



Altimune Announces Positive Topline Results from RECLAIM Phase 2 Trial of Pemvidutide in Alcohol Use Disorder

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Pemvidutide 2.4 mg delivered a statistically significant and clinically meaningful reduction in heavy drinking days, the primary endpoint of the trial. Important secondary endpoints were also met, including two-level reduction in WHO risk drinking levels and zero heavy drinking days, both of which are recognized by the FDA as registrational endpoints.

A generally favorable tolerability profile was observed in the trial.

Conference call to be held today at 8:00 am ET

GAITHERSBURG, Md., July 28, 2026 (GLOBE NEWSWIRE) -- Altimune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company focused on serious liver diseases, today announced positive topline results from the RECLAIM Phase 2 trial evaluating pemvidutide, an investigational balanced glucagon/GLP-1 dual receptor agonist, in patients with moderate to severe alcohol use disorder (AUD). The trial met its primary endpoint with a highly statistically significant reduction in heavy drinking days (HDD) versus placebo, with consistent positive results across important secondary endpoints, including the World Health Organization (WHO) Risk Drinking Levels (RDL), zero HDD and phosphatidyl ethanol (PEth) levels. A generally favorable tolerability profile was observed in the trial. The Company plans to request an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) based on the results of the trial.

"We are extremely encouraged by these compelling topline results, which showed a highly significant reduction in heavy drinking days and nearly two-thirds of patients treated with pemvidutide achieving a two-level reduction in their WHO-RDL, a clinically meaningful outcome for these patients," said Christophe Arbet-Engels, M.D., Ph.D., Chief Medical Officer at Altimune. "These data reflect pemvidutide's strong and consistent efficacy across important measures of drinking behavior, together with a generally favorable tolerability profile in this difficult-to-treat disorder. Given the known detrimental effects of alcohol on the liver, the liver-directed impact of glucagon in pemvidutide may provide further benefit in the treatment of AUD over GLP-1 alone, underscoring pemvidutide's promising potential differentiation."

Efficacy Data

Endpoint	Placebo	Pemvidutide	Treatment Effect	P-value
Change from baseline in HDD/Week at Week 24 (Primary Endpoint)	-2.75 (LS mean)	-4.20 (LS mean)	-1.45 (LS mean difference)	0.0014
2-level Reduction in WHO-RDL	34.8% (16/46)	64.4% (29/45)	Odds Ratio 3.31	0.0049
Zero HDD in Week 21 through Week 24	17.4% (8/46)	42.2% (19/45)	Odds Ratio 3.84	0.0066
Change from baseline in Percent of Days with Abstinence	20.5% (LS mean)	38.9% (LS mean)	18.4% (LS mean difference)	0.0075
Change from baseline in Serum PEth at Week 24	22.0 (LS mean)	-153.4 (LS mean)	-175.3 (LS mean difference)	<0.0001

Key efficacy results included:

- Statistically significant reduction in the primary endpoint of HDD per week versus placebo (p=0.0014)
- Statistically significant results on secondary endpoints, including two that are registrational endpoints
 - Two-level reduction in WHO Risk Drinking Levels versus placebo (p=0.0049)
 - Zero heavy drinking days versus placebo (p=0.0066)
- Statistically significant change in percent of days with abstinence versus placebo (p=0.0075)
- Statistically significant reduction in PEth levels versus placebo (p<0.0001)
- Statistically significant reduction in body weight, as measured by a placebo-adjusted difference in change from baseline of 9.1% at 24 weeks (p<0.0001), with no evidence of plateauing

Safety and Tolerability Data

Adverse Event (AE)	Placebo (N=50)	Pemvidutide 2.4mg (N=50)
Serious AEs	1 (2%)	2 (4%)
Severe AEs	3 (6%)	6 (12%)
Nausea	12 (24%)	22 (44%)
Vomiting	3 (6%)	9 (18%)
Diarrhea	5 (10%)	10 (20%)

Constipation	3 (6%)	13 (26%)
Treatment discontinuations	11 (22%)	10 (20%)
Study drug-related AEs leading to treatment discontinuation	0 (0%)	5 (10%)*

*2 vomiting, 1 constipation, 1 fatigue, 1 exacerbation of hemorrhoids

Pemvidutide was generally well tolerated in this patient population with high unmet need.

The new, simple two-step titration for the 2.4 mg dose may improve gastrointestinal (GI) tolerability compared to prior pemvidutide titration schemes. The majority of adverse events were mild to moderate in severity. There was one serious adverse event (SAE) (hyponatremia) in the pemvidutide arm that was deemed possibly related to treatment drug by the principal investigator.

"As someone who has dedicated his career to understanding and treating alcohol use disorder, I recognize the significance of these findings, particularly given the current attention on the adverse health impact of heavy drinking. These results provide a consistent picture of treatment benefit on self-reported drinking outcomes, supported by objective PETH biomarker evidence," said Henry Kranzler, M.D., Karl E. Rickels Professor of Psychiatry and Director, Center for Studies of Addiction, University of Pennsylvania Perelman School of Medicine, and Principal Investigator of the RECLAIM trial. "These data underscore the potential for pemvidutide to address multiple dimensions of alcohol use disorder by supporting abstinence and reducing heavy drinking, findings that build on prior evidence of its activity in the liver."

"These top-line data strengthen our confidence in pemvidutide's differentiation and its potential to benefit people living with MASH, AUD and ALD, who currently have limited treatment options," said Jerry Durso, Chief Executive Officer and Chairman of the Board of Altimmune. "These results represent yet another important milestone for Altimmune as we continue to execute on our goal to bring pemvidutide to patients with serious liver diseases while creating value for shareholders."

Based on these data, Altimmune plans to request an End-of-Phase 2 (EOP2) meeting with the FDA to discuss the path forward for pemvidutide in AUD. Results from the RECLAIM trial will be submitted for presentation at a forthcoming medical conference and for publication in a peer-reviewed journal.

Conference Call Information

Altimmune will host a conference call and webcast at 8:00 a.m ET today to discuss the RECLAIM topline data. The conference call will be webcast live on Altimmune's Investor Relations (IR) [website](#). Participants who would like to join by phone may register [here](#) to receive the dial-in numbers and unique pin to access the call. Following the conclusion of the call, the webcast will be available for replay on the IR page of the company's website.

About RECLAIM

RECLAIM ([NCT06987513](#)) is a Phase 2 trial evaluating the safety and efficacy of pemvidutide in Alcohol Use Disorder (AUD) patients with BMI >25 kg/m², and is the first Phase 2 multicenter study evaluating a dual glucagon-GLP-1 agonist in AUD to report results. Approximately 100 patients were randomized 1:1 to receive either 2.4 mg pemvidutide or placebo once weekly for 24 weeks. The primary endpoint of the trial was the change from baseline in the average number of heavy drinking days (HDD) per week, with secondary endpoints including the proportion of patients achieving a 2-level reduction in World Health Organization (WHO) Risk Drinking Levels (RDL), zero HDD, and absolute change from baseline in average levels of phosphatidylethanol (PETH), an objective serum biomarker of alcohol intake. The 2-level reduction in WHO risk drinking levels and zero HDD are recognized by the FDA as registrational endpoints.

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 with balanced 1:1 glucagon/GLP-1 dual receptor agonist activity, 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 receptors results in direct effects on the liver, including reductions in liver fat, inflammation and fibrosis, while GLP-1 receptors mediate metabolic effects such as appetite suppression and weight loss, and may play a role in pathways related to craving and reward.

The FDA granted Fast Track designations to pemvidutide for the treatment of MASH and AUD, as well as Breakthrough Therapy Designation for MASH. In December 2025, the Company announced 48-week data from the IMPACT Phase 2b trial in MASH. In July 2026, the Company announced results from the RECLAIM Phase 2 trial in AUD. The RESTORE trial in ALD was initiated in July 2025, and enrollment completion is expected in the third quarter 2026. The Company plans to initiate the PERFORMA Phase 3 trial, a multinational, randomized, double-blind, placebo-controlled, parallel-group study of pemvidutide in patients with MASH in the third quarter of 2026.

About Altimmune

Altimmune is a late clinical-stage biopharmaceutical company developing therapies for patients with serious liver diseases. The Company's lead candidate, pemvidutide, is a unique dual-action therapy targeting both glucagon and GLP-1 receptors in a balanced 1:1 ratio in development for the treatment of MASH, AUD and ALD. For more information, please visit www.altimmune.com.

Forward-Looking Statements

This press release has been prepared by Altimmune, Inc. ("we," "us," "our," "Altimmune" or the "Company") and includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements 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 performance of our drug candidates in ongoing and future clinical trials including the RECLAIM trial (topline results of which are described herein), the ongoing RESTORE trial and the planned PERFORMA trial, evaluating pemvidutide in patients with MASH, AUD and ALD, the potential benefits of Fast Track and Breakthrough Therapy Designations and the prospects for regulatory approval, commercializing, market size, market potential, competitive landscape, or selling any product or drug candidates. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "suggest" and similar expressions and their variants, as they relate to the Company 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 such as 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; patient baseline characteristics which may vary and impact the success of future trials; 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; whether the FDA will agree with the Company's proposed development and regulatory strategy for pemvidutide in AUD, including following any End-of-Phase 2 meeting; the risk that results from the RECLAIM trial may not be predictive of results in the RESTORE trial, the planned PERFORMA trial, or any other future or larger clinical trial; the Company's need for substantial additional capital to complete development of pemvidutide, which may not be available on acceptable terms or at all; competition from other companies developing treatments for MASH, AUD and ALD; and the success of future product advancements, including the success of current and 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 latest annual report on Form 10-K, quarterly report on Form 10-Q and our other filings with the SEC, which are available at www.sec.gov.

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