Novavax Investor Relations

Novavax' Fifth Positive Top-Line Clinical Trial Announcement of the 3rd Quarter

GAITHERSBURG, Md., Sept. 29, 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 1 clinical trial of its RSV F-protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) in healthy children.

The trial was a randomized, observer-blinded, Phase 1 study to evaluate the safety and immunogenicity of the RSV F Vaccine, with one or two doses, with or without aluminum phosphate adjuvant, in healthy pediatric participants two to six years of age. The trial's primary goal was to evaluate safety in this population and immunogenicity as measured by concentrations of serum IgG antibodies to the RSV fusion, or F-protein, palivizumab-competing antibody (PCA) titers and RSV microneutralization titers. Novavax concluded this trial's enrollment with a smaller than planned cohort so dosing could be completed ahead of the 2014-2015 RSV season.

Of the 32 total children enrolled, serum samples were collected from a subset of 18 children in the per-protocol population at 14, 28 and 56 days. All RSV F Vaccine formulations and regimens were well-tolerated and highly immunogenic. Consistent with prior trials, anti-F IgG and PCA titers increased rapidly at day 14, peaked at day 28 and remained at elevated levels through day 56; the last time point currently analyzed. There were greater than 10-fold increases in both anti-F IgG and PCA antibody titers in the adjuvanted group and greater than 6-fold increases in anti-F IgG and PCA antibody titers in the unadjuvanted group.

"Given the seasonality of RSV and the fact that infection could confound interpretation of the data, we closed out the trial prior to the initiation of the RSV season. Despite the small population, we were able to observe that the vaccine has the potential to be both safe and immunogenic in young children," said Gregory Glenn, M.D., Senior Vice President, Research and Development. "The strength of these data clearly support advancing the RSV vaccine into a Phase 2 pediatric trial."

"Our RSV F Vaccine has now elicited a robust immune response in all three of our target populations: older adults, infants via maternal immunization and pediatrics. We are evaluating this data in the context of our RSV F Vaccine overall clinical development program and look forward to providing an update in the next several months on our path forward in the pediatric population," said Stanley C. Erck, President and CEO. "It should not be lost on those interested in Novavax that this announcement is the fifth positive clinical trial readout provided during the third quarter of this year, a pivotal achievement for the Company made possible by the power of our recombinant nanoparticle platform technology and this dedicated and experienced team."

About RSV

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory tract infections and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide, with estimated annual infection and mortality rates of 64 million and 160,000, respectively1. In the US, RSV is the leading cause of hospitalization of infants2. Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common3,4. Currently, there is no approved RSV vaccine available. Palivizumab is a monoclonal antibody, licensed and sold by MedImmune as Synagis®, that targets the RSV F protein and is used for prophylaxis against RSV disease in high risk infants.

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.

References:

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3. Glezen, W.P. *et al.* Risk of primary infection and reinfection with respiratory syncytial virus. *Am J Dis Child*, 1986; 140:543-546.
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Contact:

Novavax, Inc.Barclay A. Phillips
SVP, Chief Financial Officer and Treasurer

Andrea N. Flynn, Ph.D.
Senior Manager, Investor Relations

ir@novavax.com
240-268-2000

Russo Partners, LLC

David SchullTodd Davenport, Ph.D.

david.schull@russopartnersllc.com
todd.davenport@russopartnersllc.com
212-845-4271
