Novavax Confirms Accelerated Approval Pathway Available for Licensure of NanoFlu™

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GAITHERSBURG, Md., June 27, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, today announced it will utilize the accelerated approval pathway for licensure for NanoFlu™, its nanoparticle seasonal influenza vaccine candidate. The U.S. Food and Drug Administration (FDA) acknowledged in a recent letter that the accelerated approval pathway is available to Novavax for its NanoFlu vaccine. Novavax expects to initiate its pivotal Phase 3 clinical trial by the fall of 2019 with top-line clinical data expected in the first quarter of 2020. These immunogenicity data are expected to support a U.S. biologics license application (BLA).

Novavax will conduct an End-of-Phase 2 meeting with the FDA in the third quarter of 2019 to discuss the proposed Phase 3 clinical trial design and other topics that will support the future BLA. The accelerated approval pathway enables Novavax to conduct a non-inferiority immunogenicity clinical trial against a licensed quadrivalent comparator, with a commitment to confirm efficacy post-licensure.

“NanoFlu’s encouraging results observed in prior clinical trials, which demonstrated improved immune responses against licensed comparators, provide us confidence in the future success of the Phase 3 clinical trial,” said Gregory M. Glenn, M.D., President of Research and Development of Novavax. “The accelerated approval pathway allows us to potentially obtain U.S. licensure more expeditiously, and ideally, deliver a greatly needed improved flu vaccine, which could reduce the tremendous medical and economic burden of influenza.”

“The accelerated approval pathway, combined with the strategic partnership we announced today with Catalent Biologics, allow us to efficiently and cost effectively complete the clinical development of NanoFlu through BLA and licensure,” said Stanley C. Erck, President and Chief Executive Officer of Novavax. “The Catalent deal provides an $18 million cash infusion and flexible manufacturing capacity, supported by the experienced professionals transferred from Novavax to Catalent.”

Previously Reported Phase 2 Clinical Trial Results with NanoFlu

Earlier this year, Novavax released positive top-line results of its Phase 2 clinical trial of NanoFlu in older adults. The data showed NanoFlu induced improved immune responses when compared to the best-selling flu vaccine in the older adult market. The Phase 2 clinical trial compared the safety and immunogenicity of various quadrivalent formulations of NanoFlu with or without our Matrix-M adjuvant with two licensed influenza vaccines in 1,375 healthy older adults. All formulations of NanoFlu were well tolerated and elicited vigorous immune responses to the four strains included in the vaccine. NanoFlu also demonstrated significantly improved hemagglutinin inhibition (HAI) antibody responses against wild-type H3N2 viruses, including drifted strains when compared to Fluzone High-Dose, the leading flu vaccine in older adults.

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. 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.

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, 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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