



## Altimune Announces Clinical Program Updates and Plans for Pipeline Expansion

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GAITHERSBURG, Md., Dec. 13, 2018 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage immunotherapeutics company, today announced updates to its clinical programs and plans to further expand its pipeline.

### **NasoVAX**

As previously announced in September 2018, a monovalent version of NasoVAX, Altimune's intranasally administered influenza vaccine candidate, elicited statistically significant mucosal antibody responses not seen with the commercially available injectable vaccine Fluzone®, and a nearly 6-fold higher median cellular immune response compared to Fluzone. In addition, the NasoVAX hemagglutination inhibition (HAI) antibody response was stable over the six-month follow-up period, while antibody titers elicited by Fluzone fell over 50% over the same period. The Company is now conducting an extension study for previous Phase 2a study participants to measure further durability of HAI responses one year after vaccination and will be evaluating other clinical measures of NasoVAX immunogenicity.

The US National Institutes of Health's recently published strategic plan for improved influenza vaccines specifically highlighted durability of immune response and insufficient mucosal and cellular immunity as weaknesses of currently approved influenza vaccines. Based on positive clinical results in all of these areas, Altimune is advancing the manufacture of a multivalent formulation and intends to initiate additional Phase 2 studies once manufacturing is complete.

### **NasoShield**

As announced in August 2018, in Part A of the initial Phase 1 evaluation of NasoShield, Altimune's next-generation intranasally administered anthrax vaccine candidate, a single dose was well-tolerated but did not produce an appreciable toxin neutralizing antibody (TNA) response. This was unexpected given the compelling nonclinical data obtained previously in two well-established animal models for anthrax.

Part B of the NasoShield study evaluated two intranasal doses of NasoShield at the highest previous dose tested, given 21 days apart. The two-dose regimen was also well-tolerated and provided a boost in total antibody against the antigen, but overall the immune response was very limited. Considering the single dose and two-dose clinical data, together with the disparate results from the nonclinical studies, the Company believes that there may be either a manufacturing or an administration-related issue with the vaccine used in this Phase 1 study. We are aggressively investigating all potential causes that may have contributed to these results. The results of these investigations are expected in the first half of 2019.

### **HepTcell**

In March 2018, the Company reported interim data from its first-in-human evaluation of HepTcell, Altimune's immunotherapeutic synthetic peptide vaccine candidate, in patients with chronic hepatitis B infection. The study evaluated two-dose levels of Altimune's proprietary synthetic peptides with and without IC31® adjuvant, a TLR-9 agonist. Both doses showed excellent tolerability and met the primary endpoint of safety. Although there was evidence of dose response in cellular immunity with the HepTcell containing arms, the limited interim analysis showed high median levels of HBV-specific T cell activation in the placebo group as well, making the data difficult to interpret.

The Company has completed the planned final analysis, that also included individual subject changes from baseline, and are very encouraged to note that the two adjuvanted HepTcell arms had markedly greater increases in T cell immunity over baseline than the placebo group. In addition, post-hoc analyses have demonstrated higher baseline-adjusted immune response levels and a higher responder rate in the two adjuvanted HepTcell dose groups compared to placebo.

Altimune believes that these new analyses provide clear evidence of HBV-specific immune activation by HepTcell and plans to advance the program into Phase 2 development. These data are being submitted for presentation at a scientific meeting and peer-reviewed publication and more details will be presented at that time.

### **Additional Immunotherapeutic Opportunities**

Altimune intends to pursue additional complementary indications for its differentiated synthetic immunotherapeutic peptide technology. The Company is expanding its preclinical immuno-oncology programs including Oncosyn and Adjusyn. Oncosyn is a T cell immunotherapeutic approach based on the Company's synthetic peptide technology that has been successfully combined with anti-PD1 checkpoint inhibitors and other immunotherapeutic products to provide a significant survival advantage following tumor challenge in mouse models. Adjusyn is a flexible, localized adjuvant technology that has the potential to safely improve immune response in a variety of settings including the immuno-oncology space.

Along with developing product candidates based on our synthetic immunotherapeutic peptide technology platform, the Company plans to explore opportunities to either acquire products or partner in novel immunotherapy indications to further expand our pipeline.

### **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. NasoVAX, our influenza vaccine candidate, has unique characteristics that stimulate multiple arms of the immune system and offer the potential to stop infection and the spread of flu, while being easier to administer through an intranasal spray. NasoShield is a next-generation intranasal anthrax vaccine candidate that is intended to improve protection and safety while having favorable dosage and storage properties compared to other anthrax vaccines. HepTcell is a synthetic peptide immunotherapeutic candidate designed to break immune tolerance in chronic Hepatitis B infection. By leveraging the complementary attributes of our proprietary technology platforms, Altimune is able to design and develop immunotherapeutic products tailored to address a wide range of disease indications including both acute and chronic infections and cancer. Additional information about Altimune is available at [www.altimmune.com](http://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, 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: the terms of the Company's Series B preferred stock offering and related warrants; our lack of financial resources and access to capital; realizing the benefits of the merger between Altimune, Inc. and PharmAthene, Inc.; our ability to utilize the benefits of our tax assets and the results of a tax examination initiated by the IRS; 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. 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 Company's annual reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, which are available at [www.sec.gov](http://www.sec.gov).

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