

Novavax Announces Expanded Agreement with SK bioscience to Manufacture COVID-19 Vaccine Containing Omicron Variant and Manufacture the Novavax COVID-19 Vaccine in Prefilled Syringes

July 19, 2022

GAITHERSBURG, Md., July 19, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, has signed agreements with its partner, SK bioscience, for the manufacturing and supply of a version of the Novavax COVID-19 vaccine (NVX-CoV2373) containing Omicron variant and for the manufacture of the vaccine in prefilled syringes.

The companies signed an agreement for the technology transfer of Novavax' proprietary COVID-19 variant antigen materials so that SK bioscience can manufacture the drug substance targeting COVID-19 variants including the Omicron BA.5 subvariant.

"Non-clinical data generated to date demonstrate that our COVID-19 vaccine offers broad immune responses including against circulating variants, such as Omicron BA.5," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We are accelerating our clinical program evaluating an Omicron BA.5 component to our vaccine and look forward to continuing to work with SK bioscience as an important manufacturing partner."

In addition, the companies have signed an agreement to manufacture and supply the Novavax COVID-19 vaccine in a prefilled syringe. SK bioscience will begin work to enable the manufacturing process for commercial supply of the vaccine in prefilled syringes in 2023.

Currently, SK bioscience manufactures drug substance for the vaccine. Novavax and SK bioscience also have a collaboration and licensing agreement under which SK bioscience exclusively commercializes the Novavax COVID-19 vaccine in South Korea, and with Novavax, jointly commercializes the vaccine in Vietnam and Thailand.

Authorized Use in the U.S.

The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) to provide a two-dose primary series for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted.

Warnings and Precautions

Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted. Monitor the Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to [the Centers for Disease Control \(CDC\) and Prevention guidelines](#).

Myocarditis and Pericarditis: Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of the Novavax COVID-19 Vaccine, Adjuvanted (*see Full EUA Prescribing Information*).

Syncope (fainting): May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.

Limitations of Vaccine Effectiveness: The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis.

Myocarditis, pericarditis, and anaphylaxis have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events (irrespective of attribution to vaccination),
- cases of Multisystem Inflammatory Syndrome (MIS), and
- cases of COVID-19 that results in hospitalization or death.

Complete and submit reports to VAERS online: <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Novavax COVID-19 Vaccine, Adjuvanted EUA" in the description section of the report.

To the extent feasible, report adverse events to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: www.NovavaxMedInfo.com, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

[Please click to see the Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccine Providers\) and EUA Full Prescribing Information.](#)

About the Novavax COVID-19 vaccine (NVX-CoV2373)

The Novavax COVID-19 vaccine (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. The vaccine 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. The Novavax COVID-19 vaccine contains purified protein antigen and can neither replicate, nor can it cause COVID-19.

The 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 its COVID-19 vaccine 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.

The Novavax COVID-19 vaccine and the PREVENT-19 trial have been supported in part with federal funds from the U.S. government, including the Department of Health and Human Services (HHS); Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), through the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND); and the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health at HHS. BARDA is providing up to \$1.75 billion under a Department of Defense agreement (# MCDC2011-001). The Department

of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense is also providing funding of up to \$45.7 million under a separate agreement. To date, the U.S. government has agreed to order 3.2 million doses of Novavax' vaccine under these existing agreements should it receive a recommendation from the CDC. Novavax and the U.S. government will determine the timing, pricing, and amounts for delivery of any additional doses. Novavax intends to pursue additional U.S. procurement of both its COVID-19 vaccine doses and other potential formulations.?

About the Novavax COVID-19 vaccine (NVX-CoV2373) Phase 3 Trials

The Novavax COVID-19 vaccine (NVX-CoV2373) continues being evaluated in two pivotal Phase 3 trials.

PREVENT-19 (the **PRE**-fusion protein subunit **Vaccine** **Efficacy** **Novavax** **Trial** | **COVID-19**) is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the efficacy, safety, and immunogenicity of the Novavax COVID-19 vaccine with Matrix-M adjuvant in 29,960 participants 18 years of age and over in 119 locations in the U.S. and Mexico. The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate, or severe) COVID-19 with onset at least seven 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. In the trial, the Novavax COVID-19 vaccine achieved 90.4% efficacy overall. 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* \(NEJM\)](#).

The pediatric expansion of PREVENT-19 is a 2:1 randomized, placebo-controlled, observer-blinded trial to evaluate the safety, effectiveness, and efficacy of the Novavax COVID-19 vaccine with Matrix-M adjuvant in 2,247 adolescent participants 12 to 17 years of age in 73 locations in the United States, compared with placebo. In the pediatric trial, the vaccine achieved its primary effectiveness endpoint (non-inferiority of the neutralizing antibody response compared to young adult participants 18 through 25 years of age from PREVENT-19) and demonstrated 80% efficacy overall at a time when the Delta variant of concern was the predominant circulating strain in the U.S. Additionally, immune responses were about two-to-three-fold higher in adolescents than in adults against all variants studied.

Additionally, a trial conducted in the U.K. with 14,039 participants aged 18 years and over 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 seven 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. The Novavax COVID-19 vaccine, has received authorization from multiple regulatory authorities globally, including the U.S., EC, and the WHO. 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 a COVID-seasonal influenza combination vaccine candidate in a Phase 1/2 clinical trial, which combines NVX-CoV2373 and NanoFlu*, its quadrivalent influenza investigational vaccine candidate, and is also evaluating an Omicron strain-based vaccine (NVX-CoV2515) as well as a bivalent 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](#).

*NanoFlu identifies a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine candidate produced by Novavax. This investigational candidate was evaluated during a controlled phase 3 trial conducted during the 2019-2020 influenza season.?

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, its partnerships, the potential for subsequent orders from the U.S. government for additional doses of NVX-CoV2373 and other potential formulations, the timing of clinical trial results, the ongoing development of NVX-CoV2373, including an Omicron strain based vaccine and bivalent Omicron-based / original strain based vaccine, a 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 use in adults and adolescents, and as a booster, the potential impact and reach 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 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

Alex Delacroix | 240-268-2022

ir@novavax.com

Media

Ali Chartan or Giovanna Chandler | 202-709-5563

media@novavax.com

SOURCE Novavax, Inc.

Image not found or type unknown