Novavax Investor Relations

Prepare trial is assessing the efficacy of Novavax' RSV F Vaccine for infants via maternal immunization

Enrollment of ~4,600 participants enables initiation of interim efficacy analysis

Topline efficacy data from analysis expected in the first quarter of 2019

GAITHERSBURG, Md., May 07, 2018 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX) today announced it has reached a significant milestone in the Prepare™ Phase 3 clinical trial of its respiratory syncytial virus F protein recombinant nanoparticle vaccine (RSV F Vaccine) for infants via maternal immunization. Enrollment has reached approximately 4,600 participants, of whom, at least 3,000 have received the RSV F Vaccine.

Prepare is a global, pivotal Phase 3 clinical trial of the RSV F Vaccine, in healthy, third trimester pregnant women, which initiated in December 2015. The primary objective of the Prepare trial is to determine the efficacy of maternal immunization with the RSV F Vaccine against medically significant RSV-positive lower respiratory tract infection (LRTI) in infants through a minimum of the first 90 days of life and up through the first six months of life.

"Reaching this enrollment target for the Prepare trial is a significant milestone in the advancement of our RSV F Vaccine franchise," said Stanley C. Erck, President and CEO of Novavax, Inc. "RSV remains an urgent global unmet medical need due to the mortality and morbidity associated with RSV disease in infants and the absence of a vaccine to prevent such disease. We look forward to completing the interim analysis of the Prepare trial as this is the next step on the path to filing marketing applications in the U.S. and Europe for the first-ever RSV vaccine."

Novavax will initiate a prespecified interim efficacy analysis for the Prepare trial after the last infant born to the approximately 4,600 women enrolled in the trial has been followed for six months. Novavax expects to report on the interim data in the first quarter of 2019. Assuming successful interim analysis results, the trial would be concluded without further enrollment and Novavax would file a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) and a marketing authorization application (MAA) with the European Medicines Agency (EMA) by the first quarter of 2020. With Fast Track designation previously granted by the FDA, the Novavax RSV F Vaccine could potentially be eligible for priority review of the BLA, which reduces the standard FDA review by four months.

In December 2017, Novavax conducted an informational analysis related to the prevention of medically significant RSV-positive LRTI in a subset of 1,300 infants from the Prepare trial. This analysis allows Novavax to conclude that the vaccine's potential observed efficacy in this subset group is in the range of 45% and 100%1.

The Prepare trial is supported by a grant of up to $89.1 million from the Bill & Melinda Gates Fund. This grant supports development activities, product licensing efforts and World Health Organization prequalification of the RSV F Vaccine.

About RSV

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.2 In the U.S., RSV is the leading cause of

hospitalization of infants.3 Despite the induction of post-infection immunity, repeat infection and lifelong susceptibility to RSV is common.4 Currently, there is no approved RSV vaccine available.

About the FDA's Fast Track Drug Development Program

The Fast Track Drug Development Program was established under the FDA Modernization Act of 1997. A Fast Track designation is intended for products that treat serious or life-threatening diseases or conditions, and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. Specifically, Fast Track designation facilitates meetings to discuss all aspects of development to support licensure and it provides the opportunity to submit sections of a BLA on a rolling basis as data become available, which permits the FDA to review modules of the BLA as they are received instead of waiting for the entire BLA submission. In addition, priority review (6 month review versus standard 10 month review) is a potential benefit that may be available to Novavax' RSV F vaccine in the future.

About Novavax

Novavax, Inc. is a clinical-stage biotechnology company committed to delivering novel products to prevent infectious diseases. Its RSV and influenza nanoparticle vaccine candidates are Novavax' most advanced clinical programs and are at the forefront of Novavax' efforts to improve global health. For more information, please visit www.novavax.com.

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, 2017 as 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.

Contact:

Investors
Novavax
Erika Trahan
Senior Manager, Investor & Public Relations
ir@novavax.com
240-268-2000

Westwicke Partners
John Woolford
john.woolford@westwicke.com
443-213-0506

Media
Sam Brown
Mike Beyer
mikebeyer@sambrown.com
312-961-2502

1 Assumes 2:1 randomization

2 https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv

3 Leader S. Pediatr Infect Dis J. 2002 Jul;21(7):629-32

4 PLOS. "How immunity to respiratory syncytial virus develops in childhood, deteriorates in adults." ScienceDaily. 21 April 2016. https://www.sciencedaily.com/releases/2016/04/160421145747.htm

---

https://ir.novavax.com/2018-05-07-Novavax-Reaches-Significant-Enrollment-Milestone-in-the-Prepare-TM-Phase-3-Trial-of-its-RSV-F-Vaccine