Novavax and UK Government Announce Collaboration and Purchase Agreement for Novavax' COVID-19 Vaccine Candidate

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GAITHERSBURG, Md., Aug. 14, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced it has signed a Heads of Terms (Term Sheet) with the Government of the United Kingdom (UK) for the purchase of 60 million doses of NVX-CoV2373, Novavax' COVID-19 vaccine, and a Phase 3 clinical trial to assess the efficacy of the vaccine in the UK population. Novavax will also expand its collaboration with FUJIFILM Diosynth Biotechnologies, which will manufacture the antigen component of NVX-CoV2373 from its Billingham, Stockton-on-Tees site in the UK, in addition to its sites in North Carolina and Texas in the United States. The FUJIFILM Diosynth Biotechnologies site in the UK is expected to produce up to 180 million doses annually, which further boosts the global supply of NVX-CoV2373 for additional markets.

"We are honored to partner with the UK government to deliver a vaccine that could provide vital protection in the fight against the global health crisis," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "Our Phase 3 clinical trial in the UK will be a critical component to assess the efficacy of NVX-CoV2373, which in a Phase 1 trial has already demonstrated to be generally well-tolerated and to elicit robust antibody responses. We are also delighted to expand our collaboration with FUJIFILM Diosynth Biotechnologies to manufacture our antigen at its UK site."

"It is encouraging that Novavax' recent clinical data shows their vaccine triggers an immune response greater than that in patients who have recovered from the disease," said Kate Bingham, Chair of the UK Government's Vaccines Taskforce. "We believe that Novavax has a highly innovative vaccine that could be the first in its class of protein-based vaccine options. We are happy to partner with them and global organizations such as CEPI to further our mutual commitments to ensure global access to the vaccine."

The Phase 3 clinical trial will be a randomized, double-blind, placebo-controlled efficacy study in approximately 9,000 adults 18-85 years of age in the UK. The trial is expected to begin in the third quarter of this year, with the UK government supporting and providing infrastructure to Novavax in the execution of the trial. The trial will assess the ability of NVX-CoV2373 to protect against symptomatic COVID-19 disease as well as evaluate antibody and T-cell responses.

Under the terms of the agreement, Novavax will supply 60 million doses of NVX-CoV2373 to the UK beginning as early as the first quarter of 2021. Excess supply of antigen manufactured at the FUJIFILM Diosynth Biotechnologies site in Billingham, Stockton-on-Tees may be available for Novavax to sell to additional markets outside the UK.

"To change the course of the pandemic, FUJIFILM Diosynth Biotechnologies is excited to expand our partnership with Novavax to manufacture their COVID-19 vaccine candidate at our UK site," said Paul Found, Chief Operating Officer, FUJIFILM Diosynth Biotechnologies, UK site. "We are honored to support the UK government and Novavax with the shared goal of delivering a safe and effective vaccine to the British people."

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 indication of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In its Phase 1 data of the Phase 1/2 clinical trial, NVX?CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. Phase 2 clinical trials will begin in August. Novavax has secured $2 billion in funding for its global coronavirus vaccine program, including up to $388 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

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 is undergoing clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NVX?CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera in its Phase 1 data of the Phase 1/2 clinical trial. 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.

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 8-K for the period ended June 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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