Altimmune Announces Early Completion of Enrollment in RECLAIM Phase 2 Trial Evaluating Pemvidutide in Alcohol Use Disorder

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Enrollment completed ahead of schedule, underscoring strong interest from patient community in a potential new therapeutic option

On track to complete the 24-week treatment period and announce topline results in 2026

GAITHERSBURG, Md., Nov. 03, 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 the completion of patient enrollment in RECLAIM, a Phase 2 clinical trial evaluating pemvidutide in adults with alcohol use disorder (AUD). The trial is evaluating pemvidutide in approximately 100 patients across sites in the U.S. Altimmune expects to announce topline results from the trial in 2026.

"We are thrilled to have completed enrollment in our RECLAIM trial several months ahead of schedule, signaling strong enthusiasm from both patients and physicians to explore new treatment options for AUD. Pemvidutide has the potential to be a substantial therapeutic advance for these patients in one of the largest known areas of unmet need," said Christophe Arbet-Engels, M.D., Ph.D., Chief Medical Officer of Altimmune. "The unique dual agonism of pemvidutide could not only target cravings and overall alcohol consumption but may address alcohol-related fatty liver damage, which can lead to liver inflammation and progression to alcohol-associated liver disease (ALD). We look forward to sharing results from the trial in the year ahead, and in the meantime we anticipate sharing 48-week results from the IMPACT trial of pemvidutide in metabolic dysfunction-associated steatohepatitis (MASH) later this quarter."

RECLAIM (NCT06987513) is a Phase 2 trial evaluating the safety and efficacy of pemvidutide in AUD in subjects with obesity or who are overweight. Approximately 100 patients have been 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 per week, 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.

Concurrent with the RECLAIM trial in AUD, Altimmune continues to enroll patients in the RESTORE Phase 2 trial evaluating pemvidutide in alcohol-associated liver disease (ALD).

About AUD

Alcohol use disorder (AUD) is a medical condition driven by an impaired ability to stop or control the harmful consumption of alcohol. AUD can also lead to serious health consequences, including liver cirrhosis, cardiovascular disease, and cancer. Additionally, many patients with AUD present with comorbidities including excess fat in the liver and obesity, 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 other risks of the disease.

About Pemvidutide

Pemvidutide is a novel, investigational, peptide-based 1:1 glucagon/GLP-1 dual receptor agonist in development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), alcohol use disorder (AUD), and alcohol-associated liver disease (ALD). The activation of glucagon results in direct effects on the liver, including reductions in liver fat, inflammation, and fibrosis, while GLP-1 receptors mediate appetite suppression and weight loss.

The FDA granted Fast Track designations to pemvidutide for the treatment of MASH and AUD, both areas of significant unmet medical need. The 48-week readout from the ongoing IMPACT Phase 2b MASH trial is expected in Q4 2025. Phase 2 trials in AUD (RECLAIM) and ALD (RESTORE) were initiated in May 2025 and July 2025, respectively and are currently ongoing.

About Altimmune

Altimmune is a late clinical-stage biopharmaceutical company developing novel peptide-based therapeutics for liver and cardiometabolic diseases. The Company's lead product candidate is pemvidutide, a glucagon/GLP-1 dual receptor agonist for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), alcohol use disorder (AUD), and alcohol-associated liver disease (ALD). For more information, please visit www.altimmune.com.

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