



Altimmune Announces Positive Data From Its Phase 2a Study of NasoVAX Intranasal Influenza Vaccine and Provides an Update on Its Phase 1b Study of HepTcell Targeted Immunotherapy in Chronic Hepatitis B Infection

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NasoVAX intranasal influenza vaccine demonstrated strong cellular immune response and 100% seroprotection

HepTcell vaccine was well tolerated but T-cell immunogenicity results were inconclusive

GAITHERSBURG, Md., March 27, 2018 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq:ALT), a clinical-stage immunotherapeutics company, today announced positive data from its Phase 2a study of NasoVAX intranasal influenza vaccine and provided an update on its Phase 1b study of HepTcell targeted immunotherapy in chronic hepatitis B infection. Results from the Phase 2a study of NasoVAX™ intranasal flu vaccine in 60 healthy individuals showed 100% seroprotection in the mid- and high-dose groups. Results from the Phase 1b study of HepTcell in hepatitis B infection showed that HepTcell was well tolerated at all doses tested, while the unblinded T-cell immunogenicity results were inconclusive.

"We strongly believe that NasoVAX could become an important alternative vaccine for the prevention of both seasonal flu epidemics and broader flu pandemics," said William J. Enright, president and chief executive officer of Altimmune. "The Phase 2a data are highly encouraging, especially since antibody responses like this -- with 100% seroprotection -- are unique and have not been achieved with any other needle-free vaccines, including FluMist®. In addition, the excellent tolerability attained, even at the highest dose, has us excited to complete development of the quadrivalent formulation with the intention to initiate a Phase 2 study in early 2019."

Enright continued, "As for our HepTcell study, we are disappointed by the inconclusive results, but are continuing to evaluate the data. Subjects will be followed for the full 6 months, as per the study protocol. We are evaluating our next steps and will provide an update as we better understand the results."

About the Phase 2a NasoVAX Trial

The randomized Phase 2a study compared a monovalent NasoVAX vaccine against an H1 strain of influenza (A/California/04/2009) to intranasal placebo in 60 healthy adults across three dose ranges (10^9 vp, 10^{10} vp and 10^{11} vp). In a parallel open label study, a similar population of 20 subjects were given Fluzone®, a licensed injectable influenza vaccine. Blood samples from both studies were tested and the lab was blinded to treatment assignment.

Data demonstrated 100% seroprotection for the middle and high dose groups of NasoVAX as compared to 95% seroprotection with Fluzone. Mean antibody titers against influenza, as measured by the hemagglutinin inhibition and microneutralization assays increased up to 4.3-fold, indicating that high levels of immunity were induced in this study population, even with prior immunity to the influenza strain (A/California/04/2009). The serum antibody responses were also robust and dose dependent. Seroconversion rates and breadth of antibody response were comparable to Fluzone for the highest NasoVAX dose tested. Additionally, compared to Fluzone, the highest dose of NasoVAX induced over nearly 6-fold higher levels of influenza cellular immunity, an important element in defending against influenza disease. All doses of NasoVAX were well tolerated and there were no cases of fever, serious adverse events (SAEs) or discontinuations. Rates of local and systemic side effects did not increase with dose and were not statistically different than placebo. Subjects will continue to be followed through six months after vaccination to assess durability of antibody response. The company plans to submit the full data, which will also include mucosal antibody and serum antibody levels at other time points, for presentation at an appropriate scientific conference later this year.

About the Phase 1b HepTcell Trial

The Phase 1b study was a randomized, dose-escalation trial in 60 subjects with chronic HBV infection. Subjects enrolled in the trial were well controlled on currently licensed antiviral therapy and were randomized into one of three groups: high and low dose HepTcell peptides, with and without adjuvant (IC31), adjuvant alone, and placebo. All subjects received 3 injections 4 weeks apart and were followed for 4 weeks after the 3rd injection. Subjects will continue to be followed for 6 months after the 3rd injection, as per the study protocol.

The data showed that, overall, HepTcell was well tolerated. There was one unrelated SAE (infectious colitis). Subjects were monitored carefully for evidence of liver flare, which was not observed in any of the subjects. Additionally, there were no autoimmune events noted. Results showed mild to moderate injection site reactions in < 20% of subjects in every group except the high dose with IC31 (36%). There were no severe injection site reactions.

Previous review of the blinded data by cohort indicated evidence of increased cellular immune responses in cohort 2 compared with cohort 1, both of which included control patients; however, in the unblinded analysis, the treated subjects were not appreciably different than placebo controls.

The company is continuing to evaluate the data and will provide further updates once it has completed its thorough review.

About NasoVAX

NasoVAX is a novel type of influenza vaccine that uses an adenoviral vector delivery vehicle and intranasal administration to deliver the vaccine to the respiratory tract where influenza infection occurs. Besides its easier intranasal delivery method, NasoVAX has many advantages over current vaccines. First, NasoVAX is a recombinant vaccine that is produced using cell culture, compared to traditional vaccines that use chicken eggs. As described in the [National Institute of Allergy and Infectious Disease \(NIAID\) Strategic Plan for a Universal Influenza Vaccine \(www.NIAID.nih.gov\)](http://www.NIAID.nih.gov), chicken eggs for vaccine production may allow for additional mutations during manufacture, which could compromise vaccine effectiveness. Additionally, NasoVAX is adjuvanted by its own adenoviral vector; no additional adjuvants are used. Adjuvants have been shown to enhance the immune response against an immunogen and provide dose-sparing benefits. Finally, NasoVAX stimulates cellular immunity, a T cell response, and a T cell mediated influenza vaccine may offer another pathway to achieve broad protection, making it an important part of a broad flu vaccine strategy.

About HepTcell

HepTcell is an immunotherapy product candidate directed against multiple hepatitis B virus (HBV) genotypes. HepTcell is a completely synthetic peptide composed of nine Densigen peptides that encode a high density of CD4+ and CD8+ T cell epitopes selected to broaden the HLA class reactivity of the product.

About Altimune

Altimune 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, including NasoVAX, a Phase 2 seasonal influenza vaccine candidate, and HepTcell, a Phase 1 immunotherapeutic candidate for the potential cure of chronic hepatitis B. The company also has two United States government funded, next-generation anthrax vaccine candidates that are intended to improve protection and safety while having favorable dosage and storage requirements compared to other anthrax vaccines. Additional information may be accessed at www.altimmune.com.

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, and the Company's leadership, 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 Altimune, 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 Altimune, 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, Forms 10-Q filed August 14, 2017 and November 9, 2017, and in a Form 8-K filed August 17, 2017, which are available at www.sec.gov.

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