

New England Journal of Medicine Publishes Phase 2b Clinical Trial Results Demonstrating Efficacy of Novavax COVID-19 Vaccine Against the B.1.351 Variant

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GAITHERSBURG, Md., May 5, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the publication of results from the initial primary analysis of a Phase 2b clinical trial conducted in South Africa of its NVX-CoV2373 COVID-19 vaccine candidate in the *New England Journal of Medicine* (NEJM). The published data provide additional detail of an [initial analysis](#) conducted in January, while more robust data from a complete analysis of the study was subsequently [shared](#) in March 2021. The data on the initial analysis will be published online ahead of print in NEJM's May 6, 2021 issue.

"This data publication reinforces the encouraging safety profile and cross-protective effect across variants seen in studies of our vaccine to-date," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "It also demonstrates that ongoing evaluation of COVID-19 vaccine efficacy against SARS-CoV-2 variants is urgently needed to inform vaccine development and use."

The Phase 2b randomized, observer-blinded, placebo-controlled trial conducted in South Africa evaluated efficacy, safety and immunogenicity in healthy adults, and in a small cohort of medically stable adults living with human immunodeficiency virus (HIV). The study met its primary endpoint. NVX-CoV2373 demonstrated an overall efficacy of 49% in the initial analysis (published NEJM), and 49% in the subsequent complete analysis (unpublished). Among healthy adults without HIV, NVX-CoV2373 demonstrated efficacy of 60% in the initial analysis and 55% in the subsequent complete analysis. In the initial analysis, cases were predominantly mild-to-moderate and due to the B.1.351 variant. In the subsequent complete analysis, circulation of the B.1.351 variant continued to dominate, and all five cases of severe disease observed in the trial occurred in the placebo group.

The initial analysis, now being published in NEJM, suggested that prior infection with the original COVID-19 strain did not protect against subsequent infection by the variant predominantly circulating in South Africa through 60 days of follow-up. However, with additional follow-up, the complete analysis of the South Africa trial indicates that there may be a modest protective effect of prior exposure with the original COVID-19 strain. Among placebo recipients, at 90 days of follow-up, the illness rate was 8.0% in baseline seronegative participants and 5.9% in baseline seropositive participants.

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 adjuvanted with Novavax' patented saponin-based Matrix-M™ 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 100% protection against severe disease, efficacy of 96.4% against the original virus strain, 86.3% against the B.1.1.7/501Y.V1 variant and 89.7% overall; and the PREVENT-19 trial in the U.S. and Mexico that began in December 2020. 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 100% protection against severe disease 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.

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](#).

Novavax Forward Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products 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, 2020, 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 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.

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