

Novavax Initiates Phase 1/2 Clinical Trial of Combination Vaccine for COVID-19 and Seasonal Influenza

-- First participants enrolled in Phase 1 clinical trial of combination NanoFlu™/NVX-CoV2373 vaccine with Matrix-M™ adjuvant

-- Phase 1/2 study will evaluate immunogenicity and safety

GAITHERSBURG, Md., Sept. 8, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, today announced enrollment of the first participants in a Phase 1/2 study to evaluate the safety and immunogenicity of a combination vaccine using Novavax' seasonal influenza and COVID-19 vaccines. The clinical trial combines Novavax' recombinant protein-based NVX-CoV2373 and NanoFlu™ vaccine candidates and patented saponin-based Matrix-M™ adjuvant in a single formulation (COVID-NanoFlu Combination Vaccine). Both NVX-CoV2373 and NanoFlu have previously demonstrated strong results as standalone vaccines in Phase 3 clinical trials.

"This study is the first-of-its-kind to evaluate the vaccine's potential to induce a robust immune response, augmented by our Matrix-M adjuvant, against two life-threatening diseases simultaneously," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "The combination of these two vaccines, which have individually delivered outstanding results with favorable safety and tolerability profiles, may lead to greater efficiencies for the healthcare system and achieve high levels of protection against COVID-19 and influenza with a single regimen."

The trial will evaluate the safety, tolerability and immune response to NanoFlu formulated together with NVX-CoV2373 and Matrix-M adjuvant in 640 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 will be conducted in Australia at up to 12 study sites, with results expected during the first half of 2022.

In [preclinical studies](#), the COVID-NanoFlu Combination Vaccine demonstrated robust, functional immune responses to each component of the quadrivalent influenza vaccine and the SARS-CoV-2 spike protein, with Matrix-M adjuvant playing a key role.

In a Phase 3 clinical trial with nearly 30,000 adults in the United States and Mexico, NVX-CoV2373 [demonstrated](#) 100% protection against moderate and severe COVID-19 infection and 90.4% efficacy overall. In a pivotal Phase 3 trial conducted among adults aged 65 and older, NanoFlu [achieved](#) the primary endpoints, demonstrating non-inferior immunogenicity to a licensed comparator on all four influenza virus strains included in the vaccine, while also showing both enhanced wild-type hemagglutination-inhibiting antibody responses against homologous and multiple heterologous A/H3N2 strains, and potent induction of T cell responses.

NVX-CoV2373 has also been [evaluated](#) in a co-administration study where it was administered simultaneously with an approved influenza vaccine. The study demonstrated that vaccine efficacy appeared to be preserved in those receiving both vaccines compared to those vaccinated with NVX-CoV2373 alone.

About NVX-CoV2373

NVX-CoV2373 is a protein-based vaccine candidate 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. In preclinical studies, NVX-CoV2373 induced antibodies that blocked the binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response in Phase 1/2 clinical testing.

NVX-CoV2373 is being evaluated in two pivotal Phase 3 trials: a trial in the U.K. that demonstrated efficacy of 96.4% against the original virus strain, 86.3% against the Alpha (B.1.1.7) variant and 89.7% efficacy overall;

and the PREVENT-19 trial in the U.S. and Mexico that demonstrated 100% protection against moderate and severe disease and 90.4% efficacy overall. It is also being tested in two ongoing Phase 2 studies that began in August 2020: A Phase 2b trial in South Africa that demonstrated 55% efficacy overall in HIV-negative participants and 48.6% efficacy against a newly emerging escape variant first described in South Africa, and a Phase 1/2 continuation in the U.S. and Australia.

NVX-CoV2373 is stored and stable at 2°- 8°C, allowing the use of existing vaccine supply chain channels for its distribution. It is packaged in a ready-to-use liquid formulation in 10-dose vials. Recombinant spike protein used in this study was manufactured at Novavax' plant located in the Czech Republic.

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 NanoFlu™

NanoFlu™ is a quadrivalent recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M™ adjuvant.

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 combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles designed to address urgent global health needs. Novavax is conducting late-stage clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults and will be advanced for regulatory submission. Both 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](#) and [LinkedIn](#).

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the ongoing development of NVX-CoV2373 and its partnerships, and other Novavax vaccine product candidates, the efficacy, safety and intended utilization of our product candidates, the timing of results from clinical trials, and the potential for a combination NanoFlu and NVX-CoV2373 vaccine to lead to greater efficiencies for the healthcare system and achieve high levels of protection against COVID-19 and influenza 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.

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