Novavax Initiates Phase 2 Clinical Trial of NanoFlu™ in Older Adults

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GAITHERSBURG, Md., Sept. 25, 2018 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX) today announced the initiation of a Phase 2 dose and formulation confirmation clinical trial in older adults of NanoFlu, its nanoparticle seasonal influenza vaccine candidate.

“Initiating this Phase 2 clinical trial of NanoFlu is an important milestone for Novavax,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “With top-line results expected in the first quarter of 2019, we plan to discuss these data with the FDA at an ‘End of Phase 2’ meeting and to agree on the appropriate Phase 3 clinical trial design to support licensure via accelerated approval. We continue to believe NanoFlu is a differentiated flu vaccine capable of better addressing a global public health problem, and can thereby capture a significant share of the multi-billion-dollar seasonal influenza vaccine market.”

This randomized, observer-blinded, active-controlled trial will assess the safety and tolerability of different doses and formulations of NanoFlu, both adjuvanted with its proprietary Matrix-M™ adjuvant and unadjuvanted, as compared to two U.S.-licensed comparators. The trial will enroll approximately 1,375 healthy older adults across clinical sites in the U.S. and is designed to select a dose/formulation of NanoFlu that Novavax will bring forward into its future pivotal Phase 3 immunogenicity clinical trial.

“The dual problems of antigenic drift and antigenic changes resulting from egg-based vaccine production have, in recent years, resulted in generally poor influenza vaccine effectiveness with potentially severe medical consequences, particularly in older adults. A substantially improved seasonal influenza vaccine is a widely recognized, high-priority unmet medical need,” said Gregory Glenn, M.D., President of Research and Development of Novavax. “We look forward to evaluating NanoFlu in this trial, and subsequently moving into a pivotal Phase 3 clinical trial in the second half of 2019 with the goal of introducing a more effective flu vaccine option.”

More information about the newly initiated trial can be found at www.clinicaltrials.gov.

Previously Reported Phase 1/2 Clinical Trial Results with NanoFlu

In February 2018, Novavax reported positive top-line results from its Phase 1/2 clinical trial in older adults of a NanoFlu trivalent formulation. As compared to Fluzone HD, NanoFlu demonstrated an acceptable safety profile and short-term reactogenicity. With regard to immunogenicity, NanoFlu induced:

- Hemagglutination inhibition (HAI) immune responses that were 28% to 64% greater against the homologous and four generations of drifted wild-type A(H3N2) influenza strains;
- Higher HAI responses against the homologous A(H1N1) strain and comparable responses against the homologous B/Brisbane strain; and
- Strong neutralizing antibody responses that correlate with HAI results.

About Influenza

Influenza is a world-wide infectious disease that causes illness in humans with symptoms ranging from mild to life-threatening or even death. Serious illness occurs not only in susceptible populations such as infants, young children and older adults, but also in the general population largely because of infection by continuously evolving strains of influenza which can evade the existing protective antibodies in humans. An estimated one million deaths globally each year are attributed to influenza.1 Current estimates for seasonal influenza vaccine growth in the top seven markets (U.S., Japan, France, Germany, Italy, Spain and UK), show a potential increase from approximately $3.2 billion in 2015 to $5.3 billion by 2025.2

1 Resolution of the World Health Assembly (2003) WHA56.19.28

2 Influenza Vaccines Forecasts. Datamonitor (2013)

About NanoFlu™ and Matrix-M™

NanoFlu is a recombinant hemagglutinin (HA) protein nanoparticle influenza vaccine produced by Novavax in its SF9 insect cell baculovirus system. NanoFlu uses HA amino acid protein sequences that are the same as the recommended wild-type circulating virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M adjuvant, which has demonstrated a potent and well-tolerated effect by stimulating the entry of antigen-presenting cells into the injection site and enhancing antigen presentation in local lymph nodes.

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 to predict clinical benefit. For seasonal influenza vaccines, the hemagglutination inhibition (HAI) antibody response may be an acceptable surrogate marker of activity that is reasonably likely to predict clinical benefit. To be considered for accelerated approval, a biologics license application for a new seasonal influenza vaccine should include results from one or more well-controlled studies designed to meet immunogenicity endpoints and a commitment to conduct confirmatory post-marketing studies of clinical effectiveness in preventing influenza.

About Novavax

Novavax, Inc. (Nasdaq:NVAX) is a late-stage biotechnology company that drives improved health globally through the discovery and development of innovative vaccines to prevent serious respiratory diseases. ResVax, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is poised to help prevent 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, 2017 and the Quarterly Report on Form 10-Q for the period ended June 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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