Altimmune Commences Dosing in Phase 1 Clinical Trial of ALT-801, a Long-Acting GLP-1/Glucagon Receptor Dual Agonist for the Treatment of NASH

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Preclinical data suggest potential for ALT-801 to address a significant unmet medical need; Phase 1 data readout anticipated in Q2 2021

GAITHERSBURG, Md., Dec. 08, 2020 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has commenced dosing in a Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical study of ALT-801. ALT-801 is a long-acting GLP-1/glucagon receptor dual agonist being developed for the treatment of non-alcoholic steatohepatitis (NASH), which is expected to affect more than 13 million adults in the United States.

The Phase 1 clinical trial is being conducted in Australia and is expected to enroll approximately 50 and 60 volunteers in the SAD and MAD phases of the trial, respectively. The trial is designed to evaluate the safety, pharmacokinetics and activity of ALT-801 over 6 weeks of treatment in overweight and obese but otherwise normal volunteers. Readouts from the trial, including initial weight loss and liver fat reduction, are expected in the second quarter of 2021. This 6-week study will be followed by a 12-week Phase 1b study in volunteers with non-alcoholic fatty liver disease (NAFLD) and is expected to commence in the third quarter of 2021.

“There is significant need for an effective, well-tolerated treatment for NASH,” said Scott Harris, M.D., Chief Medical Officer of Altimmune. “Unlike other metabolic approaches to treat NASH, ALT-801 combines the balanced, equipotent effects of GLP-1 and glucagon activities into a single peptide. The approach is expected to provide optimal effects in activating both a satiety signal to reduce appetite while also stimulating energy expenditure to promote a reduction in liver fat and increased weight loss. The Company anticipates that ALT-801, administered once-weekly, will have a favorable pharmacokinetic profile and improved gastrointestinal (GI) tolerability due to the proprietary EuPort™ domain, which slows the entry of the drug into the circulation. As GI intolerability is a significant limiting factor with all current GLP-1 based treatments, an improved tolerability profile is expected to be regarded favorably among clinicians. We look forward to a readout from the study in the second quarter of 2021, which could support strong competitive positioning for ALT-801 in the NASH treatment landscape.”

About ALT-801

ALT-801 is a novel peptide-based dual GLP-1/glucagon receptor agonist that is designed to treat the obesity and metabolic dysfunction that causes NASH. As the most severe form of non-alcoholic fatty liver disease, or NAFLD, NASH involves multiple metabolic pathways leading to the abnormal accumulation of liver fat, toxic lipid metabolites, and inflammation, resulting ultimately in fibrosis (cirrhosis) or liver cancer. Altimmune believes the treatment of obesity is the cornerstone of treating NASH and the principal morbidities of NASH. As observed in a well-established preclinical model of the disease, ALT-801 was capable of inducing significantly greater weight loss compared to semaglutide, a GLP-1 receptor agonist, along with significantly greater decreases in liver fat, plasma ALT, and other markers of NASH.

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 therapeutic 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 safety, efficacy and clinical progress of ALT-801 (including, without limitation, the expected timing of the Phase 1 clinical trial results) 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, access to clinical sites, enrollment, adverse effects on healthcare systems and disruption of the global economy the reliability of the results of studies relating to human safety and possible adverse effects resulting from the administration of the Company’s product candidates; the Company’s ability to secure regulatory approval for its AdCOVID investigational new drug application submission to the U.S. Food and Drug Administration, the Company’s ability to manufacture clinical trial materials on the timelines anticipated; the Company’s ability to secure manufacturing approval from its SARS-CoV-2 cell licensor on the timelines anticipated; and the success of future product advancements, including the success of future clinical trials. 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.

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