Novavax Announces Initiation of Ebola Vaccine Phase 1 Clinical Trial Supported by Non-Human Primate Challenge Data and Documented Rapid Manufacturing Capabilities

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GAITHERSBURG, Md., Feb. 12, 2015 (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 enrollment has begun in a Phase 1 clinical trial of its Ebola virus glycoprotein (GP) recombinant nanoparticle vaccine candidate adjuvanted with Matrix-M™ (Ebola GP Vaccine) in healthy subjects. Novavax initiated the development of its Ebola GP Vaccine shortly after the publication of the genetic sequence of the 2014 Ebola Makona strain (previously referred to as the 2014 Ebola Guinea strain), which is responsible for the current Ebola epidemic in West Africa. In an expedited time-frame, from the publication of the Makona sequence in September 2014, Novavax has developed the vaccine, scaled-up GMP manufacturing, delivered positive results from multiple relevant animal models, including a non-human primate challenge study, and today initiated a Phase 1 clinical trial.

Stanley C. Erck, President and CEO said, "In less than 5 months, Novavax has validated its Ebola GP Vaccine with compelling animal data, including complete protection against a lethal Ebola challenge in non-human primates, leading to the initiation of this Phase 1 clinical trial. With our ongoing efforts to develop our vaccine against the A/H7N9 influenza strain, this is the second novel strain of an emerging virus with pandemic potential, for which Novavax has been able to construct and produce a vaccine, subsequently demonstrate immunogenicity in one or more relevant animal models, and initiate a clinical trial. Additionally, like our other recombinant vaccine candidates, our Ebola GP Vaccine can be rapidly scaled-up to produce millions of doses. Creating new vaccines in such an expeditious manner exemplifies Novavax' ability to respond to a variety of global infectious disease threats."

The Ebola GP Vaccine clinical trial, which is being conducted in Australia, is a randomized, observer-blinded, dose-ranging Phase 1 study to evaluate the safety and immunogenicity of the vaccine, with and without Matrix-M adjuvant, in 230 healthy adult subjects between 18 and 50 years of age. Each subject will receive two intramuscular injections, one each on study days 0 and 21. In addition to the trial's primary goal of evaluating safety in this population, the study will also evaluate immunogenicity as measured by concentrations of serum IgG antibodies to the Ebola Makona strain glycoprotein. Secondary study endpoints include epitope-specific immune responses to the Ebola GP antigen as measured by serum titers in a competitive ELISA assay using known-neutralizing monoclonal antibodies, as well as serum Ebola virus neutralizing antibody reciprocal titers.

The Phase 1 clinical trial initiation is supported by significant immunogenicity and efficacy data demonstrating that the Ebola GP Vaccine is the first subunit Ebola GP-based vaccine to provide protection in non-human primates. Non-human primates received two injections of a 5µg dose of the Ebola GP Vaccine with the Matrix-M adjuvant, and were challenged with a lethal dose of Ebola virus. As expected, the challenge was lethal for the control animal whereas, in sharp contrast, 100% of the immunized animals were protected. Additionally, the Ebola GP Vaccine induced Ebola Makona strain GP antibody titers of 106 (ELISA EC90) after two doses and 104, after a single dose, both results well above the range reported to provide protection in non-human primate models and reported in recent Ebola Phase 1 clinical trials.

"The strong immune responses observed in our animal immunogenicity models and the protection observed in the non-human primate challenge models, confirm that our Ebola GP Vaccine is an important candidate for consideration. The use of a sequence reflecting the current circulating Makona strain of Ebola virus, along with the observed dose-sparing and enhanced antibody quality by the addition of our Matrix-M adjuvant, compelled the company to move to clinical testing," said Gregory Glenn, M.D., Senior Vice President, Research and Development. "Because of the unprecedented ongoing Ebola epidemic, and with more than 20 historical outbreaks of Ebola virus, Novavax believes there is an urgent need for a safe and effective licensed vaccine. Combined with the very promising recent data on our Ebola GP Vaccine, there is a clear rationale for moving this program forward."

The rapid progression to a Phase I clinical trial is further supported by Novavax' GMP manufacturing process, as documented in the February 10, 2015 online publication of *BioProcessing Journal* (available at novavax.com under "Publications & Presentations"). The article titled "Rapid Manufacture and Release of a GMP Batch of Zaire Ebolavirus Glycoprotein Vaccine Made Using Recombinant Baculovirus-Sf9 Insect Cell Culture Technology" details Novavax'

manufacturing development process from genetic engineering of the 2014 Makona strain gene sequence through master seed preparation, qualification of analytical methods, and ultimately GMP manufacture with product release three months after project initiation.

About Ebola

Ebola virus, formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans. Five strains of Ebola virus have been identified, the most recent of which, the 2014 Makona strain, is associated with a case fatality rate of between 50 and 90%. There are currently no licensed immunological or therapeutic treatments proven to neutralize the virus, although a range of blood, immunological vaccine and drug therapies are under development.

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.

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, 2013, 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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