

Novavax COVID-19 Vaccine Demonstrates 90% Overall Efficacy and 100% Protection Against Moderate and Severe Disease in PREVENT-19 Phase 3 Trial

- 93% efficacy against predominantly circulating Variants of Concern and Variants of Interest
- 91% efficacy in high-risk populations
- 100% efficacy against variants "not considered Variants of Concern/Interest"
- All COVID-19 hospitalizations/death occurred in the placebo group
- Company to host investor conference call today at 8:30 am ET

GAITHERSBURG, Md., June 14, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), today announced that NVX-CoV2373, its recombinant nanoparticle protein-based COVID-19 vaccine, demonstrated 100% protection against moderate and severe disease, 90.4% efficacy overall, and met the primary endpoint in its PREVENT-19 pivotal Phase 3 trial. The study enrolled 29,960 participants across 119 sites in the U.S. and Mexico to evaluate efficacy, safety and immunogenicity, with an emphasis on recruiting a representative population of communities and demographic groups most impacted by the disease.

"Today, Novavax is one step closer to addressing the critical and persistent global public health need for additional COVID-19 vaccines. These clinical results reinforce that NVX-CoV2373 is extremely effective and offers complete protection against both moderate and severe COVID-19 infection," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Novavax continues to work with a sense of urgency to complete our regulatory submissions and deliver this vaccine, built on a well understood and proven platform, to a world that is still in great need of vaccines."

The company intends to file for regulatory authorizations in the third quarter, upon completion of the final phases of process qualification and assay validation needed to meet chemistry, manufacturing and controls (CMC) requirements. Upon regulatory approvals, Novavax remains on track to reach manufacturing capacity of 100 million doses per month by the end of the third quarter and 150 million doses per month by the end of the fourth quarter of 2021.

"PREVENT-19 confirms that NVX-CoV2373 offers a reassuring tolerability and safety profile," said Gregory M. Glenn, M.D., President of Research and Development, Novavax. "These data show consistent, high levels of efficacy and reaffirm the ability of the vaccine to prevent COVID-19 amid ongoing genetic evolution of the virus. Our vaccine will be a critical part of the solution to COVID-19 and we are grateful to the study participants and trial staff who made this study possible, as well as our supporters, including the U.S. Government."

Click [here](#) to view multimedia content, including B-roll, an illustrated fact sheet and other resources that accompany this press release.

Results: Consistent, high efficacy among circulating variants

In the placebo-controlled, observer-blinded study randomized 2:1, NVX-CoV2373 demonstrated overall efficacy of 90.4% (95% CI: 82.9, 94.6), achieving its primary endpoint. Seventy-seven cases were observed: 63 in the placebo group and 14 in the vaccine group. All cases observed in the vaccine group were mild as defined by the trial protocol. Ten moderate cases and four severe cases were observed, all in the placebo group, yielding a vaccine efficacy of 100% (95% CI: 87.0, 100) against moderate or severe disease.

Efficacy endpoints were accrued from January 25 through April 30, 2021 — a time when the Alpha (B.1.1.7) variant, first identified in the U.K., became the predominant strain in the U.S. Other strains, including Variants of Interest (VoI) and Variants of Concern (VoC), were also on the rise during the PREVENT-19 endpoint accrual window. [Click here for CDC definitions of variants.](#)

Sequence data are available for 54 of the 77 cases. PREVENT-19 met its key secondary endpoint, demonstrating 100% efficacy (95% CI: 80.8, 100) against variants not considered VoC/Vol. Of the sequenced cases, 35 (65%) were VoC, 9 (17%) were Vol, and 10 (19%) were other variants. Against VoC/Vol, which represented 82% of the cases, vaccine efficacy was 93.2% (95% CI: 83.9, 97.1), achieving a key exploratory endpoint of the study. Thirty-eight of the VoC/Vol cases were in the placebo group and 6 were in the vaccine group.

NVX-CoV2373 also showed success among "high-risk" populations (defined as over age 65, under age 65 with certain comorbidities or having life circumstances with frequent COVID-19 exposure): vaccine efficacy was 91.0% (95% CI: 83.6, 95.0), with 62 COVID-19 cases in the placebo group and 13 COVID-19 cases in the vaccine group.

Results: Reasserting a favorable safety profile

Preliminary safety data from PREVENT-19 showed the vaccine to be generally well-tolerated. Serious and severe adverse events were low in number and balanced between vaccine and placebo groups. No single adverse event term was reported by more than 1% of participants. In assessing reactogenicity 7 days after Dose 1 and Dose 2, injection site pain and tenderness, generally mild to moderate in severity, were the most common local symptoms, lasting less than 3 days. Fatigue, headache and muscle pain were the most common systemic symptoms, lasting less than 2 days.

Study Endpoints

The primary endpoint for PREVENT-19 was the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second dose in serologically negative (to SARS-CoV-2) adult participants at baseline. The statistical success criterion included a lower bound of 95% CI >30%.

Novavax expects to share further details of the PREVENT-19 trial results as additional data become available. Further analyses of the trial are ongoing and will be shared via preprint servers as well as submitted to peer-review journals for publication.

The placebo-controlled portion of PREVENT-19 continues in adolescents from 12 to less than 18 years of age, which recently completed enrollment with 2,248 participants.

Variant Virus Strains

The CDC has defined Variant of Interest (Vol) as a variant with genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, or predicted increase in transmissibility or disease severity. A Variant of Concern (VoC) is defined as a variant for which there is evidence of an increase in transmissibility, more severe disease, significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures.

About PREVENT-19

PREVENT-19 (the **PRE**-fusion protein subunit **Vaccine Efficacy Novavax Trial | COVID-19**) is a 2:1 randomized, placebo-controlled, observer-blinded study to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M™ adjuvant in 29,960 participants 18 years of age and older in 119 locations in the United States and Mexico, compared with placebo.

PREVENT-19 is being conducted with support from the U.S. government, including the Department of Defense, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (HHS), and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS. BARDA is providing up to \$1.75 billion under a Department of Defense agreement.

Conference Call

Novavax will host a conference call today at 8:30am ET. The dial-in numbers for the conference call are (866) 652-5200 (Domestic) or (412) 317-6060 (International). Participants will be prompted to request to join the Novavax, Inc. call. A replay of the conference call will be available starting at 7:30 p.m. ET on June 14, 2021, until 11:59 p.m. ET on June 21, 2021. To access the replay by telephone, dial (877) 344-7529 (Domestic) or (412) 317-0088 (International) and use passcode 10157478.

A webcast of the conference call can also be accessed on the Novavax website at [novavax.com/events](https://www.novavax.com/events). A replay of the webcast will be available on the Novavax website until September 14, 2021.

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 B.1.1.7 (Alpha) 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 55% efficacy overall in HIV-negative participants and 48.6% efficacy against the B.1.351 (Beta) variant, and a Phase 1/2 study 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.

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<https://ir.novavax.com/2021-06-14-Novavax-COVID-19-Vaccine-Demonstrates-90-Overall-Efficacy-and-100-Protection-Against-Moderate-and-Severe-Disease-in-PREVENT-19-Phase-3-Trial>