U.S. FDA Grants Fast Track Designation to Novavax' RSV F Vaccine for Older Adults

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GAITHERSBURG, Md., May 25, 2016 (GLOBE NEWSWIRE) -- Novavax, Inc. (Nasdaq:NVAX), a clinical-stage vaccine company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to Novavax' RSV F-Protein nanoparticle vaccine candidate (RSV F Vaccine) for the protection of older adults (60 years of age and older).

"The FDA's granting of Fast Track designation for our RSV F Vaccine in older adults underscores its recognition of RSV as a significant unmet medical need in this large population segment," said Stanley C. Erck, President and CEO. "This joins our prior Fast Track designation for the RSV F Vaccine for the protection of infants via maternal immunization. Fast Track designation could allow for an expedited timeline to licensure, accelerating the access to this vaccine for the most vulnerable populations."

It is estimated that 16,000 older adults die of RSV infection or its complications annually in the U.S., with approximately 900,000 medical interventions for a total economic burden of disease of approximately $28 billion. We fully enrolled the Resolve™ Phase 3 clinical trial of our RSV F Vaccine in 11,850 older adults in December 2015. The primary efficacy objective of the Resolve trial is the prevention of moderate-severe RSV-associated lower respiratory tract disease, as defined by the presence of multiple lower respiratory tract symptoms.

Gregory M. Glenn, M.D., President, Research and Development, said, "RSV is a widespread disease that causes infections of the lower respiratory tract. While RSV affects individuals of all ages, it acutely impacts older adults and infants. Our Phase 3 Resolve trial will examine the efficacy of our RSV F Vaccine and further define the burden of disease in older adults. We look forward to announcing data from the trial in the third quarter of this year."

The Fast Track Drug Development Program was established under the FDA Modernization Act of 1997 and 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 provides the opportunity to submit sections of a Biologics License Application (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. Finally, 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. (Nasdaq:NVAX) is a clinical-stage vaccine 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.

References

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