Novavax Announces COVID-19 Vaccine Clinical Development Progress

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GAITHERSBURG, Md., Nov. 30, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today provided an update on its COVID-19 vaccine program. NVX?CoV2373 is a stable, prefusion protein antigen derived from the genetic sequence of the SARS-CoV-2 coronavirus spike (S) protein and adjuvanted with Novavax' proprietary Matrix?M™.

"Novavax is in a leading position to significantly contribute to the need for safe and efficacious vaccines that will ultimately end the worldwide COVID-19 pandemic," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "We continue to make meaningful progress as we work to test, manufacture and ultimately deliver NVX-CoV2373 with unprecedented speed, as well as put partnerships in place that would ensure widespread and equitable access worldwide."

Two of the three planned late-stage efficacy trials for NVX-CoV2373 sponsored by Novavax are fully enrolled, and more than 20,000 participants have been dosed to-date. The primary efficacy endpoints for these trials have been harmonized and reviewed by global regulatory agencies in order to facilitate regulatory approval and ensure that the results are generalizable across global populations. In alignment with Novavax' commitment to transparency, Phase 3 clinical trial protocols are posted to the company's website at Novavax.com/resources upon finalization.

United Kingdom (U.K.) pivotal Phase 3 trial update

Novavax completed enrollment of 15,000 participants in a pivotal Phase 3 clinical trial being conducted in the U.K. to determine efficacy and safety of NVX-CoV2373. The U.K. Vaccines Taskforce and National Institute for Health Research played pivotal roles in the rapid recruitment and enrollment of volunteers.

Interim data in this event-driven trial are expected as soon as early first quarter 2021, although the timing depends on the overall COVID-19 rate in the region. These data are expected to serve as the basis for licensure application in the U.K., European Union and other countries. More than 25 percent of enrollees in the trial are over the age of 65, while a large proportion of volunteers had underlying co-morbid medical conditions generally representative of the population.

South Africa Phase 2b trial update

The Phase 2b trial taking place in South Africa to evaluate safety and provide an early indication of efficacy is now fully enrolled. A total of 4,422 volunteers are taking part in the trial, which includes 245 medically stable, HIV-positive participants.

This trial is expected to increase the body of efficacy data of NVX-CoV2373 in racially and geographically diverse populations as well as in older adults. As in the U.K., availability of efficacy data depends on the illness rate in South Africa and may be available as soon as the first quarter 2021. The trial is being conducted in collaboration with Professor Shabir Mahdi and Wits University and is funded in part by the Bill & Melinda Gates Foundation. The Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacturing of doses of NVX-CoV2373 for this Phase 2b clinical trial.

U.S./Mexico pivotal Phase 3 trial update

Novavax expects its pivotal Phase 3 clinical trial in the United States and Mexico to begin in the coming weeks. More than 100 trial sites have been selected with some alternate sites in place, should they be needed.

Preliminary blinded data on NVX-CoV2373 in older adults needed to proceed to Phase 3 has previously been positively reviewed by the Food and Drug Administration (FDA). Additional clinical data from the Phase 2 trial conducted in the U.S. and Australia are expected to be unblinded in Q1 and will be targeted for publication.

Novavax will use vaccine material produced at commercial scale for this trial. Therefore, the Company has been working closely with the FDA to complete trial-initiation gating activities related to its commercial-scale production at FUJIFILM Diosynth Biotechnologies in Research Triangle Park, North Carolina.

Novavax was awarded $1.6 billion in funding from the U.S. government to meet its Operation Warp Speed goals to expedite the delivery of millions of doses of safe, effective vaccines for COVID-19. The award is funding the U.S. and Mexico

pivotal Phase 3 trial and manufacturing scale-up.

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 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. NVX-CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera in Phase 1/2 clinical testing. NVX-CoV2373 is being evaluated in a Phase 3 trial in the U.K. and two ongoing Phase 2 studies that began in August: a Phase 2b trial in South Africa, and a Phase 1/2 continuation in the U.S. and Australia. Novavax has secured $2 billion in funding for its global coronavirus vaccine program, including up to $399 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI) and more than $1.6 billion from the U.S. Government's Operation Warp Speed program.

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 undertaking 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 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 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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