

Novavax Announces Positive Topline Data from Phase 2 Older Adult Trial and Provides Path Forward for RSV F Vaccine Programs

July 24, 2017

GAITHERSBURG, Md., July 24, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX) today announced positive topline data from its Phase 2 safety and immunogenicity trial of the RSV F Vaccine in older adults, new preclinical data on its RSV F Vaccine construct, additional findings from the prior Phase 2 and Phase 3 clinical trials in older adults (E201 and E301), and an operational update on the Phase 3 clinical trial of the RSV F Vaccine for infants via maternal immunization, known as Prepare™. The Company anticipates initiating a Phase 2 efficacy trial in older adults in 2018.

Topline data from the Phase 2 older adult safety and immunogenicity trial (E205) demonstrate the benefit of adjuvant formulations and two-dose regimens. The objective of the Phase 2 randomized, observer-blinded, placebo-controlled trial was to assess safety and immunogenicity of one and two-dose regimens of the RSV F Vaccine, with and without aluminum phosphate or Novavax' proprietary Matrix-M™ adjuvant, in 300 older adults. Participants were enrolled and vaccinated outside of the RSV season to best assess immunogenicity of the treatment arms. Immunogenicity outcomes indicate both aluminum phosphate and Matrix-M adjuvants significantly increased the magnitude, duration and quality of the immune response relative to a control of 135 microgram dose of the RSV F antigen alone (the formulation used in the prior Phase 3 older adults efficacy study). Similarly, two-dose regimens significantly increased immune responses and suggests two doses of the RSV F Vaccine with adjuvant may augment durability of the immune response to the vaccine. The data strongly support the inclusion of adjuvanted formulations of the RSV F Vaccine in future older adult trials. All formulations and regimens were safe and well-tolerated.

Recent scientific advances in protein structure imaging and immune measures have led to new insights about the structure and immune responses elicited by the Novavax RSV F antigen. These new findings identify Novavax' vaccine construct as a stable prefusogenic RSV F protein nanoparticle. In addition, new analyses have confirmed and expanded the data, demonstrating that the vaccine induces a repertoire of broadly neutralizing RSV F antibodies in humans that are more potent than palivizumab (Synagis®). These new structural and immunological analyses validate the RSV F Vaccine as a highly immunogenic antigen with the potential to provide protection against RSV disease.

Older adult Phase 3 trial data in a recent post-hoc analysis indicate the RSV F Vaccine was associated with a 61% reduction in hospitalizations due to chronic obstructive pulmonary disease (COPD) exacerbations. Review of the E201 database showed a similar signal supporting this finding. COPD exacerbations represent an unmet medical need and a significant healthcare cost burden. Novavax plans to initiate a Phase 2 efficacy trial in older adults in 2018, that will evaluate COPD exacerbations as a prospective endpoint.

Prepare, the Phase 3 trial of the RSV F Vaccine for infants via maternal immunization, conducted in collaboration with the Bill and Melinda Gates Foundation, continues its momentum into the third global season of enrollment. Prepare's global footprint has grown from 16 sites in five countries in its first global RSV season of enrollment to 80 sites in 11 countries. The clinical trial infrastructure and experience developed over the last two seasons establish the foundation to efficiently enroll and execute this first of its kind global maternal immunization clinical trial.

"Since September, we have worked to confirm that our RSV F Vaccine elicits a broadly neutralizing antibody response. Through our E205 trial, we have demonstrated adjuvant strategies that magnify and enrich the quality of that underlying antibody response. When combined with the COPD data seen in both E301 and E201, we believe protecting individuals from COPD exacerbation presents a very exciting path forward in older adults," said Gregory Glenn, M.D., President of R&D.

"The new data that further characterizes the RSV F Vaccine and the benefit of adjuvants, combined with the hospitalization data in the COPD population, places us in a strong position to partner our RSV program," said Stanley C. Erck, President and CEO. "We also look forward to continued momentum in Prepare trial enrollment and to developing our plans for the next steps in our RSV older adult program over the next 12 months."

Conference Call and Webcast

Date: Monday, July 24, 2017

Time: 4:30 p.m. U.S. Eastern Time (ET)

Dial-in number: (877) 212-6076 (Domestic) or (707) 287-9331 (International)

Passcode: 54820069

Webcast: www.novavax.com, “Investors”/ “Events”

Conference call and webcast replay:

Dates: Starting at 7:30 p.m. ET, July 24, 2017, until 7:30 p.m. ET, October 24, 2017

Dial-in number: (855) 859-2056 (Domestic) or (404) 537-3406 (International)

Passcode: 54820069

Webcast: www.novavax.com, “Investors”/ “Events”, until October 24, 2017

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.

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. Its recombinant nanoparticles and Matrix-M™ adjuvant technology are the foundation for groundbreaking innovation that improves global health through safe and effective vaccines.

- 1 Nair, H., *et al.*, (2010) Lancet. 375:1545 - 1555
- 2 Hall, C.B. *et al.* (2013) Pediatrics; 132(2):E341-348
- 3 Oxford Vaccine Group: <http://www.ovg.ox.ac.uk/rsv>
- 4 Glezen, W.P. *et al.* (1986) Am J Dis Child; 140:543-546
- 5 Glenn, G.M. *et al.* (2016) JID; 213(3):411-12

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