Altimmune Announces Initiation of Phase 2b IMPACT Trial Evaluating the Efficacy and Safety of Pemvidutide in Non-Alcoholic Steatohepatitis (NASH)

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GAITHERSBURG, Md., Aug. 01, 2023 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has enrolled the first subject in the Phase 2b IMPACT trial evaluating the efficacy and safety of pemvidutide in subjects with non-alcoholic steatohepatitis (NASH). Pemvidutide is a novel, investigational GLP-1/glucagon dual receptor agonist under development for the treatment of obesity and NASH.

This randomized, placebo-controlled biopsy-driven trial is being conducted at approximately 60 sites in the United States, with Dr. Stephen Harrison, Medical Director, Pinnacle Research, and Adjunct Professor of Medicine, Oxford University, serving as the Principal Investigator. The trial is expected to enroll approximately 190 subjects with and without diabetes randomized 1:2:2 to receive either 1.2 mg, 1.8 mg pemvidutide or placebo weekly for 48 weeks. The key efficacy endpoints are NASH resolution and fibrosis improvement at 24 weeks of treatment, with subjects followed for an additional 24 weeks to a total of 48 weeks for safety and biomarker responses. Top-line results are expected in Q1 2025.

Results from a blinded, 24-week Phase 1b trial of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD) showed a greater than 75% relative reduction in liver fat and 19% relative reduction in liver volume, with over 50% of the subjects achieving normalization of liver fat at the 1.8 mg dose. In addition, significant reductions in serum alanine aminotransferase (ALT) and MRI-based corrected T1 (cT1) were observed, both established markers of liver inflammation. Glycemic control was maintained, with trends toward improvements in fasting glucose and HbA1c in subjects with diabetes. Subjects on 1.8 mg pemvidutide also achieved a mean weight loss of 6.2%, with continuing weight loss at the end of treatment. Preclinical studies have shown pemvidutide to have anti-fibrotic effects in animal studies.

“Initiation of the IMPACT Phase 2b trial represents an important milestone in the development of pemvidutide for NASH,” said Scott Harris, M.D., Chief Medical Officer of Altimmune. “We are encouraged by the robust reductions of liver fat, inflammatory markers, serum lipids and body weight in our Phase 1b trial and anti-fibrotic effects in preclinical studies of pemvidutide and are excited about the prospect of achieving impressive rates of NASH resolution and fibrosis improvement in our IMPACT trial.”

About Pemvidutide
Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and NASH. Activation of the GLP-1 and glucagon receptors is believed to mimic the complementary effects of diet and exercise on weight loss, with GLP-1 suppressing appetite and glucagon increasing energy expenditure. Glucagon is also recognized as having direct effects on hepatic fat metabolism, leading to rapid reductions in levels of liver fat. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while likely slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability.

About Altimmune
Altimmune is a clinical-stage biopharmaceutical company focused on developing innovative next-generation therapeutics for the treatment of patients with liver diseases and obesity. The Company’s lead product candidate, pemvidutide, is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and NASH. In addition, Altimmune is developing HepTcell™, an immunotherapeutic designed to achieve a functional cure for chronic hepatitis B. For more information, please visit www.altimmune.com.

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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 timing of the data readout of the Phase 2b IMPACT trial of pemvidutide in NASH and the prospects for the utility of, 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. 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: 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 manufacture clinical trial materials 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 most recent annual report on Form 10-K and our other filings with the SEC, which are available at www.sec.gov.

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