



Altimmune Submits Investigational New Drug Application for NasoVAX in Preparation for Phase 2 Trial

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60 volunteers to be enrolled

Data expected in the first quarter of 2018

GAITHERSBURG, Md., Aug. 21, 2017 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq:ALT), a clinical-stage immunotherapeutics company, today announced the Company has submitted an Investigational New Drug (IND) application to the U.S Food and Drug Administration (FDA) for NasoVAX, the Company's intranasally administered recombinant flu vaccine. NasoVAX uses an adenovector to achieve expression of the influenza antigen in the target cell, thereby potentially stimulating a broader and more rapid immune response than traditional flu vaccines. Previous versions of NasoVAX evaluated in two Phase 1 studies under earlier INDs were immunogenic and well tolerated.

"Our IND filing is an important milestone for our development program that we hope will eventually lead to the availability of NasoVAX for patients in the US who are at risk for developing the flu," said Dr. Sybil Tasker, Chief Medical Officer at Altimmune. "The risks from flu and flu-related complications are well-known, particularly in populations with weakened immune systems. Current vaccines leave significant room for improvement, and according to the CDC, have about a 40% efficacy rate over the ten year period 2005-2015. In pre-clinical studies, NasoVAX generated cross protection against divergent strains. If this is confirmed in the clinic, it will be a very promising sign that the vaccine has the potential to be more efficacious than currently licensed vaccines."

The Phase 2 NasoVAX study will evaluate the safety and immunogenicity of a single administration of an intranasal dose at three dose levels of a single flu strain. The Company will evaluate the antibody response to both matched and divergent strains, along with cellular and mucosal immunity. The study will enroll 60 volunteers, who will receive a single intranasal dose of vaccine or placebo. Data is expected sometime in the first quarter of 2018.

Following this study, Altimmune intends to confirm the dose in a larger trial evaluating immunogenicity of a quadrivalent vaccine formulation and may also conduct a challenge study to confirm the protection within days of vaccination demonstrated in preclinical studies. Both of these studies could commence as soon as the second half 2018.

About NasoVAX

NasoVAX, Altimmune's next generation rapid response influenza vaccine candidate, uses Altimmune's RespirVec technology to mobilize multiple components of the immune system, with the aim to rapidly establish immunity against influenza infections. NasoVAX uses an easy and painless intranasal administration, which Altimmune expects will activate mucosal and innate immunities, and may provide a first line of defense against influenza infections while the antibody response is being developed. Protection against a lethal challenge of influenza has been demonstrated in preclinical models in days instead of weeks and against broad and divergent strains of influenza. NasoVAX is produced in cell culture instead of chicken eggs. This is a more efficient, scalable process where product can be produced in less than half the time as traditional influenza vaccines.

About Altimmune

Altimmune is a clinical-stage immunotherapeutics company focused on the development of products to stimulate robust and durable immune responses for the prevention and treatment of disease and on the development of two next-generation anthrax vaccines that are intended to improve protection and safety while having favorable dosage and storage requirements compared to other anthrax vaccines. The company has two proprietary platform technologies, RespirVec and Densigen, each of which has been shown to activate the immune system in distinctly different ways than traditional vaccines.

Forward-Looking Statement

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the prospects for commercializing or selling any product or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Altimmune, Inc. (the "Company") may identify forward-looking statements. The Company cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including risks relating to: realizing the benefits of the merger between Altimmune, Inc. and PharmAthene, Inc.; clinical trials and the commercialization of proposed product candidates (such as marketing, regulatory, product liability, supply, competition, dependence on third parties and other risks); the regulatory approval process; dependence on intellectual property; the Company's BARDA contract and other government programs, reimbursement and regulation; and the lack of financial resources and access to capital to fund proposed operations. Further information on the factors and risks that could affect the Company's business, financial conditions and results of operations are contained in the Company's filings with the U.S. Securities and Exchange Commission, including under the heading "Risk Factors" in the Form 10-K filed March 14, 2017, Form 10-Q filed August 11, 2017 and in the Form 8-K filed on August 17, 2017, which are available at www.sec.gov.

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