Novavax Initiates Global Pivotal Phase 3 Trial of the RSV F Vaccine to Protect Infants via Maternal Immunization

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GAITHERSBURG, Md., Dec. 03, 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 the enrollment of the first participant in a global pivotal Phase 3 clinical trial, known as Prepare™, of its respiratory syncytial virus F-protein nanoparticle vaccine candidate (RSV F Vaccine) in healthy pregnant women.

The Prepare trial is a randomized, observer-blinded, placebo-controlled trial that utilizes a group sequential design, offering flexibility in trial size that is responsive to the rate of endpoint events and evolving evidence of efficacy while maintaining the trial's blinding integrity. Thus, the eventual sample size may vary between 5,000 and 8,255 pregnant women over a period of two to four years. Participants are being vaccinated at a number of global clinical sites in advance of each region's RSV season. Novavaxpreviously announced it was awarded a grant up to $89 million from the Bill & Melinda Gates Foundation to support development of this RSV F Vaccine Phase 3 clinical trial in pregnant women.

The primary objective of the Prepare trial is to determine the efficacy of maternal immunization with the RSV F Vaccine against symptomatic RSV lower respiratory tract infection (LRTI) with hypoxemia in infants through the first 90 days of life. The trial's objectives, endpoints and statistical approach were finalized following a recent End of Phase 2 meeting with the FDA. The results of a Phase 2 trial in pregnant women, as reported by Novavax in September 2015, provided the basis for the Phase 3 trial design, including the determination of anti-RSV antibody responses in mothers and antibody transfer from mothers to infants.

"We believe that maternal immunization offers the optimal way of protecting young infants, who are among the most susceptible populations to RSV disease. Initiation of this trial builds on our groundbreaking Phase 2 clinical data in this important population, and incorporates discussions with experts in the field and the FDA," said Stanley C. Erck, President and CEO. "The initiation of our second pivotal Phase 3 trial this quarter, ahead of our guidance, demonstrates the ability of our team to execute along aggressive timelines."

A fact sheet on maternal immunization is available at:
http://novavax.com/download/files/pipeline/151_Novavax_FactSheet_FIN_D_9x10.pdf

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.1 In the US, RSV is the leading cause of hospitalization of infants, and globally, is second only to malaria as a cause of death in children under 1 year of age.2,3 Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.4,5 Currently, there is no approved RSV vaccine available.

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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2. Hall, C.B. *et al.* Respiratory Syncytial Virus-Associated hospitalizations Among Children Less Than 24 Months of Age. *Pediatrics*, 2013; 132(2): E341-348.
3. Oxford Vaccine Group: http://www.ovg.ox.ac.uk/rsv
4. Glezen, W.P. *et al.* Risk of primary infection and reinfection with respiratory syncytial virus. *Am J Dis Child*, 1986; 140:543-546.

5. Glenn GM, *et al.* Modeling maternal fetal RSV F vaccine induced antibody transfer in guinea pigs. *Vaccine,* 2015; In press. http://dx.doi.org/10.1016/j.vaccine.2015.08.039.

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, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015, 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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