Novavax Investor Relations

GAITHERSBURG, Md., Nov. 09, 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 initiation of a Phase 3 clinical trial, known as Resolve™, of its respiratory syncytial virus F-protein nanoparticle vaccine candidate (RSV F Vaccine) in older adults (60 years of age and older).

The Resolve trial is a randomized, observer-blinded, placebo-controlled trial designed to enroll up to 11,850 older adults at 60 sites in the United States. Participants are being enrolled and vaccinated in advance of the 2015-16 RSV season, with top-line results expected in the second half of 2016.

The primary efficacy objective of the Resolve trial is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms. The trial's objectives, endpoints and statistical approach were finalized based on the FDA's recommendations during the recent End of Phase 2 meeting. The results of a Phase 2 trial in older adults, reported by Novavax in August 2015, provided the basis for the Phase 3 trial design, including the determination of the attack rate, vaccine efficacy and case definitions.

"We have taken advice and recommendations from the FDA, along with numerous key opinion leaders and clinical experts, to design the Resolve trial to align with and build on the strength of our previous clinical results," said Stanley C. Erck, President and CEO. "The primary objective of this clinical trial captures moderate-severe RSV disease that drives an estimated annual economic burden of more than $24 billion in the United States alone. The Resolve trial takes Novavax one step closer to bringing this important vaccine to licensure, years ahead of other RSV vaccine development efforts."

About RSV

Respiratory syncytial virus, commonly referred to as RSV, is a respiratory infectious disease that causes serious infection of the respiratory tract, similar to influenza. For some, RSV may progress in severity, and lead to hospitalization or even death. The spread of RSV occurs annually, with an incidence rate of 2.5 million infections per year in the United States, RSV is increasingly being recognized as a significant cause of morbidity and mortality in the population of 64 million older adults.1,2The U.S. Centers for Disease Control and Prevention (CDC) reports that each year the disease causes 177,000 hospitalizations and 14,000 deaths among adults older than 65.3 Annually, there are approximately 900,000 medical interventions directly caused by RSV disease.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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- Widmer, K. *et al.* Rates of Hospitalizations for Respiratory Syncytial Virus, Human Metapneumovirus and Influenza Virus in Older Adults. *J Infect Dis*, 2012; 206: 56-62.
- Widmer, K. et al. Respiratory Syncytial Virus & Human Metapneumovirus-Associated Emergency Department and Hospital Burden in Adults. *Influenza Other Respir Viruses,* 2014; 8(3): 347-352.

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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