Novavax Initiates Phase 1/2 Trial of NanoFlu™ Vaccine in Older Adults

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GAITHERSBURG, Md., Sept. 19, 2017 (GLOBE NEWSWIRE) -- Novavax, Inc., (Nasdaq:NVAX) today announced the enrollment of the first participant in a Phase 1/2 clinical trial of its nanoparticle influenza vaccine candidate including its proprietary Matrix-M™ adjuvant (NanoFlu™) in older adults.

The trial is a randomized, observer-blinded, active comparator-controlled trial in approximately 330 healthy older adults. The primary objective of the trial is to assess the safety and immunogenicity of two concentrations (15 µg or 60 µg) of NanoFlu compared to a licensed influenza vaccine, Fluzone® High-Dose (Fluzone HD).

“The trial is designed to identify an immune response, characterized by hemagglutination-inhibiting (HAI) and neutralizing antibodies, that is similar to or better than Fluzone HD,” said Gregory Glenn, M.D., President of Research and Development. “We will evaluate immunogenicity using HAI titers, which are the industry standard and an established surrogate marker of protection. Data from this trial may provide the basis to request accelerated approval for initial licensure of our NanoFlu vaccine.

"Our recent preclinical data further indicate NanoFlu elicits improved protective responses against drifted strains, which could be a key differentiating factor of the vaccine. Current influenza vaccine protection is typically limited to strain-specific immune responses. Strain mismatch or antigenic drift between seasonal vaccines and circulating influenza strains can lead to reduced protection.”

“The data described in our recent *Vaccine* publication provided strong rationale for advancing our NanoFlu program into the clinic,” said Stanley C. Erck, President and CEO. “Seasonal influenza remains a significant threat to older adults, with nearly three million infections and over 250,000 hospitalizations annually1. Our goal is to deliver a differentiated flu vaccine to the greater than $3 billion global seasonal influenza commercial market2 and we look forward to delivering clinical data from this trial by the end of the year.”

About Accelerated Approval

Accelerated approval may be granted for certain biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments.

Such an approval will be based on adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit. More information on accelerated approval can be found here: https://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/vaccines/ucm074794.htm

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. 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

1. Average of 3 past seasons, 2010-2013; includes vaccine averted cases. C. Reed et al. Estimating Influenza Disease Burden from Population-Based Surveillance Data in the United States. PLOS One. 2015, DOI:10.1371/journal.pone.0118369

2. PharmaPoint Seasonal Influenza Vaccines Global Drug Forecast and Market Analysis to 2025, October 2016

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, 2016 and the Report on Form 10-Q for the period ended June 30, 2017, both 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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