Novavax Announces Shipments of its COVID-19 Vaccine to European Union Member States

February 23, 2022

Immunizations with Nuvaxovid™ to begin in coming days

GAITHERSBURG, Md., Feb. 23, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced the first doses of Nuvaxovid™ COVID-19 Vaccine (recombinant, adjuvanted) have begun shipping to European Union (EU) member states. Nuvaxovid, also known as NVX-CoV2373, is the first protein-based COVID-19 vaccine authorized for use in Europe.

Local test and release procedures were completed and Nuvaxovid doses are shipping from Novavax' Netherlands distribution center to EU member states beginning this week. The first wave of shipments includes several countries, such as Germany, France and Austria. Shipments to additional EU member states are expected to quickly follow.

"Today's announcement paves the way for vaccination with Nuvaxovid to begin in Europe within the coming days. The Novavax COVID-19 vaccine provides a differentiated option to bolster vaccination rates across Europe," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Nuvaxovid has demonstrated efficacy, a reassuring safety and tolerability profile, and is built on a well-understood protein-based vaccine platform used for other vaccines for decades."

The European Commission (EC) granted conditional marketing authorization (CMA) for Nuvaxovid for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older. The authorization followed the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommendation to authorize the vaccine and is applicable in all 27 EU member states. Novavax expects to submit its regulatory filing for a pediatric indication in adolescents aged 12 through 17-years to global regulatory authorities, including EMA, during the first quarter of 2022.

Novavax and the EC have an advance purchase agreement for up to 100 million doses of Nuvaxovid with the option for an additional 100 million doses (up to 200 million doses total). Through the second quarter, Novavax has received a commitment for orders from the EC totaling 69 million doses. The initial doses were manufactured by Novavax' partner, the Serum Institute of India, the world's largest vaccine manufacturer by volume. Information about dose administration will be available through each member state.

For more information on Nuvaxovid, including the European approved Product Information, European approved Consumer Medicines Information and Important Safety Information, or to request additional information, please visit the following websites:

- European Medicines Agency website
- Novavax global authorization website

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

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

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 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 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, including a COVID-seasonal influenza combination vaccine candidate with NanoFlu, its quadrivalent influenza investigational vaccine candidate, the scope, timing and outcome of future regulatory filings and actions, including Novavax' plans to submit global regulatory filings for a NVX-CoV2373 pediatric indication during the first quarter of 2022, and 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 delivery 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 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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