Novavax Investor Relations

Seasonal influenza nanoparticle approach replaces VLP program

HHS BARDA contract will complete its term as scheduled in September 2016

Nanoparticle design builds on advances achieved with RSV F Vaccine

Animal immunogenicity and efficacy data demonstrate broadly neutralizing antibodies

Data presented at Keystone Symposia

GAITHERSBURG, Md., June 02, 2016 (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 Dr. Louis F. Fries, III, Senior Vice President and Chief Medical Officer, presented data on Novavax' nanoparticle program at the New Approaches to Vaccines for Human and Veterinary Tropical Diseases Keystone Symposia in Cape Town, South Africa.

Data included in the presentation demonstrate Novavax' progress in developing seasonal influenza nanoparticles that are protective in a ferret influenza challenge model when combined with our proprietary adjuvant, Matrix-M™. The vaccine candidate is based on a hemagglutinin nanoparticle and elicited broadly neutralizing antibodies to all three types of influenza viruses: A(H3N2), A(H1N1), and B, with specificity to both contemporary and historical influenza strains.

The presentation can be accessed at: http://www.novavax.com/download/files/presentations/Novavax_Nanoparticle%20Vaccines%20for%20Keystone.pdf

Nanoparticle Design Builds on Advances Achieved with RSV F Vaccine

"Our seasonal influenza nanoparticle approach builds on the advances achieved with our RSV nanoparticle. Our breakthrough in RSV vaccine development leverages conserved sites within the F protein to provide protection from contemporary and historical strains of RSV. We have replicated that approach in developing our seasonal influenza nanoparticle. Novavax pioneered the use of palivizumab-competing antibodies as a metric for an effective immune response to RSV and we have developed a similar, influenza-specific, broadly neutralizing monoclonal antibody competition assay to test responses to our new influenza vaccine," said Gregory Glenn M.D., President of Research and Development. "Our seasonal influenza nanoparticle antigens elicit antibodies that neutralize the influenza virus at nanomolar concentrations and interact with epitopes that lead to traditional hemagglutination-inhibition, as well as other protective epitopes. The capacity of these antibodies to neutralize across drifted influenza A and B strains and the two B strain lineages suggest our seasonal influenza nanoparticles may offer improved protection and address the frequent mismatch of vaccine versus circulating strains.

We also demonstrated that we can combine the RSV F and influenza nanoparticle vaccines, bringing together a vaccine approach that induces broadly neutralizing antibodies against both influenza and RSV. A vaccine with these attributes covering both influenza and RSV, which together are the major cause of serious respiratory infections in older adults and pediatrics, would be a major advance for public health. Matrix-M adjuvant, which enhances the broadly-neutralizing preclinical antibody response, will be used together with the nanoparticle vaccines in a Phase 1/2 clinical trial early next year."

Advantages of Nanoparticle Influenza Vaccine versus VLP

Using lessons learned from the development of our RSV and Ebola nanoparticle vaccines we have identified several advantages, representing an evolution in vaccinology that have guided our strategic approach:

- Influenza nanoparticles are engineered to display conserved antigenic regions, which elicit broadly neutralizing antibodies;
- Improved manufacturing yields; and

- Use of Matrix M adjuvant, shown to be well-tolerated and highly effective at stimulating enhanced immunity.

HHS BARDA Contract Will Complete its Term as Scheduled in September 2016

Since 2011, Novavax has been developing influenza vaccines as part of a project that has been funded under our contract with the U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS BARDA). The scope of the HHS BARDA contract (HHSO100201100012C) has been to develop seasonal and pandemic influenza vaccine candidates, based on our proprietary virus-like particle (VLP) technology. The advances in our seasonal influenza nanoparticle program have resulted in a natural conclusion of our activities under the HHS BARDA contract, which will continue through the completion of its term in September 2016.

“Although our efforts have progressed beyond the scope of our current HHS BARDA contract and VLP vaccines, we are very excited to develop a differentiated seasonal influenza approach that builds on the proven success of our RSV F Vaccine,” said Stanley C. Erck, President and CEO. “We also see enormous value in a combination respiratory vaccine that combines our seasonal influenza nanoparticle vaccine with our RSV F Vaccine. The next step in our program will be to conduct a multi-arm Phase 1/2 clinical trial of our seasonal influenza nanoparticles alone and in combination with our RSV F Vaccine, with and without our potent Matrix-M adjuvant. We expect to initiate this trial in early 2017.”

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. Its recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for ground-breaking innovation that improves global health through safe and effective vaccines. Additional information about Novavax is available on the company's website, novavax.com.

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, 2015 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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