be generally well-tolerated. Serious and severe adverse events 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. The most common adverse reactions observed were injection site tenderness/pain, headache, myalgia, fatigue, and malaise.

The submission builds on Novavax' efforts to expand authorizations of its COVID-19 vaccine to younger populations. The Drugs Controller General of India recently approved NVX-CoV2373 for restricted use in emergency situation for adolescents aged 12 through 17 years in India. SK bioscience, Novavax' licensee in South Korea, also recently submitted a regulatory filing for adolescent authorization of the vaccine to the Korean Ministry of Food and Drug Safety. Novavax expects to initiate rolling submissions of regulatory filings in this age group to additional regulatory authorities worldwide and to initiate additional studies globally evaluating younger age groups during the second quarter of 2022.

The European Commission granted CMA for Nuvaxovid to prevent COVID-19 in people 18 years of age and older in December 2021. Doses of Nuvaxovid began shipping to EU member states shortly thereafter. For additional information on Nuvaxovid, please visit the following websites:

- European Medicines Agency
- European Commission

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.

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.

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 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. 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 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 additional safety information, including the full Summary of Product Characteristics with Package Leaflet, please visit www.NovavaxCovidVaccine.com.

Information on this medicine is also available on the European Medicines Agency website.

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. 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 aged 18 years and older, 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%. 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. 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)*.

A trial conducted in the U.K. with 14,039 participants aged 18 years and older 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*.

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, has received conditional authorization from multiple regulatory authorities globally, including the European Commission and the World Health Organization. The vaccine is also under review by multiple regulatory agencies worldwide. In addition to its COVID-19 vaccine, Novavax is also currently evaluating a COVID-seasonal influenza combination vaccine in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and NanoFlu, its quadrivalent influenza investigational vaccine candidate. 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 timing of clinical trial results, the ongoing development of NVX-CoV2373, including Novavax' plans to initiate pediatric studies in Q2 2022, its COVID-seasonal 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 adolescents, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, controlling the pandemic and protecting populations, and the efficacy, safety and intended utilization 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; 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, 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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