Novavax Investor Relations

- First respiratory syncytial virus (RSV) vaccine to demonstrate efficacy in any population

- Statistically significant vaccine efficacy in prevention of symptomatic RSV disease in older adults

- Large prospective epidemiological study of RSV; detected a seasonal attack rate of 4.9% for symptomatic RSV disease

GAITHERSBURG, Md., Aug. 10, 2015 /PRNewswire/ -- Novavax, Inc. (Nasdaq: NVAX), a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants, today announced positive top-line data from a Phase 2 clinical trial of its RSV F-protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) in older adults (60 years of age and older). The RSV F Vaccine was well-tolerated and fulfilled the Company's expectations of the primary, secondary and exploratory objectives of the trial.

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"It's increasingly appreciated that RSV causes an enormous amount of illness on an annual basis, particularly in the older population. An RSV infection can predispose older adults to developing secondary pneumonia and admission to the hospital," said Dr. William Schaffner, Professor of Preventive Medicine and Infectious Diseases, Vanderbilt University Medical Center. "Each year in the United States, approximately 14,000 people ages 65 or older die of RSV infections and approximately 900,000 have some sort of medical encounter with a doctor, or emergency room, or are hospitalized. Prevention remains the highest goal of medicine and those of us in preventative medicine and public health would like to prevent as many of these infections as possible."

The Novavax trial was a randomized, observer-blinded, placebo-controlled Phase 2 trial of 1,600 older adult participants conducted at 10 sites in the United States. The trial was designed to prospectively examine the incidence of all symptomatic respiratory illnesses associated with RSV, in community-living older adults who were treated with placebo. The trial also evaluated safety and immunogenicity of the unadjuvanted, 135 microgram dose of the RSV F Vaccine compared to placebo. Finally, the trial estimated the efficacy of the RSV F Vaccine in reducing the incidence of respiratory illness due to RSV.

The trial is the first to demonstrate efficacy of an active RSV immunization in any clinical trial population, and showed statistically significant vaccine efficacy in prevention of all symptomatic RSV disease (44%) and RSV disease with symptoms of lower respiratory tract infection (46%) in older adults. The observed efficacy was similar to or better than multiple recent effectiveness estimates for a number of licensed respiratory vaccines tested in older adults including pneumococcal and standard-dose seasonal influenza.1,2 The trial also established an attack rate for symptomatic RSV disease of 4.9% in older adults, 95% of which included lower respiratory track symptoms, and confirmed the significant burden of RSV disease in this population. In addition, statistically significant efficacy against more severe RSV illness, as defined by the presence of multiple lower respiratory tract symptoms associated with difficulty breathing, was 64% in several *ad hoc* analyses. Kaplan-Meier curves showed continued divergence of active vaccinees from placebo recipients over the nearly 6 months during which RSV was detected, demonstrating the durability of protection throughout the RSV season.

As expected from the Company's prior trials, anti-F IgG and palivizumab-competing antibody (PCA) titers peaked rapidly at day 14, plateaued at day 28 and remained at elevated levels through day 56; the last time point currently analyzed. There were greater than four-fold increases in both anti-F IgG and PCA concentrations at trial days 14, 28 and 56, and serologic responses in over 90% of vaccinated subjects, indicating a robust immune response, similar to the findings from the Company's prior trial in older adults. Finally, the safety profile in vaccine recipients was nearly identical to that of placebo recipients with regard to both local and systemic events.

"These efficacy data represent a historic advance for the field," said Gregory Glenn, M.D., Senior Vice President, Research and Development. "This is also an important confirmation of the burden of RSV disease in older adults and highlights the high rate of lower respiratory tract symptoms in those infected by RSV in a large, prospective trial. It is clear that our RSV F Vaccine provided statistically significant efficacy in older adults, a population that historically has been difficult to protect. The reduction in symptomatic RSV, RSV with lower respiratory tract illness and RSV associated with difficulty breathing are breakthrough results. We look forward to making details of these data public at an appropriate forum in the future."

"The development of an RSV vaccine has been a decades-long challenge," said Stanley C. Erck, President and CEO. "We are thrilled by the groundbreaking efficacy of our RSV F Vaccine in older adults. We are committed to pursuing an aggressive developmental timeline for this program which includes discussions with regulatory

authorities and initiation of a pivotal Phase 3 trial as early as the fourth quarter of this year. We also expect to announce safety and immunogenicity data from the RSV F Vaccine Phase 2 trial to protect infants via maternal immunization later this quarter."

A live webcast link to a presentation that details data from the trial is available under the "Investors/Events" section of the Novavax website at novavax.com.

About RSV
RSV is a major respiratory pathogen in infants, children, and adults. RSV infections in adults represent re-infections and are generally mild to moderate in severity, except in persons with high-risk conditions including the elderly and adults with underlying chronic cardiac or pulmonary disease. It is estimated that 2.4 million adults 65 years of age or older are infected with RSV annually in the U.S. leading to as many as 900,000 medical interventions and 14,000 deaths each year. 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. http://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm
2. Bonten, M.J.M. *et al*. Polysaccharide Conjugate Vaccine against Pneumococcal Pneumonia in Adults. *NEJM*, 2015; 372:1114-1125.

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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