Altimmune Announces Initiation of RECLAIM Phase 2 Trial Evaluating the Efficacy and Safety of Pemvidutide in Alcohol Use Disorder (AUD)

May 19, 2025 at 7:30 AM EDT

GAITHERSBURG, Md., May 19, 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 subject in the RECLAIM Phase 2 trial evaluating the efficacy and safety of pemvidutide in subjects with Alcohol Use Disorder (AUD). Pemvidutide is a novel, investigational GLP-1/glucagon dual receptor agonist under development for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), obesity, AUD and alcohol liver disease (ALD). IMPACT, a Phase 2b trial of pemvidutide in MASH, is expected to read out topline data in the second quarter of 2025, and a Phase 2 trial of pemvidutide in ALD is expected to initiate enrollment in the third quarter of 2025.

RECLAIM is a randomized, placebo-controlled trial being conducted at approximately 15 sites in the United States, with Dr. Henry Kranzler, Karl E. Rickels Professor of Psychiatry and Director, Center for Studies of Addiction at the University of Pennsylvania Perelman School of Medicine, serving as the Principal Investigator. The trial is expected to enroll approximately 100 subjects randomized 1:1 to receive either 2.4 mg pemvidutide or placebo weekly for 24 weeks. The primary endpoint of the trial is a change in alcohol consumption, assessed as the change from baseline in the average number of heavy drinking days per week at Week 24, with the key secondary endpoints including the proportion of subjects achieving a 2-level reduction in World Health Organization (WHO) risk drinking level and the absolute change from baseline in average levels of phosphatidylethanol (PEth), a serum biomarker of alcohol intake. An investigational new drug (IND) application for pemvidutide in AUD was filed in December 2024 and was cleared by FDA in January 2025.

“Over 28 million individuals in the U.S. alone have AUD, and the lack of effective treatments has resulted in one of the largest known treatment gaps in this country,” said Dr. Kranzler. “It has been estimated that less than 10% of patients are currently receiving treatment for AUD and that 2% or less are being treated with any of the 3 medications approved for AUD in the US[1]. These medications were approved decades ago and have limited beneficial effects and inadequate compliance rates. Thus, there is an urgent need for new therapies for AUD.”

“There are compelling data that GLP-1 agents may reduce the craving for alcohol in addition to reducing food consumption,” said Scott Harris, M.D., Chief Medical Officer of Altimmune. “In a preclinical hamster model of free-choice alcohol intake, pemvidutide demonstrated a greater than 80% reduction in alcohol preference after the initiation of treatment[2]. Importantly, AUD is the precursor for alcohol liver disease (ALD), a disease characterized by excess liver fat, liver inflammation and fibrosis with features similar to MASH. In addition, obesity is a major risk factor for MASH, AUD and ALD, and because excess alcohol is a known risk factor for hypertension and dyslipidemia, patients with AUD could benefit further from the metabolic effects of pemvidutide.”

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, obesity, Alcohol Use Disorder (AUD) and Alcohol Liver Disease (ALD). For more information, please visit www.altimmune.com.

Follow @Altimmune, Inc. on LinkedIn
Follow @AltimmuneInc on X

Forward-Looking Statement
Any statements made in this press release related to the development or commercialization of product candidates and other business and financial matters, including without limitation, trial results and data, the timing of key milestones for our clinical assets, 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.

Company Contact:
Greg Weaver
Chief Financial Officer
Phone: 240-654-1450
ir@altimmune.com

Investor Contact:
Lee Roth
Burns McClellan
Phone: 646-382-3403
lroth@burnsmc.com

Media Contact:
Jake Robison
Inizio Evoke, Biotech
Phone: 619-849-5383
jake.robison@inizioevoke.com

[1] SAMHSA 2023 NSDUH Survey
[2] Altimmune R&D Day Presentation, slide #47

This press release was published by a CLEAR® Verified individual.

Source: Altimmune, Inc