Novavax Announces Topline Results from Phase 3 PrepareTM Trial of ResVax™ for Prevention of RSV Disease in Infants via Maternal Immunization

February 28, 2019

- *Trial did not meet primary objective of prevention of medically significant RSV LRTI*
- *Trial did show efficacy against secondary objective (RSV LRTI hospitalization); first RSV vaccine to show Phase 3 efficacy*
- *Other pre-specified exploratory endpoints and post-hoc analyses highlight potential to improve global health against RSV disease*
- *Favorable safety and tolerability data*
- *Next step to meet with key regulatory authorities to discuss licensure pathways*
- *Investor conference call today at 8:00 am EST*

GAITHERSBURG, Md., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq: NVAX) today announced results from Prepare™, a global Phase 3 clinical trial using ResVax, an aluminum adjuvanted respiratory syncytial virus (RSV) fusion (F) protein recombinant nanoparticle vaccine. ResVax is being developed to protect infants via maternal immunization against RSV disease. In the Prepare trial, efficacy of ResVax against the primary and two secondary endpoints in per-protocol infants with RSV lower respiratory tract infection (LRTI) through 90 days of life was:

- 39% against medically significant RSV LRTI (97.5%CI, -1% to 64%)
- 44% against RSV LRTI hospitalizations (95%CI, 20% to 62%)
- 48% against RSV LRTI with severe hypoxemia (95%CI, -8% to 75%)

Pre-specified exploratory analyses of these same vaccine efficacy endpoints, which include additional data ascertained from hospitalization records, were:

- 41% against medically significant RSV LRTI (95%CI, 16% to 58%)
- 42% against RSV LRTI hospitalizations (95%CI, 17% to 59%)
- 60% against RSV LRTI with severe hypoxemia (95%CI, 32% to 76%)

“Pneumonia stubbornly remains the leading killer of children under the age of five worldwide. The new maternal vaccine from Novavax shows promise in the fight against RSV, the most common cause of viral pneumonia in young children,” said Dr. Keith Klugman, Director of the Bill & Melinda Gates Foundation’s Pneumonia Program. “We are very encouraged that the Novavax maternal RSV vaccine reduced severe RSV hypoxemia by 60% in the first months of life and believe this vaccine has great potential for reducing RSV-associated deaths in young babies.” The Prepare trial was supported in part by a grant of up to $89.1 million from the Bill & Melinda Gates Foundation.

“Importantly, while this study did not meet the pre-specified success criterion for the primary clinical endpoint of this trial, the data indicate that ResVax protects infants from some of the most serious consequences of RSV, including RSV LRTI hospitalizations and RSV LRTI with severe hypoxemia,” said Stanley C. Erck, President and Chief Executive Officer of Novavax, Inc. “The potential to prevent these most serious outcomes during infants’ most vulnerable months of life could have a profound impact upon the global burden of RSV disease. Our next steps include meeting with U.S. and European regulators to review these data and to discuss the path forward for licensure. We wish to acknowledge and thank the investigators, the Novavax team and the many mothers and their families around the world that participated in this historic trial, bringing the world one step closer to an RSV vaccine.”

Other observations from the Prepare trial:

- Reduction in all-cause LRTI hospitalizations (25%) and all-cause LRTI severe hypoxemia (39%) in infants observed through the first 180 days of life
- Mothers vaccinated from 28 up to < 33 weeks of pregnancy, showed vaccine efficacy rates against RSV LRTI hospitalization of 53% and severe RSV hypoxemia of 70% through the first 90 days of their infants’ lives, compared with 26% and 44% for mothers vaccinated ≥ 33 weeks of pregnancy
- Over 90% of RSV LRTI hospitalizations and RSV LRTI severe hypoxemia in the placebo group occurred in the first 90 days of life
- 99% of vaccinated mothers had measurable antibody responses to the vaccine, with ≥100% transplacental transfer for all antibody types measured
- ResVax appears safe in mothers and their infants through 180 days post-delivery

Novavax intends to present additional results from the Prepare trial at an upcoming medical meeting.

Webcast Conference Call

Novavax will host a webcast/conference call today at 8:00 a.m. EST. The webcast can be accessed via a link on the home page of the Novavax website (novavax.com) or through the “Investor Info”/“Events” tab on the Novavax website. Listeners who wish to ask questions or don’t have internet access can dial-in to the conference call at (877) 212-6076 (domestic) or (707) 287-9331 (international) and use passcode 7679808.

A replay of the webcast will be available on the Novavax website until May 28, 2019 and a replay of the conference call only will be available starting at 11:00 a.m. ET on February 28, 2019 until 11:00 a.m. ET on March 7, 2019. To access the conference call replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and use passcode 7679808.

About RSV in Infants

Globally, RSV (respiratory syncytial virus) is the leading viral cause of severe lower respiratory tract disease in infants and young children.[1] It is the second leading cause of death in children under one year of age.[2] Estimated annual hospitalizations of 1.4 million and an estimated 27,300 in-hospital deaths were due to RSV acute lower respiratory infection in children under six months of age.[3] RSV results in a total global economic burden of $6.2 billion annually.

In the U.S., RSV is the leading cause of hospitalization of infants, with estimated annual hospitalizations of up to 76,000.[4,5,6] While RSV can impact all infants, babies under six months of age are among those at highest risk, as approximately 77% of all first-year RSV infections occur before six months.[7] In the U.S., the total economic burden is $2.7 billion annually.

About ResVax™

ResVax is an RSV fusion (F) protein recombinant nanoparticle vaccine with aluminum phosphate as an adjuvant. It is being developed to protect infants from RSV disease via maternal immunization, which may offer the best method of protection from RSV disease in infants through the first months of life. ResVax is being evaluated in Prepare™, a global Phase 3 clinical trial in 4,636 pregnant women, at least 3,000 of whom received the vaccine, and their infants. Prepare is supported by an $89.1 million grant from the Bill & Melinda Gates Foundation (BMGF).

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that drives improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing urgent global health needs. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is designed to prevent severe lower respiratory tract infection which is the second leading cause of death in children under one year of age worldwide. Novavax is also advancing NanoFlu™, its quadrivalent influenza nanoparticle vaccine, to address key factors that can lead to the poor effectiveness of currently approved flu vaccines.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

Forward-Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of ResVax 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 and the Quarterly Report on Form 10-Q for the period ended September 30, 2018 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.

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