Novavax Announces Positive Phase 2 NanoFlu Results in Older Adults

January 3, 2019

GAITHERSBURG, Md., Jan. 03, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX) today announced top-line results of its Phase 2 clinical trial of NanoFlu™. The trial compared the safety and immune responses of various quadrivalent formulations of NanoFlu, with or without Novavax' Matrix-M™ adjuvant, with two U.S.-licensed influenza vaccines in 1,375 healthy adults 65 years of age and older.

Key findings of the Phase 2 clinical trial:

- All formulations of NanoFlu were well-tolerated and elicited vigorous immune responses to the four strains included in the vaccine.
- Matrix-M adjuvant resulted in significant enhancement of immune responses when compared to the unadjuvanted formulation.
- NanoFlu is a differentiated flu vaccine, as evidenced by significantly superior hemagglutination inhibition (HAI) antibody responses against wild-type A(H3N2) viruses, including drifted strains, when compared to Fluzone High-Dose, the leading flu vaccine in older adults.
    - 45% increase against vaccine-homologous virus, A/Singapore ($p<0.001$)
    - 22% increase against a historic drifted virus, A/Switzerland ($p=0.014$)
    - 42% increase against a forward drifted virus, A/Wisconsin ($p<0.001$)
- NanoFlu formulation identified for the Phase 3 clinical trial and commercialization.

"The superior immunogenicity against wild-type H3N2 viruses holds promise that NanoFlu will more effectively address the mismatch between circulating viruses and the strains included in most commercial vaccines due to genetic drift and vaccine virus egg adaptation," said Gregory Glenn, M.D., President of Research and Development of Novavax. "Older adults experienced the brunt of the serious health consequences of this mismatch, with H3N2 driving the majority of influenza hospitalizations and death during 2017-2018, the worst flu season in four decades. Over the past several years, influenza vaccine effectiveness has been suboptimal in this population, and there is broad agreement that better vaccines are needed. These confirmatory data from the second clinical trial of NanoFlu further justify continued rapid development of an improved vaccine."

As Novavax previously announced, the U.S. Food and Drug Administration (FDA) acknowledged that the accelerated approval pathway may be available for NanoFlu, which could allow for licensure of NanoFlu in a shorter timeframe. Novavax will again meet with the FDA in the first half of 2019 to discuss the Phase 2 clinical trial data, the proposed Phase 3 trial design, and the use of accelerated approval for licensure.

"The Phase 2 clinical trial results with NanoFlu demonstrate the potential impact our vaccine can make in preventing serious disease caused by influenza in older adults, a high-risk population that has proven difficult to protect in recent years," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "Our goal remains to advance to the market an improved vaccine that addresses the serious global public health threat that exists for older adults, and ultimately to make NanoFlu available to all populations."

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 2021.2

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 protein amino acid sequences that are the same as the recommended wild-type

virus HA sequences. NanoFlu contains Novavax' patented saponin-based Matrix-M adjuvant, which is potent, well-tolerated and stimulates both high quality and durable antibody responses as well as multifunctional CD4 and CD8 T-cell responses.

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 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, 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, 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.

Contacts:

Investors
Novavax, Inc.
Erika Trahan
Senior Manager, Investor & Public Relations
ir@novavax.com
240-268-2000

Westwicke Partners
John Woolford
john.woolford@westwicke.com
443-213-0506

Media
Sam Brown
Andrea Cohen
andreacohen@sambrown.com
917-209-7163

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

2 Influenza Vaccines Forecasts. Datamonitor (2013)