Novavax Investor Relations

GAITHERSBURG, Md., Jan. 18, 2023 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced that partner SK bioscience has received expanded manufacturing and marketing approval from the Korean Ministry of Food and Drug Safety (KMFDS) for Nuvaxovid™ (NVX-CoV2373) for use as a booster for active immunization to prevent COVID-19 in adults aged 18 and older. Prior to the approval, in September 2022, the Korean Centers for Disease Control and Prevention set out recommendations that advised that Nuvaxovid could be used as a booster in adults aged 18 and older.

"We are pleased to collaborate with SK bioscience to offer our protein-based vaccine, Nuvaxovid, for use as a booster in adults regardless of previous vaccine history," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "This is an important step in ensuring broad access to diversified vaccine options."

This approval is based on data from Novavax' Phase 2 trial conducted in the U.S. and Australia, from a separate Phase 2 trial conducted in South Africa, and from the United Kingdom-sponsored COV-BOOST trial. As part of the Novavax Phase 2 trials, a single booster dose of Nuvaxovid was administered to adult participants approximately six months after their primary two-dose vaccination series of Nuvaxovid. The third dose produced increased immune responses comparable to or exceeding levels associated with protection in Phase 3 clinical trials. In the COV-BOOST trial, Nuvaxovid induced a significant antibody response when used as a booster dose following prior vaccination with other authorized COVID-19 vaccines.

In the Novavax-sponsored trials, following the booster, local and systemic reactions had a median duration of approximately two days. The incidence of Grade 3 or higher events remained relatively low. Safety reporting of reactogenicity events showed an increasing incidence across all three doses of Nuvaxovid, often seen with increased immunogenicity. Medically attended adverse events (AE), potentially immune-mediated medical conditions, and severe AEs occurred infrequently following the booster dose and were balanced between vaccine and placebo groups.

Novavax' COVID-19 vaccine is authorized for use as an adult booster in more than 35 countries, and a number of other countries have policy recommendations allowing use of the vaccine as a booster dose. The vaccine is actively under review in other markets and has ongoing trials to further explore its efficacy and safety as a booster.

KFMDS previously approved Nuvaxovid as a primary series in adults aged 18 and older in January 2022 and as a primary series in adolescents aged 12 through 17 in August 2022. In Korea, SK bioscience signed a licensing agreement with Novavax and is manufacturing drug substance and drug product of Nuvaxovid for domestic use.

Trade Name in the U.S.
The trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration (FDA).

Important Safety Information: South Korea

- 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 seven 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 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:

- **KMFDS**
- **SK bioscience**
- **Novavax global authorization website**

About Nuvaxovid™ (NVX-CoV2373)
Nuvaxovid (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. The vaccine was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike protein and is formulated with Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. Nuvaxovid contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

Nuvaxovid 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 Nuvaxovid worldwide. Existing authorizations leverage Novavax' manufacturing partnership with Serum Institute of India, 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. The Novavax COVID-19 vaccine, has received authorization from multiple regulatory authorities globally, including the U.S. FDA, the European Commission, and the World Health Organization. The vaccine is currently under review by multiple regulatory agencies worldwide, including for additional indications and populations such as adolescents and as a booster. In addition to its COVID-19 vaccine, Novavax is also currently evaluating its COVID-19-Influenza Combination (CIC) vaccine candidate, its quadrivalent influenza investigational vaccine candidate, and an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent format Omicron-based / original strain-based vaccine. 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 timing of clinical trial results, the ongoing development of NVX-CoV2373, NVX-CoV2515 and a bivalent Omicron-based / original strain based vaccine, the CIC investigational vaccine candidate, a 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, additional worldwide authorizations of NVX-CoV2373 for use in adults and adolescents, and as a booster, the potential impact and reach of Novavax and NVX-CoV2373 in addressing vaccine access, increasing vaccination rates, controlling the pandemic, and protecting populations, the efficacy, safety, intended utilization, and expected administration 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; unanticipated challenges or delays in conducting clinical trials; 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 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
Erika Schultz | 240-268-2022
ir@novavax.com

Media
Ali Chartan and Giovanna Chandler | 202-709-5563
media@novavax.com

SOURCE Novavax, Inc.
