Novavax Identifies Coronavirus Vaccine Candidate; Accelerates Initiation of First-in-Human Trial to Mid-May

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- NVX-CoV2373 identified as SARS-CoV-2 candidate for Phase 1 clinical trial
- In preclinical studies, NVX-CoV2373 demonstrated high immunogenicity and stimulated high levels of neutralizing antibodies
- First-in-human Phase 1 clinical trial accelerated to mid-May with preliminary results in July
- GMP clinical production initiated at Emergent BioSolutions with ability to leverage capacity for large scale manufacturing

GAITHERSBURG, Md., April 08, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced it has identified a coronavirus vaccine candidate, NVX-CoV2373, a stable, prefusion protein made using Novavax' proprietary nanoparticle technology, and will initiate a first-in-human trial in mid-May. Novavax' proprietary Matrix-M™ adjuvant will be incorporated with NVX-CoV2373 in order to enhance immune responses and stimulate high levels of neutralizing antibodies.

NVX-CoV2373 was shown to be highly immunogenic in animal models measuring spike protein-specific antibodies, antibodies that block the binding of the spike protein to the receptor and wild-type virus neutralizing antibodies. High levels of spike protein-specific antibodies with ACE-2 human receptor binding domain blocking activity and SARS-CoV-2 wild-type virus neutralizing antibodies were observed after a single immunization. In addition, the already high microneutralization titers seen after one dose increased eight fold with a second dose. High titer microneutralizing antibodies are generally accepted evidence that a vaccine is likely to be protective in humans.

"Our scientists identified an ideal vaccine candidate selected from a number of constructs and, in partnership with Dr. Matthew Frieman, demonstrated that NVX-CoV2373 produces high levels of neutralizing antibodies against SARS-CoV-2 in animal studies," said Gregory Glenn, M.D., President of Research and Development at Novavax. "In addition, we have worked closely with our colleagues at Emergent BioSolutions to transfer our production technology that allows the manufacture of GMP vaccine for clinical trials. With preliminary CEPI funding, these heroic efforts, combined with the candidate's excellent early results, put us in position to have preliminary human data in July."

"We validated that NVX-CoV2373 generates high titer neutralizing antibodies against live SARS-CoV-2 virus," said Matthew Frieman, Ph.D., Associate Professor at the University of Maryland School of Medicine. "This is strong evidence that the vaccine created by Novavax has the potential to be highly immunogenic in humans which could lead to protection from COVID-19 and helping to control the spread of this disease."

The NVX-CoV2373 clinical development plan combines a Phase 1/Phase 2 approach to allow rapid advancement during the current coronavirus pandemic. The Phase 1 clinical trial is a placebo-controlled observer blinded study of ~130 healthy adults and includes assessment of dosage amount and number of vaccinations. The trial is expected to begin in mid-May with preliminary immunogenicity and safety results in July.

As previously announced, in March, Novavax entered into an agreement with Emergent BioSolutions to provide contract development and manufacturing services, supplying Novavax with GMP vaccine product for use in its clinical trials. This agreement offers the potential to leverage Emergent's rapid deployment capabilities and expertise that provide Novavax scalability and capacity to produce vaccine product. Also in March, the Coalition for Epidemic Preparedness Innovations (CEPI) awarded an initial funding of $4 million to support Novavax' efforts, with additional funding discussions ongoing.

"Because of the tireless efforts and commitment of the Novavax team and our collaborators, we are preparing to initiate the NVX-CoV2373 Phase 1 trial in mid-May, weeks ahead of schedule," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "This progress demonstrates the ability of our recombinant nanoparticle technology to rapidly create vaccine candidates for emerging viruses like SARS-CoV-2. In addition, the performance of NVX-CoV2373 in multiple preclinical studies and testing gives us increased confidence in its potential to protect against COVID-19 disease."

About Coronavirus

A new strain of coronavirus, SARS-CoV-2, first appeared in late 2019 in China before beginning its rapid spread across the globe. The disease, named COVID-19, continues to cause severe pneumonia-like symptoms in many of those infected. Coronaviruses, so named for their "crown-like" appearance, are a large family of viruses that spread from animals to humans and include diseases such as Middle East Respiratory Syndrome (MERS) and SARS in addition to COVID-19. While much remains unknown about the new coronavirus, it is known that the virus can spread via human-to-human transmission before any symptoms appear.

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 and address urgent, global health needs. Novavax recently initiated development of a vaccine program against COVID-19, with human results expected in July of 2020. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine to demonstrate efficacy in a Phase 3 clinical trial. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing urgent global health needs.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

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, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the 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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