Novavax Confirms High Levels of Efficacy Against Original and Variant COVID-19 Strains in United Kingdom and South Africa Trials

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- 100% protection against severe disease

- Final analysis in U.K. trial confirms 96% efficacy against original strain of COVID-19

- Efficacy against variants confirmed in U.K. and South Africa

GAITHERSBURG, Md., March 11, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced final efficacy of 96.4% against mild, moderate and severe disease caused by the original COVID-19 strain in a pivotal Phase 3 trial in the United Kingdom (U.K.) of NVX–CoV2373, the company's vaccine candidate. The company also announced the complete analysis of its Phase 2b trial taking place in South Africa, with efficacy of 55.4% among the HIV- negative trial participants in a region where the vast majority of strains are B1.351 escape variants. Across both trials, NVX-CoV2373 demonstrated 100% protection against severe disease, including all hospitalization and death. Both studies achieved their statistical success criteria. Today's final analyses build on the successful interim results announced in January 2021, adding substantially more COVID-19 cases and statistical power.

"We are very encouraged by the data showing that NVX-CoV2373 not only provided complete protection against the most severe forms of disease, but also dramatically reduced mild and moderate disease across both trials. Importantly, both studies confirmed efficacy against the variant strains," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Today marks one year since the WHO officially declared the COVID-19 pandemic, and with this data in hand, we are even more motivated to advance our vaccine as a potential weapon in the fight to end the suffering caused by COVID-19."

United Kingdom Phase 3 Trial
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 U.K. 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.

Efficacy was 96.4% (95% CI: 73.8, 99.5) against the original virus strain and 86.3% (95% CI: 71.3, 93.5) against the B.1.1.7/501Y.V1 variant circulating in the U.K (post hoc). The primary efficacy endpoint demonstrated an overall vaccine efficacy of 89.7% (95% CI: 80.2, 94.6). 106 cases were observed, with 10 in the vaccine group and 96 in the placebo group. NVX-CoV2373 was effective against severe disease: five severe[1] cases were observed in the study, and all occurred in the placebo group. Four of the five severe cases were attributed to the B.1.1.7/501Y.V1 variant. Fourteen days after dose 1, vaccine efficacy was 83.4% (95% CI: 73.6, 89.5).

In volunteers 65 years of age and older, 10 cases of COVID-19 were observed, with 90% of those cases occurring in the placebo group. Older adults are among the groups most impacted by the disease and are at high risk of complications from COVID-19.

Novavax expects the data to serve as the basis for submission for authorization to various regulatory agencies worldwide.

South Africa Phase 2b Trial
The South Africa trial was a randomized, observer-blinded, placebo-controlled Phase 2b clinical trial of NVX-CoV2373. One cohort evaluated efficacy, safety and immunogenicity in approximately 2,665 healthy adults. The second cohort evaluated safety and immunogenicity in approximately 240 medically stable, HIV-positive adults.

A complete analysis of vaccine efficacy among 147 PCR-positive cases (51 cases in the vaccine group and 96 in the placebo group) demonstrated an overall efficacy of 48.6% against predominantly variant strains (95% CI: 28.4, 63.1). The vast majority of cases circulating during the efficacy analysis were due to the B.1.351/501Y.V2 variant circulating in South Africa. All five cases of severe disease observed in the trial occurred in the placebo group. Among HIV-negative participants, 55.4% efficacy was observed (95% CI: 35.9, 68.9). The complete analysis shows that vaccine-induced protection began 14 days after dose 1 (42.7% 95% CI: 25.0, 56.3), although increased efficacy was observed 7 days after dose 2, the primary endpoint for the study.

A previously reported initial analysis from the study through 60 days indicated that prior infection with the original COVID-19 strain might not completely protect against subsequent infection by the variant predominantly circulating in South Africa. However, the complete analysis of the South Africa trial indicates that there may be a late protective effect of prior exposure with the original COVID-19 strain. In placebo recipients, at 90 days the illness rate was 7.9% in baseline seronegative individuals, with a rate of 4.4% in baseline seropositive participants.

In both the U.K. and South Africa trials, these analyses showed that the vaccine is well-tolerated, with low levels of severe, serious (SAEs) and medically attended adverse events at day 35, balanced between vaccine and placebo groups.

For further information, including media-ready images, b-roll, downloadable resources and more, click here.

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. In preclinical studies, NVX-CoV2373 induced antibodies that block binding of spike protein to cellular receptors and provided protection from infection and disease. It was generally well-tolerated and elicited robust antibody response numerically superior to that seen in human convalescent sera 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 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: a Phase 2b trial in South Africa that demonstrated 48.65% efficacy against a newly emerging escape variant, 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™
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, 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.

[1] Please see trial protocols for endpoint definitions of COVID-19 severity at https://www.novavax.com/resources#protocols

View original content:http://www.prnewswire.com/news-releases/novavax-confirms-high-levels-of-efficacy-against-original-and-variant-covid-19-strains-in-united-kingdom-and-south-africa-trials-301246019.html

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