

GAITHERSBURG, Md., Sept. 15, 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 its RSV F-protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) was shown to be highly immunogenic in a guinea pig model of maternal immunization. The preclinical study was published in the journal [Vaccine](#).¹

Direct immunization of infants is complicated by their immature immune systems which are unable to fight off viral infection early in life when infants are most vulnerable to RSV. In mammals, the passage of maternal antibodies to offspring is largely achieved either by *in utero* transplacental transfer of immunoglobulin G antibodies (IgG) or by postpartum breast-feeding of colostrum containing high levels of IgG and sIgA.² For human infants, maternally-derived IgG appears to be provided entirely *in utero*, via transplacental Fc receptor-mediated antibody transfer.² The protective effects of human serum IgG, transferred from mothers to infants in utero,² against a number of infections, including influenza and pertussis, has been well-described.³⁻⁵

Presumptive pregnant guinea pigs were immunized with the RSV F Vaccine on gestational days 25 and 46. The vaccine induced high levels of anti-F IgG antibodies, palivizumab-competing antibodies (PCA) and microneutralizing titers. The peer-reviewed manuscript also demonstrates transfer of placental anti-RSV antibodies, as measured by a number of immunoassays, at days 15 and 30 postpartum.

“RSV is the leading cause of infant hospitalizations in the U.S. and a significant unmet need in full-term infants,” said Gregory M. Glenn, M.D., Senior Vice President, Research and Development at Novavax. “The placental architecture in guinea pigs reflects the anatomy found in humans, making them an appropriate model to evaluate placental transfer of antibodies. These preclinical data further support our RSV F Vaccine maternal immunization program, and we look forward to announcing data from our Phase 2 clinical trial to protect infants via maternal immunization this quarter.”

Copies of this paper are available to credentialed journalists upon request; please contact Elsevier's Newsroom at newsroom@elsevier.com or +31 20 4853564.

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, respectively.⁶ 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 age.⁷⁻¹¹ Despite the induction of post-infectious immunity, repeat infection and lifelong susceptibility is common.¹² 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 Vaccine

Vaccine is the pre-eminent journal for those interested in vaccines and vaccination. It is the official journal of The Edward Jenner Society, The International Society for Vaccines and The Japanese Society for Vaccinology and is published by Elsevier. www.elsevier.com/locate/vaccine

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:

- “Modeling Maternal Fetal RSV F Vaccine Induced Antibody Transfer in Guinea Pigs,” by Gregory M. Glenn, Louis F. Fries, Gale Smith, Eloi Kpamegan, Hanxin Lu, Mimi Guebre-Xabier, Somia P. Hickman, and David Flyer. DOI: [10.1016/j.vaccine.2015.08.039](https://doi.org/10.1016/j.vaccine.2015.08.039). It appears in *Vaccine*, In Press, 2015, published by Elsevier.
- “Comparative placental structure,” by A.C. Enders, T.N. Blankenship. *Adv Drug Delivery Rev*, 38 (1999), pp. 3–15.
- “The protective role of maternally derived antibodies against Bordetella pertussis in young infants,” by U. Heininger et al. *Pediatr Infect Dis J*, 32 (2013), pp. 695–698.
- “Influenza vaccination of pregnant women and protection of their infants,” by S.A. Madhiet al. *N Engl J Med*, 371 (2014), p. 2340.
- “Neonatal outcomes after influenza immunization during pregnancy: a randomized controlled trial.” by M.C. Steinhoff et al. *CMAJ* 184 (2012), pp. 645–653.
- “Global burden of acute lower respiratory infections due to respiratory syncytial virus in young children: a systematic review and meta-analysis,” by Nair, H. et al. *Lancet*, 2010; 375: 1545-1555.
- “Respiratory syncytial virus-associated hospitalizations among infants and young children in the United States, 1997-2006,” by L.J. Stockman et al. *Pediatr Infect Dis J*, 2012; 31:5-9.
- 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>
- “Rates of hospitalization for respiratory syncytial virus infection among children in Medicaid,” by T.G. Boyce et al. *J Pediatr*, 2000; 137:865-870.
- “The Burden of Respiratory Syncytial Virus Infection in Young Children,” by C.B. Hall et al. *N Engl J Med*, 2009; 360(6): 588-98.
- “Respiratory Syncytial Virus-Associated hospitalizations Among Children Less Than 24 Months of Age.” by C.B. Hallet al. *Pediatrics*, 2013; 132(2): E341-348.
- “Risk of primary infection and reinfection with respiratory syncytial virus,” by W.P. Glezen et al. *Am J Dis Child*, 1986; 140:543-546.

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