Novavax RSV F Vaccine Phase 2 Clinical Trial Data in Women of Child Bearing Age Published in Vaccine

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GAITHERSBURG, Md., June 7, 2017 /PRNewswire/ -- Novavax, Inc., (Nasdaq:NVAX) today announced that data from the second of two Phase 2 trials of its RSV F protein recombinant nanoparticle vaccine candidate (RSV F Vaccine) in women of child bearing age have been published in the journal *Vaccine* (the data contained in this publication have been shared in prior scientific conferences). The Company previously announced top line results from this trial in April 2014. Novavax is developing the RSV F Vaccine with the goal of protecting infants from RSV disease.

The manuscript describes the randomized, observer-blinded, placebo-controlled dose-ranging trial which evaluated the safety and immunogenicity of the RSV F Vaccine with and without varying doses of aluminum-phosphate adjuvant. The trial enrolled 720 women of child bearing age (18-35 years) at 10 clinical trial sites in the United States who received either one or two intramuscular injections of vaccine (at 60 or 120 µg doses) or placebo at study days 0 and 28.

The manuscript documents the significant antibody response elicited by the RSV F Vaccine, including 11.6 to 12.7-fold increases in anti-F IgG responses in women receiving a single dose of 120 µg RSV F Vaccine with 0.2 or 0.4 mg of aluminum. These antibody responses peaked 14 days post-vaccination and persisted at significantly elevated levels for the 3 month period during which immunogenicity was evaluated. Palivizumab-competing antibody (PCA) levels were low or undetectable at day 0 but increased to 341-423 µg/mL on day 14 for the 120 µg 1-dose regimens. While baseline levels of RSV/A and RSV/B microneutralizing titers did not vary in the placebo group, they more than doubled at day 28 against both RSV strains for the 120 µg, 0.4 mg aluminum formulation, which the Company selected for further development.

Importantly, confirming results from the Company's prior trial in a similar population, serologic evidence of a new RSV infection by Western Blot was present in 21% (18/84) of placebo recipients, compared to only 10% (36/352) of vaccinees, a 52% (p=0.009) overall reduction of infection.

"The Western Blot finding from this trial, which demonstrates a reduction in recent RSV infections of approximately 52% in the vaccine relative to the placebo arms, is consistent with the Western Blot data we reported from a comparable trial and population in September of 2015. Together, these data suggest that the RSV F Vaccine provided protection against RSV infection in controlled trials of over 1,000 women," said Gregory Glenn, M.D., President, Research and Development. "The results from this trial not only demonstrate significant increases in anti-F IgG, PCA and microneutralizing antibody titers in response to a 120 µg dose of the RSV F Vaccine with 0.4 mg aluminum, the same dose and regimen used in our global Phase 3 trial, Prepare, they are consistent with the immunogenicity results reported in our prior trial in women of child bearing age. While it was not the primary endpoint in the trial, the Western Blot data suggest the potential to protect both the pregnant mothers and their infants from RSV disease."

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a clinical-stage biotechnology 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.

About Prepare™

Prepare is a global pivotal Phase 3 clinical trial of RSV F Vaccine candidate for the protection of infants via maternal immunization. The Prepare trial is a randomized, observer-blinded, placebo-controlled trial in healthy pregnant women. Participants are being vaccinated at a number of global clinical sites in advance of each region's RSV season. Novavax previously announced it was awarded a grant of up to $89 million from the Bill & Melinda Gates Foundation to support development of this RSV F Vaccine, which includes Prepare, product licensing efforts and World Health Organization ("WHO") prequalification of our RSV F Vaccine.

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.

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, 2016 and Report on Form 10-Q for the period ended March 31, 2017 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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