

Novavax Publishes Results of United Kingdom Phase 3 Clinical Trial in New England Journal of Medicine, Demonstrating High Levels of Efficacy of COVID-19 Vaccine

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GAITHERSBURG, Md., June 30, 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 final analysis of a pivotal Phase 3 clinical trial of its COVID-19 vaccine candidate conducted in the United Kingdom in the *New England Journal of Medicine* (NEJM). The final analysis confirmed an overall efficacy of 89.7% with over 60% (half) of the cases caused by the B.1.1.7 (Alpha) variant, and a 96.4% efficacy against non-B.1.1.7 (non-Alpha) variants which represents strains most similar to the original virus.

The manuscript published today in NEJM, 'Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine,' provides the final trial analysis, building on an [initial interim analysis](#) conducted in January 2021, and the updated analysis [announced](#) in March 2021, while additional data from the study was subsequently [shared](#) in preprint server medRxiv in May 2021. Today's publication may be accessed [here](#).

"We continue to be very encouraged by data showing high levels of efficacy against even mild disease, and that NVX-CoV2373 offers strong cross-protection against both the B.1.1.7 (Alpha) variant and non-B.1.1.7 (non-Alpha) variant strains which are widely circulating," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "This publication also reinforces the reassuring safety and efficacy profile shown in studies of our vaccine to-date and underscores the potential for NVX-CoV2373 to play an important role in solving this ongoing global public health crisis."

The randomized, observer-blinded, placebo-controlled study, led by researchers at St George's, University of London and St George's Hospital, London, enrolled more than 15,000 adults at trial sites across the United Kingdom. The research demonstrated that a two-dose regimen of Novavax' COVID-19 vaccine candidate conferred 96.4% protection against non-B.1.1.7 (non-Alpha) variant strains and nearly 90% protection against all strains in circulation at that time. It also demonstrated that initial vaccine side effects were mostly mild and transient, and that no imbalance was seen in more serious adverse events compared with the placebo arm. The study assessed efficacy during a period when the B.1.1.7 (Alpha) variant strain of the virus was emerging and circulating widely in the United Kingdom and is the same variant that is currently widespread in the United States.

"It is quite remarkable how well the vaccine efficacy from our United Kingdom trial matches the results seen in the United States in the recently released PREVENT-19 trial results, giving even more confidence in the potential role of this vaccine in helping to control the pandemic," said Professor Paul Heath, FRCPCH, Vaccine Institute, St George's, University of London and St George's Hospital, London, who is chief investigator of the Novavax United Kingdom trial. "It really highlights the consistent performance of this vaccine in different populations and against a variety of evolving strains."

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-MTM 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 B.1.1.7 (Alpha) variant and 89.7% 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.

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 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 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.

Contacts:

Investors

Novavax, Inc.

Erika Schultz | 240-268-2022

ir@novavax.com

Solebury Trout

Alexandra Roy | 617-221-9197

aroy@soleburytrout.com

Media

Alison Chartan | 240-720-7804

Laura Keenan | 202-709-7521

media@novavax.com

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