Novavax Investor Relations

Funding supports late-stage clinical development, including pivotal Phase 3 clinical trial to support licensure

OWS award funds large-scale manufacturing of NVX-CoV2373, including production of 100 million doses starting in late 2020

GAITHERSBURG, Md., July 07, 2020 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX), a late stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced that it has been selected to participate in Operation Warp Speed (OWS), a U.S. government program that aims to begin delivering millions of doses of a safe, effective vaccine for COVID-19 in 2021. Novavax has been awarded $1.6 billion by the federal government to complete late-stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX-CoV2373, Novavax' COVID-19 vaccine candidate, as early as late 2020. NVX-CoV2373 consists of a stable, prefusion protein made using its proprietary nanoparticle technology and includes Novavax' proprietary Matrix-M™ adjuvant.

"The pandemic has caused an unprecedented public health crisis, making it more important than ever that industry, government and funding entities join forces to defeat the novel coronavirus together. We are honored to partner with Operation Warp Speed to move our vaccine candidate forward with extraordinary urgency in the quest to provide vital protection to our nation's population," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "We are grateful to the U.S. government for its confidence in our technology platform, and are working tirelessly to develop and produce a vaccine for this global health crisis."

Under the terms of the agreement, Novavax will demonstrate it can rapidly stand up large-scale manufacturing and transition into ongoing production, including the capability to stockpile and distribute large quantities of NVX-CoV2373 when needed. The agreement will fund the late-stage clinical studies necessary to determine the safety and efficacy of NVX-CoV2373, including a pivotal Phase 3 clinical trial with up to 30,000 subjects beginning in the fall of 2020.

"Adding Novavax' candidate to Operation Warp Speed's diverse portfolio of vaccines increases the odds that we will have a safe, effective vaccine as soon as the end of this year," said U.S. Health and Human Services Secretary Alex Azar. "Today's $1.6 billion investment supports the Novavax candidate, depending on success in clinical trials, all the way through to manufacturing 100 million doses for the American people."

Today's agreement also allows for a follow-on agreement with the U.S. government for additional production and procurement to support OWS' vaccine production goal. This latest federal funding supports Novavax plans to file submissions for licensure with the U.S. Food and Drug Administration (FDA).

A Phase 1/2 clinical trial of NVX-CoV2373 in 130 healthy participants 18 to 59 years of age began in Australia in May. Preliminary immunogenicity and safety results are expected at the end of July, and the Phase 2 portion to assess immunity, safety, and COVID-19 disease reduction is expected to begin thereafter. The Phase 1/2 clinical trial is being supported by an up-to $388 million funding arrangement with the Coalition for Epidemic Preparedness Innovations (CEPI).

For further information, including media-ready images, b-roll, downloadable resources and more, click here.

About Operation Warp Speed

Operation Warp Speed is facilitating, at an unprecedented pace, the development, manufacturing, and distribution of COVID-19 countermeasures, between components of Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), FDA, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA, part of the HHS Office of the Assistant Secretary for Preparedness and Response); the Department of Defense. OWS is coordinate existing HHS-wide efforts, including the NIH's ACTIV partnership for vaccine and therapeutic development, NIH's RADx initiative for diagnostic development, and work by BARDA.

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. 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, and Department of Defense (DoD) is investing up to $60 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, including statements regarding the manufacturing of vaccine antigen dose amounts and timing, 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) and updated by any Quarterly Report on Form 10-Q, particularly the risks inherent to developing novel vaccines. 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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