

# Novavax Announces Publication of Phase 1 Data for COVID-19 Vaccine Candidate in The New England Journal of Medicine

*NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera*

GAITHERSBURG, Md., Sept. 02, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the publication in *The New England Journal of Medicine* of Phase 1 data from its Phase 1/2 clinical trial of NVX-CoV2373, its COVID-19 vaccine candidate adjuvanted with Matrix-M™, in healthy adults 18-59 years of age. The publication offers further detail on the previously announced results, in which NVX-CoV2373 demonstrated a reassuring safety and reactogenicity profile and induced robust antibody responses numerically superior to that seen in human convalescent sera. The manuscript is available at [https://www.nejm.org/doi/full/10.1056/NEJMoa2026920?query=featured\\_coronavirus](https://www.nejm.org/doi/full/10.1056/NEJMoa2026920?query=featured_coronavirus).

“The rapid publication of Phase 1 results from our trial in a prestigious peer-reviewed journal reflects both the importance of the data and the urgent need for an effective vaccine to slow the COVID-19 pandemic,” said Gregory M. Glenn, M.D., President of Research and Development at Novavax. “Based on the positive Phase 1 results, we have begun multiple Phase 2 clinical trials, from which we expect to collect preliminary efficacy. Novavax is committed to generating the safety, immunogenicity and efficacy data that will support confident usage of the vaccine, both in the US and globally, and the data published today further bolsters our conviction that this is possible.”

The Phase 1 portion of the Phase 1/2 clinical trial was randomized, observer-blinded, and placebo-controlled.

NVX-CoV2373 is currently in multiple Phase 2 clinical trials. The Phase 2 portion of the Phase 1/2 clinical trial to evaluate the safety and immunogenicity of NVX-CoV2373 began in August in the United States and Australia, and expands on the age range of the Phase 1 portion by including older adults 60-84 years of age as approximately 50 percent of the trial population. Secondary objectives include preliminary evaluation of efficacy. In addition, a Phase 2b clinical trial to assess efficacy began in South Africa in August.

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

## Phase 1 Results Summary

- NVX-CoV2373 was well-tolerated and reactogenicity events were generally mild
- There were no severe (Grade 3) unsolicited adverse events (AEs); the vast majority of AEs were mild and deemed not related to vaccination. No serious AEs were reported. Safety follow-up continues.
- All subjects in the 5 µg group developed anti-spike IgG antibodies after a single dose of vaccine, many of which included neutralizing antibody responses to wild-type virus
- 100 percent of participants developed wild-type virus neutralizing antibody responses after Dose 2
- Both 5 µg and 25 µg adjuvanted doses generated peak geometric mean titer (GMT) greater than 1:3,300
- Anti-spike IgG and viral neutralization responses compared favorably to responses from patients with clinically significant COVID-19 disease
- Matrix-M adjuvant was dose-sparing, with the lower 5 µg dose of NVX-CoV2373 performing comparably with the 25 µg dose
- Cellular immune responses measured in a subset of participants demonstrated induction of antigen-specific polyfunctional CD4+ T cell responses with a strong Th1 phenotype bias
- NVX-CoV2373 has a favorable product profile; it 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

Further details may be found in Novavax' August 4 announcement of Phase 1 results and may be accessed [here](#).

## 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. In its Phase 1 portion of the Phase 1/2 clinical trial, NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. Phase 2 clinical trials began in August 2020. Novavax has secured \$2 billion in funding for its global coronavirus vaccine program, including up to \$388 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

## 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](http://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, 2019, and Quarterly Report on Form 8-K for the period ended June 30, 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](http://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/2020-09-02-Novavax-Announces-Publication-of-Phase-1-Data-for-COVID-19-Vaccine-Candidate-in-The-New-England-Journal-of-Medicine>

