

Novavax COVID-19 Vaccine Demonstrates 89.3% Efficacy in UK Phase 3 Trial

January 28, 2021

GAITHERSBURG, Md., Jan. 28, 2021 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that NVX-CoV2373, its protein-based COVID-19 vaccine candidate, met the primary endpoint, with a vaccine efficacy of 89.3%, in its Phase 3 clinical trial conducted in the United Kingdom (UK). The study assessed efficacy during a period with high transmission and with a new UK variant strain of the virus emerging and circulating widely. It was conducted in partnership with the UK Government's Vaccines Taskforce. Novavax also announced successful results of its Phase 2b study conducted in South Africa.

“With today’s results from our UK Phase 3 and South Africa Phase 2b clinical trials, we have now reported data on our COVID-19 vaccine from Phase 1, 2 and 3 trials involving over 20,000 participants. In addition, our PREVENT-19 US and Mexico clinical trial has randomized over 16,000 participants toward our enrollment goal of 30,000. NVX-CoV2373 is the first vaccine to demonstrate not only high clinical efficacy against COVID-19 but also significant clinical efficacy against both the rapidly emerging UK and South Africa variants,” said Stanley C. Erck, President and Chief Executive Officer, Novavax. “NVX-CoV2373 has the potential to play an important role in solving this global public health crisis. We look forward to continuing to work with our partners, collaborators, investigators and regulators around the world to make the vaccine available as quickly as possible.”

NVX-CoV2373 contains a full-length, prefusion spike protein made using Novavax’ recombinant nanoparticle technology and the company’s proprietary saponin-based Matrix-M™ adjuvant. The purified protein is encoded by the genetic sequence of the SARS-CoV-2 spike (S) protein and is produced in insect cells. It can neither cause COVID-19 nor can it replicate, is stable at 2°C to 8°C (refrigerated) and is shipped in a ready-to-use liquid formulation that permits distribution using existing vaccine supply chain channels.

UK Phase 3 Results: 89.3% Efficacy

The study enrolled more than 15,000 participants between 18-84 years of age, including 27% over the age of 65. The primary endpoint of the UK Phase 3 clinical trial is based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

The first interim analysis is based on 62 cases, of which 56 cases of COVID-19 were observed in the placebo group versus 6 cases observed in the NVX-CoV2373 group, resulting in a point estimate of vaccine efficacy of 89.3% (95% CI: 75.2 – 95.4). Of the 62 cases, 61 were mild or moderate, and 1 was severe (in placebo group).

Preliminary analysis indicates that the UK variant strain that was increasingly prevalent was detected in over 50% of the PCR-confirmed symptomatic cases (32 UK variant, 24 non-variant, 6 unknown). Based on PCR performed on strains from 56 of the 62 cases, efficacy by strain was calculated to be 95.6% against the original COVID-19 strain and 85.6% against the UK variant strain [post hoc].

The interim analysis included a preliminary review of the safety database, which showed that severe, serious, and medically attended adverse events occurred at low levels and were balanced between vaccine and placebo groups.

“These are spectacular results, and we are very pleased to have helped Novavax with the development of this vaccine. The efficacy shown against the emerging variants is also extremely encouraging. This is an incredible achievement that will ensure we can protect individuals in the UK and the rest of the world from this virus,” said Clive Dix, Chair, UK Vaccine Taskforce.

Novavax expects to share further details of the UK trial results as additional data become available. Additional analysis on both trials is ongoing and will be shared via prepublication servers as well as submitted to a peer-reviewed journal for publication. The company initiated a rolling submission to the United Kingdom’s regulatory agency, the MHRA, in mid-January.

South Africa Results: Approximately 90% of COVID-19 cases attributed to South Africa escape variant

In the South Africa Phase 2b clinical trial, 60% efficacy (95% CI: 19.9 – 80.1) for the prevention of mild, moderate and severe COVID-19 disease was observed in the 94% of the study population that was HIV-negative. Twenty-nine cases were observed in the placebo group and 15 in the vaccine group. One severe case occurred in the placebo group and all other cases were mild or moderate. The clinical trial also achieved its primary efficacy endpoint in the overall trial population, including HIV-positive and HIV-negative subjects (efficacy of 49.4%; 95% CI: 6.1 – 72.8).

This study enrolled over 4,400 patients beginning in August 2020, with COVID-19 cases counted from September through mid-January. During this time, the triple mutant variant, which contains three critical mutations in the receptor binding domain (RBD) and multiple mutations outside the RBD, was widely circulating in South Africa. Preliminary sequencing data is available for 27 of 44 COVID-19 events; of these, 92.6% (25 out of 27 cases) were the South Africa escape variant.

Importantly in this trial, approximately 1/3 of the patients enrolled (but not included in the primary analyses described above) were seropositive, demonstrating prior COVID-19 infection at baseline. Based on temporal epidemiology data in the region, the pre-trial infections are thought to have been caused by the original COVID-19 strain (i.e., non-variant), while the subsequent infections during the study were largely variant virus. These data suggest that prior infection with COVID-19 may not completely protect against subsequent infection by the South Africa escape variant, however, vaccination with NVX-CoV2373 provided significant protection.

“The 60% reduced risk against COVID-19 illness in vaccinated individuals in South Africans underscores the value of this vaccine to prevent illness from the highly worrisome variant currently circulating in South Africa, and which is spreading globally. This is the first COVID-19 vaccine for which we now have objective evidence that it protects against the variant dominating in South Africa,” says Professor Shabir Madhi, Executive Director of the Vaccines and Infectious Diseases Analytics Research Unit (VIDA) at Wits, and principal investigator in the Novavax COVID-19 vaccine trial in South Africa. “I am encouraged to see that Novavax plans to immediately begin clinical development on a vaccine specifically targeted to the variant, which together with the current vaccine is likely to form the cornerstone of the fight against COVID-19.”

Novavax initiated development of new constructs against the emerging strains in early January and expects to select ideal candidates for a booster and/or combination bivalent vaccine for the new strains in the coming days. The company plans to initiate clinical testing of these new vaccines in the second quarter of this year.

“A primary benefit of our adjuvanted platform is that it uses a very small amount of antigen, enabling the rapid creation and large-scale production of combination vaccine candidates that could potentially address multiple circulating strains of COVID-19,” said Gregory M. Glenn, M.D., President of Research and Development, Novavax. “Combined with the safety profile that has been observed in our studies to-date with our COVID-19 vaccine, as well as prior studies in influenza, we are optimistic about our ability to rapidly adapt to evolving conditions.”

The Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacturing of doses of NVX-CoV2373 for this Phase 2b clinical trial, which was supported in part by a \$15 million grant from the Bill & Melinda Gates Foundation.

Significant progress on PREVENT-19 Clinical Trial in US and Mexico

To date, PREVENT-19 has randomized over 16,000 participants and expects to complete our targeted enrollment of 30,000 patients in the first half of February. PREVENT-19 is being conducted with support from the U.S. government partnership formerly known as Operation Warp Speed, which includes the Department of Defense, the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) at HHS. BARDA is also providing up to \$1.75 billion under a Department of Defense agreement.

PREVENT-19 (the PRE-fusion protein subunit Vaccine Efficacy Novavax Trial | COVID-19) is a Phase 3, randomized, placebo-controlled, observer-blinded study in the US and Mexico to evaluate the efficacy, safety and immunogenicity of NVX-CoV2373 with Matrix-M in up to 30,000 subjects 18 years of age and older compared with placebo. The trial design has been harmonized to align with other Phase 3 trials conducted under the auspices of Operation Warp Speed, including the use of a single external independent Data and Safety Monitoring Board to evaluate safety and conduct an unblinded review when predetermined interim analysis events are reached.

The trial’s primary endpoint is the prevention of PCR-confirmed, symptomatic COVID-19. The key secondary endpoint is the prevention of PCR-confirmed, symptomatic moderate or severe COVID-19. Both endpoints will be assessed at least seven days after the second study vaccination in volunteers who have not been previously infected with SARS-CoV-2.

Conference Call

Novavax will host a conference call today at 4:30pm ET. The dial-in numbers for the conference call are (877) 212-6076 (Domestic) or (707) 287-9331 (International), passcode 7470222. A replay of the conference call will be available starting at 7:30 p.m. ET on January 28, 2021 until 7:30 p.m. ET on February 4, 2021. To access the replay by telephone, dial (855) 859-2056 (Domestic) or (404) 537-3406 (International) and use passcode 7470222.

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 April 28, 2021.

About NVX-CoV2373

NVX-CoV2373 is a protein-based 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 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. Over 37,000 participants have participated to date across four different clinical studies in five countries. NVX-CoV2373 is currently being evaluated in two pivotal Phase 3 trials: a trial in the U.K that completed enrollment in November and the PREVENT-19 trial in the U.S. and Mexico that began in December.

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 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, 2019, and Quarterly Report on Form 10-Q for the period ended September 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, 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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