Altimmune Completes Enrollment in Phase 1b Clinical Trial of NasoShield™, a Single Dose Intranasal Anthrax Vaccine Candidate

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GAITHERSBURG, Md., Aug. 07, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has completed enrollment in its Phase 1b clinical trial of NasoShield, a single dose intranasal anthrax vaccine candidate. With this milestone, the data readout for the Day 28 immunogenicity endpoint remains on target for Q4 2020.

The clinical trial has enrolled 42 evaluable healthy subjects to receive intranasally administered NasoShield or placebo and be followed for 6 months following dosing. The primary immunogenicity readouts are the serum antibody response to protective antigen and toxin-neutralizing antibody titer 28 and 56 days after dosing. As with Altimmune's other vaccine programs, stimulation of a mucosal IgA immune response in the nasal cavity will also be assessed as a potential additional benefit to other immunologic responses. Nasal mucosal immunity, which can play an important role in the body's defense against respiratory diseases, is best stimulated by the nasal route of vaccine administration.

The NasoShield program is being developed under a contract with the Biomedical Advanced Research and Development Authority (BARDA), with a total potential value of $133.7 million if all options in the contract (HHSO100201600008C) are exercised. At the conclusion of the Phase 1b NasoShield trial, BARDA will have the option of exercising the remaining contract options valued at approximately $105 million to enable Phase 2 development.

NasoShield has the potential to be a convenient and simple alternative to the current approved multi-dose anthrax vaccine, as it is intended to confer protection after a single intranasal dose instead of the three-injection regimen required by the only licensed vaccine. Intranasal dosing provides the potential to be administered rapidly and without the need for needles, syringes or trained healthcare personnel in the event of an anthrax incident. In addition, NasoShield's expected room temperature stability profile may allow for broad distribution of the vaccine without the need for expensive cold-chain logistics, such as refrigeration or freezing.

Earlier this quarter, the Company reported positive preclinical data on AdCOVID, a single dose intranasal COVID-19 vaccine candidate which is derived from the same replication-deficient adenovirus 5 vaccine platform technology as NasoShield. In these preclinical studies performed in collaboration with the University of Alabama at Birmingham (UAB), AdCOVID elicited a strong systemic antibody response against the receptor-binding domain (RBD) in mice, stimulated serum viral neutralization titers, and activated a 29-fold induction of mucosal IgA against SARS-CoV-2 in bronchoalveolar fluid of vaccinated mice. The Company plans to initiate a Phase 1 clinical trial of AdCOVID during the fourth quarter of 2020.

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing intranasal vaccines, immune modulating therapies and treatments for liver disease. Our diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID™), anthrax (NasoShield™) and influenza (NasoVAX™); an intranasal immune modulating treatment for COVID-19 (T-COVID™); and next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™). For more information on Altimmune, please visit 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 timing of key milestones for our clinical assets, the initiation and timing of the NasoShield clinical trial and receipt of data from the clinical trial in 2020, the potential for additional funding from BARDA, the potential immunization effects of NasoShield, and the prospects for regulatory approval, 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: potential impacts due to the COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; funding delays, reductions in or elimination of U.S. government funding and/or non-renewal of expiring funding under the Company's agreement with BARDA; the Company's ability to satisfy certain technical milestones under the Company's contracts with BARDA that would entitle the Company to receive additional funding over the period of the agreement; the Company's ability to obtain potential regulatory approvals on the timelines anticipated, or at all; and the Company's ability to expand its pipeline of products and the success of future product advancements, including the success of future clinical trials, and the Company's ability to commercialize its products. 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 report on Form 10-K for the fiscal year ended December 31, 2019 and quarterly report on Form 10-Q for the quarter ended March 31, 2020 filed with the SEC, which are available at www.sec.gov.

Investor Contacts:

Will Brown
Chief Financial Officer
Phone: 240-654-1450
wbrown@altimmune.com

Ashley R. Robinson
LifeSci Advisors, LLC
617-430-7577
arr@lifesciadvisors.com

Media Contacts:
Warren Rizzi
Sard Verbinnen & Co.
Phone: 212-687-8080
altimmune-svc@sardverb.com

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