Altimmune Announces Initiation of RESTORE Phase 2 Trial Evaluating the Efficacy and Safety of Pemvidutide in Alcohol-Associated Liver Disease (ALD)

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GAITHERSBURG, Md., July 09, 2025 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company developing novel peptide-based therapeutics for liver and cardiometabolic diseases, today announced that it has enrolled the first patient in the RESTORE Phase 2 trial evaluating the efficacy and safety of pemvidutide in subjects with Alcohol-Associated Liver Disease (ALD). Pemvidutide is a novel, investigational GLP-1/glucagon dual receptor agonist in development for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH), Alcohol Use Disorder (AUD), ALD and obesity.

RESTORE (NCT07009860) is a randomized, placebo-controlled trial enrolling approximately 100 patients across 34 sites, with Dr. Rohit Loomba, Professor of Medicine, Chief of the Division of Gastroenterology and Hepatology, and Director of the MASLD Research Center at the University of California, San Diego, serving as the principal investigator. Patients will be randomized 1:1 to 2.4mg pemvidutide or placebo for 48 weeks. The primary endpoint of the trial is the change from baseline in liver stiffness measurement (LSM) by vibration controlled transient elastography (VCTE) at Week 24. Key secondary endpoints include the change from baseline in LSM by VCTE at Week 48, changes in Enhanced Liver Fibrosis (ELF) score at Weeks 24 and 48, and changes in alcohol consumption and body weight at the same time points. An investigational new drug (IND) application for pemvidutide in ALD was filed in December 2024 and cleared by FDA in January 2025.

“Of the 28 million Americans with AUD, over 6 million have progressed to ALD, a condition for which there are no approved treatments and few in development,” said Dr. Loomba. “Alcohol-related liver mortality is highest in patients with comorbid obesity, highlighting the urgent need for a liver-directed therapy that can also drive weight loss. The robust reductions in body weight, liver fat and VCTE and the low rates of adverse event discontinuation in the recently completed IMPACT Phase 2b MASH trial support my expectation for success, and I am honored to be a part of this important clinical trial.”

“We are excited to launch the RESTORE trial in ALD,” added Scott Harris, M.D., Chief Medical Officer of Altimmune. “We believe that the statistically significant reductions in VCTE, liver fat and markers of fibrosis and inflammation in the recent IMPACT trial at 24 weeks position pemvidutide for a positive efficacy readthrough in the RESTORE trial.”

About Pemvidutide

Pemvidutide is a novel, investigational, peptide-based 1:1 GLP-1/glucagon dual receptor agonist in development for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH), Alcohol Use Disorder (AUD) and Alcohol-Associated Liver Disease (ALD) and obesity. 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, which is believed to lead to rapid reductions in levels of liver fat and serum lipids. In the ongoing IMPACT Phase 2b trial, at Week 24, once weekly pemvidutide demonstrated statistically significant MASH resolution without worsening of fibrosis, positive trends in liver fibrosis stage improvement without worsening of MASH, statistically significant reductions in non-invasive tests of fibrosis, weight loss, and liver fat content, and improvements in blood pressure. In a post-hoc AI-based analysis of the biopsies from the IMPACT trial, pemvidutide achieved a statistically significant reduction in liver fibrosis. In earlier trials, pemvidutide also demonstrated class-leading lean mass preservation and robust reductions in triglycerides and LDL cholesterol. Pemvidutide was well tolerated in the IMPACT trial, demonstrating potentially best-in-class tolerability among drugs in development for MASH with very low rates of discontinuation due to adverse events. The U.S. FDA granted Fast Track designation to pemvidutide for the treatment of MASH. The MOMENTUM Phase 2 obesity trial was completed in 2024 and the ongoing IMPACT Phase 2b MASH trial 48-week readout is expected in Q4 2025. In addition, RECLAIM, a Phase 2 trial in AUD and RESTORE, a Phase 2 trial in ALD, were initiated in May 2025 and July 2025, respectively.

About Altimmune

Altimmune is a late clinical-stage biopharmaceutical company focused on developing novel peptide-based therapeutics for liver and cardiometabolic diseases. The Company’s lead program is pemvidutide, a GLP-1/glucagon dual receptor agonist for the treatment of MASH, AUD, ALD and obesity. For more information, please visit www.altimmune.com.

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Forward-Looking Statement
Any statements made in this press release related to the development or commercialization of pemvidutide, an investigational product candidate, and other business and financial matters including without limitation, clinical trial study design, status, correspondence, results and data, including the RESTORE trial and ongoing RECLAIM and IMPACT Trials, the timing of key milestones for the Company’s clinical assets, future plans or expectations for pemvidutide for the treatment of MASH, AUD, ALD and obesity, and the prospects for receiving regulatory approval or 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, quarterly report on Form 10-Q and the Company's other filings with the SEC, which are available at www.sec.gov.

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