Novavax Provides Updates on the Global Pathways to Licensure for ResVax™

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GAITHERSBURG, Md., June 10, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX) a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced updates on the pursuit of global licensure for ResVax™ following the Prepare™ Phase 3 clinical trial.

- The U.S. Food & Drug Administration (FDA) has recommended that Novavax conduct an additional Phase 3 clinical trial to confirm efficacy against medically significant RSV disease in infants born to mothers vaccinated with ResVax.

- Novavax has recently held meetings with several European national regulatory agencies to solicit input on the Prepare trial and possible pathways to licensure in Europe. The next step will be to seek formal scientific advice this fall from the European Medicines Authority (EMA), the agency responsible for licensing vaccines for the European Union.

- Bill & Melinda Gates Foundation, which provided an $89.1 million grant in support of the Prepare trial, continues to work with Novavax on a path to introduce ResVax to low and middle income countries.

“We remain encouraged by the ResVax efficacy observed with more severe RSV disease and hospitalizations. These data, coupled with the favorable safety profile of ResVax, demonstrate a positive public health benefit that warrants continued development to address the global unmet medical need in preventing serious RSV disease,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “We aim to identify pathways to licensure that allow pregnant women globally to be vaccinated, so that their babies are protected from the serious short- and long-term consequences of RSV disease.”

AboutRSV in Infants

Globally, RSV (respiratory syncytial virus) is the leading viral cause of severe lower respiratory tract disease in infants and young children. It is the second leading cause of death in children under one year of age. 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. 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. 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. In the U.S., the total economic burden is $2.7 billion annually.

AboutResVax™

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. 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. 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.

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 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, 2018, and Quarterly Report on Form 10-Q for the period ended March 31, 2019, 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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