Health Canada Authorizes Novavax COVID-19 Vaccine

February 17, 2022

Nuvaxovid™ is the first protein-based COVID-19 vaccine authorized for use in Canada

GAITHERSBURG, Md., Feb. 17, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that Health Canada has granted authorization for Nuvaxovid™ COVID-19 Vaccine (Recombinant protein, Adjuvanted) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine, also known as NVX-CoV2373, is the first protein-based vaccine to be authorized for use in Canada.

"We are proud that Canada is part of the growing list of regions to authorize Nuvaxovid and that Canadians will have a protein-based COVID-19 vaccine option," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We thank the Canadian government and the National Research Council of Canada for their ongoing partnership and commitment to helping combat the evolving pandemic."

The Health Canada decision was 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 enrolled approximately 30,000 participants aged 18 years and older in the U.S. and Mexico and was published in the *New England Journal of Medicine (NEJM)*; and a trial with almost 15,000 adult participants in the U.K. which was also published in *NEJM*. In both trials, NVX-CoV2373 demonstrated efficacy and a reassuring safety and tolerability 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.

Novavax and the Government of Canada signed an advance purchase agreement for 52 million doses of Novavax' COVID-19 vaccine, with the option for up to an additional 24 million doses, in January 2021 and established a memorandum of understanding to produce NVX-CoV2373 at the National Research Council of Canada's (NRC) Biologics Manufacturing Centre in Montréal in February 2021. Novavax and the NRC have been working closely to establish the production of NVX-CoV2373 at the Biologics Manufacturing Centre. Good Manufacturing Practice (GMP) production is expected to begin later this year.

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

- Health Canada
- Novavax global authorization website

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

Authorization of Nuvaxovid™ in Canada
Health Canada has granted authorization for registration of Nuvaxovid™ COVID-19 Vaccine (Recombinant protein, Adjuvanted) to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (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 ingredient or to any ingredients in the formulation
- Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection
- Individuals may not be optimally protected until 7 days after their second dose.
- 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.

- 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 effects with Nuvaxovid may temporarily affect the ability to drive or use machines.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
- 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.
- Administration of Nuvaxovid in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.
- The most common adverse reactions observed during clinical studies were injection site tenderness, injection site pain, fatigue, myalgia, headache, malaise, arthralgia, and nausea or vomiting.

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 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, the expected large-scale Good Manufacturing Practice production, 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.

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

SOURCE Novavax, Inc.