Australia Therapeutic Goods Administration (TGA) Grants Provisional Registration for Novavax COVID-19 Vaccine

Nuvaxovid™ is the first protein-based COVID-19 vaccine to receive approval for provisional registration in Australia

GAITHERSBURG, Md., Jan. 19, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that Australia's Therapeutic Goods Administration (TGA) has granted approval for provisional registration of NVX-CoV2373, Novavax' COVID-19 vaccine (adjuvanted), for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 18 years of age and older. The vaccine will be supplied to Australia under the brand name Nuvaxovid™.

"The grant of provisional registration of Nuvaxovid by the TGA reflects Novavax' increasing momentum around the globe and represents the first-protein based COVID-19 vaccine authorized for use in Australia," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "While the world continues to grapple with the ever-changing nature of the virus, we look forward to delivering our vaccine to the people of Australia. We would also like to extend our gratitude to the Australian clinical trial participants who contributed so significantly to the development of our vaccine."

Australia has played a pivotal role in Novavax' Phase 1 and Phase 2 clinical trials supporting the development of Nuvaxovid. Additionally, a booster trial for Nuvaxovid and a Phase 1/2 trial for a combination seasonal influenza and COVID-19 vaccine are currently underway in Australia. Overall, nearly 1,500 Australians have participated in Novavax COVID-19 and combination vaccine clinical trials.

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

The approval for provisional registration by the TGA 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 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)*; and a trial with almost 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 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 Commonwealth of Australia announced an advance purchase agreement (APA) for 51 million doses of Novavax' COVID-19 vaccine in January 2021, with the option for an additional 10 million doses (up to 61 million doses total). The approval for provisional registration leverages Novavax' manufacturing partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer by volume, which will supply initial doses to Australia. It will later be supplemented with data from additional manufacturing sites in Novavax' global supply chain.

Novavax received conditional marketing authorization (CMA) for NVX-CoV2373 in the European Union and emergency use listing (EUL) from the World Health Organization (WHO). The Novavax/SII vaccine (brand name, Covovax™) recently received emergency use authorization (EUA) in India, Indonesia and the Philippines, as well as EUL from the WHO. The Novavax/SK bioscience vaccine was granted approval in South Korea by the Ministry of Food and Drug Safety (MFDS). The vaccine is also currently under review by multiple regulatory agencies worldwide. The company submitted its complete chemistry, manufacturing and controls (CMC) data package to the U.S. Food and Drug Administration (FDA) at the end of 2021 and expects to submit a request for EUA for the vaccine in the U.S. after one month in accordance with guidance from the FDA regarding submission of all EUA vaccines.

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

- Novavax global authorization website
- TGA vaccines website

The brand name Nuvaxovid™ has not yet been authorized for use in the U.S. by the FDA. Novavax' sponsor in Australia is Biocelect Pty. Ltd.

Provisional Registration of Nuvaxovid™ in Australia

The Therapeutic Goods Administration (TGA) has granted approval for provisional registration of Nuvaxovid™ COVID-19 Vaccine (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.
- 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 (frequency category of very common ≥1/10) were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

For additional safety information, please visit www.NovavaxCovidVaccine.com for the full Australian Product Information (PI) and Australian Consumer Medicine Information (CMI). Information regarding adverse event reporting instructions can also be found at www.NovavaxCovidVaccine.com.

Information on this vaccine is also available on the Australia Therapeutic Goods Administration website: www.tga.gov.au.

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 Australia is 6 months.

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.

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. 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 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, received Conditional Marketing Authorization from the European Commission, Emergency Use Listing from the World Health Organization, 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, which combines the company's NVX-CoV2373 and NanoFlu vaccine candidates. 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 data submitted to the TGA 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, 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 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.
