Novavax Investor Relations

GAITHERSBURG, Md., Jan. 19, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX) today announced the initiation of a Phase 2 clinical trial of its respiratory syncytial virus F-protein nanoparticle vaccine candidate (RSV F Vaccine) in older adults (60 years of age and older).

The objective of the trial is to assess safety and immunogenicity to one and two dose regimens of the RSV F Vaccine, with and without aluminum phosphate or Novavax' proprietary Matrix-M™ adjuvant, in older adults. The trial is a randomized, observer-blinded, placebo-controlled trial designed to enroll up to 300 older adults in the Southern Hemisphere. Participants are being enrolled and vaccinated outside of the RSV season to best assess immunogenicity. Top-line results are expected in the third quarter of 2017.

"We believe that a more immunogenic vaccine in the older adult population should translate into a more efficacious vaccine," said Stanley C. Erck, President and CEO. "We expect the results from this trial to inform the next steps in our older adults program, and would ensure we maintain our leadership position in this very attractive market opportunity."

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.1,2 Each year, RSV is responsible for approximately 207,000 hospitalizations and 16,000 deaths among adults older than 65.1,3 Annually, there are approximately 900,000 medical interventions directly caused by RSV disease.4,5 Currently, there is no approved RSV vaccine available.

About Matrix-M

Matrix-M™ is a next-generation, patented adjuvant comprised of purified saponin fractions mixed with synthetic cholesterol and a phospholipid to form stable particles than can be readily formulated with a variety of vaccine antigens. Saponin-based adjuvants act in part by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in the local lymph nodes. Thus, Matrix-M™ induces both a cell-mediated and antibody mediated immune response. Matrix-M is manufactured by Novavax, Inc., in Uppsala Sweden.

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. A.R. Falsey et al. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med. 2005; 352:1749–59.

2. A.R. Falsey et al. Respiratory syncytial virus and influenza A infections in the hospitalized elderly. J. Infect Dis. 1995; 172:389-94.

3. W.W. Thompson et al. Mortality associated with influenza and respiratory syncytial virus in the United States. JAMA 2003; 289(2): 179-186.

4. K. Widmer et al. Rates of hospitalizations for respiratory syncytial virus, human metapneumovirus, and influenza virus in older adults. J Infect Dis. 2012; 206: 56-62.

5. K. Widmer et al. Respiratory syncytial virus & human metapneumovirus-associated emergency department and hospital burden in adults. Influenza and Other Respiratory 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, 2015, and our Quarterly Reports on Form 10-Q for the quarters ended June 30, 2016 and September 30, 2016, 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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