Novavax Investor Relations

Novavax Initiates COVID-19 Vaccine Clinical Trial Crossover

Crossover allows participants to continue in trials and remain blinded

Ensures that all trial participants receive active vaccine

South Africa and UK crossover arms initiated; US/Mexico PREVENT-19 crossover planned

GAITHERSBURG, Md., April 5, 2021 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced the initiation of crossover arms in two ongoing clinical trials of NVX-CoV2373, the company's COVID-19 vaccine candidate. Crossover ensures the administration of active vaccine to all participants in the trials and has begun for Novavax' Phase 2b trial in South Africa and its pivotal Phase 3 trial in the United Kingdom.

Under Novavax' updated clinical trial protocols[1], all participants in the UK and US Phase 3 trials will be offered the opportunity to receive an additional round of injections. Participants who elect to do so will receive an additional two-dose regimen of either vaccine (for those who originally received placebo) or placebo (for those who originally received vaccine). Participants in the South Africa Phase 2b trial will receive either active vaccine for those who initially received placebo, or a booster dose of active vaccine for those who initially received active vaccine. Participants across all three trials will remain blinded to their courses of treatment to preserve the ability to assess efficacy in each trial, and all will be followed for up to two years to monitor the safety and durability of protection the vaccine. In the trials taking place in South Africa and the United Kingdom, half of the participants initially received the active vaccine while two-thirds of participants in PREVENT-19, the trial being conducted in the US and Mexico, initially received active vaccine.

"The crossover arms ensure that all participants have access to an active vaccine candidate while allowing Novavax to continue to monitor the safety and efficacy of our vaccine over the long term," said Filip Dubovsky, M.D., Chief Medical Officer, Novavax. "We are grateful to the volunteers who stepped forward to take part in our clinical trials, without whom we would be unable to develop, study and ultimately deliver what we hope will be a significant tool in the fight against COVID-19."

The company is also planning a crossover in the PREVENT-19 study, for which the company expects to read out initial clinical data during the second quarter. In addition, the company is planning to expand the trial to include pediatric and adolescent arms, which are also expected to begin in the second quarter.

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 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 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 48.6% 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 s0peak 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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1 Clinical trial protocols may be found in the Resources section of the Novavax website and will be updated as appropriate.

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