Altimmune Announces FDA Fast Track Designation for Pemvidutide in Alcohol Use Disorder (AUD)

August 19, 2025 at 7:30 AM EDT

Pemvidutide is the only drug currently granted Fast Track Designation in AUD

RECLAIM, a Phase 2 trial of pemvidutide in AUD, is currently enrolling

GAITHERSBURG, Md., Aug. 19, 2025 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company developing peptide-based therapeutics for liver and cardiometabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to pemvidutide for the treatment of Alcohol Use Disorder (AUD). Fast Track designation is intended to accelerate the development and review of new drugs that target serious conditions and address unmet medical needs.

RECLAIM (NCT06987513), a Phase 2 trial evaluating the safety and efficacy of pemvidutide in AUD, is currently enrolling. Approximately 100 patients will be randomized 1:1 to receive either 2.4 mg pemvidutide or placebo once weekly for 24 weeks. The primary endpoint of the trial is the change from baseline in the average number of heavy drinking days, with key secondary endpoints including the proportion of subjects achieving a 2-level reduction in World Health Organization (WHO) risk drinking level and absolute change from baseline in average levels of phosphatidylethanol (PEth), a serum biomarker of alcohol intake. The trial began enrolling in May 2025.

“Despite an estimated prevalence of AUD in more than 28 million adults in the U.S. alone, the scarcity of effective treatment options has created a sizeable treatment gap in AUD, with only 2% being treated with medication today,” said Vipin K. Garg, Ph.D., President and CEO of Altimmune. “Currently approved therapies have shown limited effectiveness and fail to adequately address the comorbidities of AUD, such as hepatic steatosis, hyperlipidemia and hypertension, or other comorbidities of obesity from which individuals with AUD often suffer. The Fast Track designation recognizes both the urgent unmet need associated with AUD and the potential for pemvidutide to play a role in the treatment of this serious condition.”

Scott Harris, M.D., Chief Medical Officer of Altimmune added, “There is a clear scientific rationale for the use of pemvidutide in AUD. Fatty liver develops in up to 90% of problem drinkers and places individuals with AUD at risk for alcohol-associated hepatitis. Treatment with GLP-1 agonists is recognized to reduce cravings for alcohol, while glucagon is recognized to reduce hepatic steatosis and inflammation. In a preclinical model of free-choice alcohol use, pemvidutide was shown to produce rapid and significant reduction in alcohol intake. We look forward to evaluating the potential of pemvidutide in the treatment of AUD through the ongoing RECLAIM trial.”

Fast Track designation is designed to facilitate development and expedite the review of therapies with the potential to treat serious or life-threatening conditions that demonstrate the potential to address a major unmet medical need. Product candidates that receive Fast Track designation have the opportunity to benefit from early and frequent communication with the FDA and may be eligible for rolling submission and priority review of a New Drug Application (NDA).

About AUD
Alcohol use disorder (AUD) is a medical condition driven by an impaired ability to stop or control the harmful consumption of alcohol. Alcohol use disorder can also lead to serious downstream health consequences, including liver disease, cardiovascular disease, and cancer. Additionally, most patients with AUD have comorbid overweight or obesity and present with liver steatosis, further amplifying their risk for poor outcomes. The World Health Organization estimates that harmful alcohol consumption is the seventh leading cause of global death and disability, with alcohol accounting for 50% of all liver-related deaths.

Today, it is estimated that 28 million adults in the U.S. suffer from AUD. Patients with AUD are characterized as mild, moderate or severe according to the DSM-5 criteria with approximately 12 million having moderate or severe forms of the disease. Only three drugs for AUD have been approved by the FDA, but these agents have limited efficacy for AUD and its comorbidities, and are used by less than 2% of patients. There is a substantial unmet need for new and more effective treatments that not only reduce alcohol cravings and heavy drinking days but also can address the numerous comorbidities of the disease.

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), 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 FDA granted Fast Track designation to pemvidutide for the treatment of MASH. 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 product candidate is pemvidutide, a GLP-1/glucagon dual receptor agonist for the treatment of MASH, Alcohol Use Disorder (AUD), Alcohol-Associated Liver Disease (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, regulatory and financial matters including without limitation, clinical trial study design, status, correspondence, results and data, including the ongoing RECLAIM, RESTORE 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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Source: Altimmune, Inc