First participants enrolled in Phase 1 portion of clinical trial of NVX-CoV2373

Preliminary immunogenicity and safety results expected in July 2020

Phase 2 portion to begin promptly following successful Phase 1 results

GAITHERSBURG, Md., May 25, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced enrollment of the first participants in a Phase 1/2 clinical trial of its coronavirus vaccine candidate, NVX-CoV2373, a stable, prefusion protein made using its proprietary nanoparticle technology. NVX-CoV2373 includes Novavax' proprietary Matrix-M™ adjuvant to enhance immune responses and stimulate high levels of neutralizing antibodies. Preliminary immunogenicity and safety results from the Phase 1 portion of the trial are expected in July 2020.

"Administering our vaccine in the first participants of this clinical trial is a significant achievement, bringing us one step closer toward addressing the fundamental need for a vaccine in the fight against the global COVID-19 pandemic," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "We look forward to sharing the clinical results in July and, if promising, quickly initiating the Phase 2 portion of the trial."

The Phase 1/2 clinical trial is being conducted in two parts. The Phase 1 portion is a randomized, observer-blinded, placebo-controlled trial designed to evaluate the immunogenicity and safety of NVX-CoV2373, both adjuvanted with Matrix-M and unadjuvanted. The trial is enrolling approximately 130 healthy participants 18 to 59 years of age at two sites in Australia. The protocol's two-dose trial regimen assesses two dose sizes (5 and 25 micrograms) with Matrix-M and without.

The Phase 2 portion is expected to be conducted in multiple countries, including the United States, and would assess immunity, safety and COVID-19 disease reduction in a broader age range. This Phase 1/2 approach allows for rapid advancement of NVX-CoV2373 during the pandemic. The trial is being supported by the recently announced funding arrangement with the Coalition for Epidemic Preparedness Innovations (CEPI).

Novavax identified NVX-CoV2373 as its lead SARS-CoV-2 candidate following pre-clinical testing that demonstrated high immunogenicity and high levels of neutralizing antibodies. These results provide strong evidence that the vaccine candidate will be highly immunogenic in humans, potentially leading to protection from COVID-19 and thus helping to control the spread of this disease.

Dr. Richard Hatchett, CEO of CEPI said, "Entering clinical trials is an important step on the path to delivering a safe, effective and globally accessible vaccine against COVID-19. Vaccines provide our best hope of permanently defeating this pandemic, so it is encouraging to see rapid progress being made in the development of Novavax' vaccine candidate. CEPI's priority in building our portfolio has been to focus on vaccine candidates with the potential to be developed at speed and scale and made globally accessible. Our investment in Novavax allows us to focus on manufacturing in parallel with the clinical development of the vaccine, so that if the vaccine is proven to be safe and effective, we can make doses available to those who need them without delay."

For more information about the trial, read here on clinicaltrials.gov.

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil society organizations, launched at Davos in 2017, to develop vaccines to stop future epidemics. CEPI has moved with great urgency and in coordination with WHO in response to the emergence of COVID-19. CEPI has initiated 9 partnerships to develop vaccines against the novel coronavirus. The programs will leverage rapid response platforms already supported by CEPI as well as new partnerships. The aim is to advance COVID-19 vaccine candidates into clinical testing as quickly as possible.

Before the emergence of COVID-19 CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).

About NVX-CoV2373

NVX-CoV2373 is a 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 contains Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. In preclinical trials, NVX-CoV2373 demonstrated efficient binding with receptors targeted by the virus, a critical aspect for effective vaccine protection. A Phase 1 clinical trial of NVX-CoV2373 initiated in May 2020, with preliminary immunogenicity and safety results expected in July 2020. The Coalition for Epidemic Preparedness Innovations (CEPI) is investing up to $388 million of funding to advance clinical development of NVX-CoV2373.

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. Novavax recently initiated development of NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19, with Phase 1 clinical trial results expected in July of 2020. 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 in order 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.

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.

Contacts:

Investors
Novavax, Inc.
Erika Trahan
ir@novavax.com
240-268-2022

Westwicke
John Woolford
john.woolford@westwicke.com
443-213-0506

Media
Brandzone/KOGS Communication
Edna Kaplan
kaplan@kogspr.com
617-974-8659

---

https://ir.novavax.com/2020-05-25-Novavax-Initiates-Phase-1-2-Clinical-Trial-of-COVID-19-Vaccine