Novavax Announces Positive Data From Phase 2 Trial of Quadrivalent Seasonal Influenza VLP

July 30, 2015

GAITHERSBURG, Md., July 30, 2015 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX), a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants, today announced positive top-line data from a Phase 2 clinical trial of its recombinant quadrivalent seasonal influenza virus-like particle (VLP) vaccine candidate (Seasonal Influenza VLP). This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, Department of Health and Human Services under the Company's contract with HHS-BARDA (HHSO100201100012C). The trial demonstrated that the Seasonal Influenza VLP vaccine candidate was well-tolerated with no vaccine-related serious adverse events. The trial met its immunogenicity targets and demonstrated potential to meet the Center for Biological Evaluation and Research (CBER) criteria for accelerated approval.

Novavax' technology platform enables the creation of recombinant, strain-specific VLPs. Novavax' Seasonal Influenza VLP consists of VLPs representing four different strains of influenza virus, each expressing strain-specific hemagglutinin and neuraminidase antigens. This dose-ranging clinical trial was designed to evaluate the safety and immunogenicity of the Seasonal Influenza VLP in 400 healthy adults. The primary outcomes of the trial assessed safety and tolerability of the Seasonal Influenza VLP and quantified immune responses to each of the four influenza strains based on hemagglutination-inhibiting antibody titers. The secondary outcomes evaluated neuraminidase-inhibiting antibody titers for all four influenza strains.

"Titers of antibodies that inhibit hemagglutination by the influenza virus – called hemagglutination-inhibiting or HAI antibodies – remain the best-accepted correlates of the protection provided by influenza vaccines. We were very pleased to see that our Seasonal Influenza vaccine candidate elicited increases in HAI titers for all four viral strains that would allow our vaccine to fulfill CBER's criteria for accelerated approval," said Louis F. Fries III, M.D., Chief Medical Officer, Novavax. "Novavax has made a concerted effort to improve the antigens in our Seasonal Influenza vaccine. In particular, for the two viral strains (out of the four) for which we had sought immunogenic improvement, we showed robust HAI titer responses, approximately 50% greater than those in our prior phase 2 trial. Further, we measured neuraminidase-inhibiting (NAI) antibody responses against seasonal influenza viruses for the first time, and were able to detect significant NAI antibody responses to all four influenza strains, including strong responses against the B virus strains."

Novavax President and CEO, Stanley C. Erck, said, "These positive topline data from the Phase 2 trial of our Seasonal Influenza vaccine candidate represent an important achievement in this program. We look forward to a complete review of these data with our partner BARDA to determine next steps in the development of this product. Our collaboration with BARDA also includes the development of our novel H7N9 Influenza vaccine candidate in combination with Matrix-M™. We expect the next steps in our collaboration will be the initiation of a Phase 2 clinical trial of the H7N9 vaccine candidate in the adult population in the first quarter of 2016."

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage vaccine company committed to delivering novel products to prevent a broad range of infectious diseases. Our recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for groundbreaking innovation that improves global health through safe and effective vaccines. Additional information about Novavax is available on the Company's website, novavax.com.

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