Initial Results from Novavax' COVID-19-Influenza Vaccine Trial are First to Show Feasibility of Combination Vaccine

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- *Phase 1/2 clinical trial of COVID-19-Influenza combination vaccine candidate indicates vaccine is well-tolerated and immunogenic*
- *Data from this combination trial will inform planned Phase 2 dose confirmation trial, scheduled to begin by the end of 2022*
- *Immune response confirmed in stand-alone influenza vaccine and combination vaccine with potential path forward for both*

GAITHERSBURG, Md., April 20, 2022 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced initial results from the Phase 1/2 clinical trial of its COVID-Influenza Combination Vaccine (CIC). The CIC combines Novavax' COVID-19 vaccine, NVX-CoV2373, and its quadrivalent influenza vaccine candidate. The CIC trial demonstrated that formulating the combination vaccine is feasible, well-tolerated and immunogenic.

"We continue to evaluate the dynamic public health landscape and believe there may be a need for recurrent boosters to fight both COVID-19 and seasonal influenza," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "We're encouraged by these data and the potential path forward for a combination COVID-19-influenza vaccine as well as stand-alone vaccines for influenza and COVID-19."

The safety and tolerability profile of the combination vaccine was consistent with the stand-alone NVX-CoV2373 and quadrivalent nanoparticle influenza vaccine reference formulations in the trial. The combination vaccine was found to be generally well tolerated. Serious adverse events were rare and none were assessed as being related to the vaccine.

The study employed descriptive endpoints, assessing safety and the immunological responses of different CIC vaccine formulations. A Design of Experiments (DOE) modeling-based approach was used to design the trial, enabling more powerful fine-tuning of dose selection of both the COVID-19 and influenza antigens for further development compared to traditional approaches. The preliminary trial results found that various CIC vaccine formulations induced immune responses in participants comparable to reference stand-alone influenza and stand-alone COVID-19 vaccine formulations (for H1N1, H3N2, B-Victoria HA and SARS-CoV-2 rS antigens). Modeling results also showed that a combined formulation has the potential to reduce total antigen amount by up to 50% overall, optimizing production and delivery.

Both protein-based vaccines used in the trial were formulated with the patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. These data support advancement to a Phase 2 confirmation trial, expected to begin by the end of 2022.

Data from the trial were presented at the World Vaccine Congress (WVC) in Washington, DC.

Influenza Program Update

At the WVC, Novavax also reviewed key findings from the Phase 3 trial of its stand-alone influenza candidate, previously referred to as NanoFlu, which met its primary immunogenicity endpoint. These results have previously been published in The Lancet.

Authorization in the U.S.

Neither NVX-CoV2373 or the influenza vaccine candidate have been authorized or approved for use in the U.S. by the U.S. Food and Drug Administration.

Important Safety Information for NVX-CoV2373

- NVX-CoV2373 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 NVX-CoV2373.
- 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.
- NVX-CoV2373 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 NVX-CoV2373 may be lower in immunosuppressed individuals.
- Administration of NVX-CoV2373 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.
- The effects with NVX-CoV2373 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 NVX-CoV2373 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 additional safety information, including the full Summary of Product Characteristics with Package Leaflet, please visit www.NovavaxCovidVaccine.com.

About the COVID-19-Influenza Combination Vaccine Phase 1/2 trial

The Phase 1/2 CIC vaccine trial is evaluating a combination of Novavax' recombinant protein-based NVX-CoV2373 and influenza vaccine candidates and patented saponin-based Matrix-M adjuvant in a single formulation. The trial will evaluate the safety, tolerability and immune response to the combination vaccine in 642 healthy adults 50 to 70 years of age. Participants will have been either previously infected with the SARS-CoV-2 virus that causes COVID-19 or vaccinated through an authorized vaccine at least eight weeks prior to enrollment. All participants will be randomly assigned to cohorts to evaluate multiple formulations and will be dosed on Day 0 and again at Day 56. The trial is being conducted in Australia at 10 sites. (ClinicalTrials.gov Identifier: NCT04961541)

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, 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' Influenza Program

Novavax' influenza vaccine, previously known as NanoFlu, is a quadrivalent recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. The influenza vaccine uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences, and contains Novavax' patented saponin-based Matrix-M adjuvant. This investigational candidate was evaluated during a controlled phase 3 trial conducted during the 2019-2020 influenza season.

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.

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, including the Phase 2 confirmation trial expected to begin by the end of 2022, the ongoing development of NVX-CoV2373, NanoFlu, its COVID-seasonal influenza investigational vaccine candidate, and its COVID-Influenza Combination Vaccine, 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, the potential impact and reach of Novavax and its COVID-19 Influenza Combination Vaccine in protecting populations, and the efficacy, safety and intended utilization of the COVID-19 Influenza Combination Vaccine, NanoFlu, and 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; 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, 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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