

Novavax Announces Positive Phase 1 Data for its COVID-19 Vaccine Candidate

August 4, 2020

GAITHERSBURG, Md., Aug. 04, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced Phase 1 data from its Phase 1/2 randomized, observer-blinded, placebo-controlled trial of its COVID-19 vaccine with and without Matrix-M™ adjuvant in healthy adults 18-59 years of age. NVX-CoV2373, the Company's recombinant COVID-19 vaccine candidate adjuvanted with Matrix-M, was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. The data have been submitted for peer-review to a scientific journal and to an online preprint server at medRxiv.org.

NVX-CoV2373 was well-tolerated and had a reassuring safety profile.

Overall, the vaccine was well-tolerated and reactogenicity events were generally mild. Following Dose 1, tenderness and pain were the most frequent local symptoms and systemic events were individually less frequent with headache, fatigue and myalgia being reported most commonly. As expected, following Dose 2, greater reactogenicity was reported, although the majority of symptoms were reported as ≤ Grade 1. The average duration of events was < 2 days.

Unsolicited adverse events were collected through 28 days after Dose 2. There were no severe (Grade 3) unsolicited adverse events, and the vast majority of adverse events were mild and deemed not related to vaccination. No serious adverse events (SAEs) were reported and safety follow-up continues.

NVX-CoV2373 induced neutralization titers in 100% of participants; 5 µg adjuvanted dose group peak GMT: 3,906 (95% CI: 2,556; 5,970).

All subjects developed anti-spike IgG antibodies after a single dose of vaccine, many of them also developing wild-type virus neutralizing antibody responses, and after Dose 2, 100% of participants developed wild-type virus neutralizing antibody responses. Both anti-spike IgG and viral neutralization responses compared favorably to responses from patients with clinically significant COVID-19 disease. Importantly, the IgG antibody response was highly correlated with neutralization titers, demonstrating that a significant proportion of antibodies were functional.

Matrix-M™ adjuvant induced robust polyfunctional CD4+ T cell responses.

The adjuvant was dose-sparing, with the lower 5 µg dose of NVX-CoV2373 performing comparably with the 25 µg dose. Cellular immune responses were measured in a subset of participants, and NVX-CoV2373 induced antigen-specific polyfunctional CD4+ T cell responses with a strong bias toward the Th1 phenotype (IFN-γ, IL-2, and TNF-α).

Favorable product profile.

NVX-CoV2373 is stable and will allow handling in a liquid formulation that can be stored at 2°C to 8°C, allowing for successful cold chain management with existing infrastructure.

“The Phase 1 data demonstrate that NVX-CoV2373 with our Matrix-M adjuvant is a well-tolerated COVID-19 vaccine with a robust immunogenicity profile,” said Gregory M. Glenn, M.D., President, Research and Development at Novavax. “Using a stringent wild-type virus assay performed by investigators at the University of Maryland School of Medicine, NVX-CoV2373 elicited neutralizing antibody titers greater than those observed in a pool of COVID-19 patients with clinically significant disease.”

The trial was supported by funding from the Coalition for Epidemic Preparedness Innovations (CEPI) and was conducted at two sites in Australia.

Novavax also submitted to a peer-reviewed journal data showing results of NVX-CoV2373 immunization in cynomolgus macaques. The vaccine induced sterile immunity that prevented viral replication in the upper and lower respiratory tracts, thus showing potential to reduce COVID-19 transmission. There was no evidence of enhanced disease following challenge. These data have also been submitted to an online preprint server at medRxiv.org.

For further information, including media-ready images, b-roll, downloadable resources and more, click [here](#).

Conference Call

Novavax will host a conference call today at 5:00 p.m. ET. The dial-in numbers for the conference call are (866) 324-3683 (Domestic) or (509) 844-0959 (International), passcode 4319447. A replay of the conference call will be available starting at 8:00 p.m. ET on August 4, 2020 until 11:59 p.m. ET on August 11, 2020. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 4319447.

A webcast of the conference call can also be accessed via a link on the home page of the Novavax website ([novavax.com](https://www.novavax.com)) or through the “For Investors”/“Events” tab on the Novavax website. A replay of the webcast will be available on the Novavax website until November 4, 2020.

About NVX-CoV2373

NVX-CoV2373 is a vaccine candidate engineered from the genetic sequence 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 contains Novavax’ patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. In preclinical trials, NVX-CoV2373 demonstrated indication of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. Novavax was awarded \$1.6 billion by the federal government as part of Operation Warp Speed (OWS), a U.S. government program to deliver millions of doses of a safe, effective vaccine for COVID-19 to the U.S. population. The OWS funding is being used by Novavax to complete late-stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373 beginning as early as late 2020. The Coalition for Epidemic Preparedness Innovations (CEPI) is also investing up to \$388 million, and Department of Defense (DoD) is investing up to \$60 million of funding to advance clinical development of NVX-CoV2373.

About Matrix-M™

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 late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is undergoing 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. Both vaccine candidates incorporate Novavax’ proprietary saponin-based Matrix-M™ adjuvant in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

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 and the ongoing development of its vaccine and adjuvant products, including statements regarding the manufacturing of vaccine antigen dose amounts and timing, are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading “Risk Factors” in the Novavax Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission (SEC) and updated by any Quarterly Report on Form 10-Q, particularly the risks inherent to developing novel vaccines. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at sec.gov, 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 and Media

Silvia Taylor and Erika Trahan

ir@novavax.com

240-268-2022

Media

Brandzone/KOGS Communication

Edna Kaplan

kaplan@kogspr.com

617-974-8659