Novavax Investor Relations

GAITHERSBURG, Md., Sept. 10, 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 that the full data set from its clinical trial of the RSV F-protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) in women of childbearing age (18-35 years) were published in the *Journal of Infectious Disease*. The Company previously announced top-line results from the trial.

The manuscript describes the randomized, blinded, placebo-controlled Phase 2 clinical trial that evaluated the safety and immunogenicity of two dose levels of the RSV F Vaccine with and without aluminum phosphate adjuvant. The trial enrolled 330 women of childbearing age who received either one or two intramuscular injections of a single-dose (60 or 90 μg) of vaccine or placebo at study days 0 and 28.

The manuscript details the significant antibody response to the RSV F Vaccine including a 6.5-15.6-fold increase in anti-F IgG antibodies across all vaccine doses at day 56, with significantly higher levels in the two-dose adjuvanted regimens. Palivizumab-competing antibody (PCA) levels were undetectable at day 0 but increased up to between 205-325 μg/mL at day 56. Further, a 2.7 and 3.5-fold rise in RSV/A and RSV/B microneutralizing antibodies were detected at day 56, prior to the RSV season. Finally, between days 56 and 112, 21% (12/56) of placebo recipients showed evidence of a recent RSV infection by Western Blot compared to 11% of vaccinees (26/244) ($p = 0.04$).

“These data are the foundation for our ongoing RSV F Vaccine development program to protect infants via maternal immunization,” said Gregory Glenn, M.D., Senior Vice President of Research and Development. “The RSV F Vaccine stimulated high levels of anti-F, PCA and microneutralizing antibodies. Further, our *ad hoc* analysis via Western Blot, together with our recent data in older adults, provides an additional indication that the vaccine-induced immunity can protect against RSV infections in humans. We look forward to announcing additional data from our trial of the RSV F Vaccine in pregnant women later this quarter, a key milestone in our strategy to develop a vaccine designed to protect infants via maternal immunization.”

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 responsible for approximately 57,000 hospitalizations of children under five years of age annually, the vast majority of which occur in infants less than one year old, and especially those under six months of age2-4. Despite the induction of post-infectious immunity, repeat infection and lifelong susceptibility is common5. 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:

1. Nair, H. *et al.* Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children: a systematic review and meta-analysis. *Lancet*, 2010; 375: 1545-1555.
2. Stockman, L.J. *et al.* Respiratory syncytial virus-associated hospitalizations among infants and young children in the United States, 1997-2006. *Pediatr Infect Dis J*, 2012; 31:5-9.
3. Centers for Disease Control and Prevention, update May 5, 2015. Respiratory Syncytial Virus Infection. Trends and Surveillance. http://www.cdc.gov/rsv/research/us-surveillance.html
4. Boyce, T.G. *et al.* Rates of hospitalization for respiratory syncytial virus infection among children in Medicaid. *J Pediatr*, 2000; 137:865-870.
5. Glezen, W.P. *et al.* Risk of primary infection and reinfection with respiratory syncytial virus. *Am J Dis Child*, 1986; 140:543-546.

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, 2014, 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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