Altimmune Presents AI-Based Analysis of Liver Fibrosis Reduction from IMPACT Phase 2b Trial of Pemvidutide in MASH in Late-breaking Poster at AASLD The Liver Meeting® 2025

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AI-based digital pathology analysis provides high-resolution quantification of hepatic fibrosis and objective measurement of fibrosis improvement

Pemvidutide demonstrated significant reductions in liver fibrosis and improvements in non-invasive tests vs. placebo at 24 weeks

GAITHERSBURG, Md., Nov. 07, 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 results from an artificial intelligence (AI)-based analysis of biopsies from the IMPACT Phase 2b trial of pemvidutide in patients with metabolic dysfunction-associated steatohepatitis (MASH).

The AI-based pathology tool Liver Explore™ showed that pemvidutide treatment resulted in significant reductions in the proportionate areas of early, advanced and total liver fibrosis compared to placebo at 24 weeks. These data are supported by significant improvements in non-invasive markers of fibrosis compared to placebo. The AI-based analysis will be presented on Saturday, November 8, in a late-breaking poster session at The Liver Meeting 2025, hosted by the American Association for the Study of Liver Diseases (AASLD) in Washington, D.C.

“Changes in fibrosis can be difficult to quantify by traditional histological methods, which are semi-quantitative and prone to observer variability. AI-based methods can provide an automated, sensitive and truly quantitative analysis of changes in fibrosis in patients with MASH,” said Vlad Ratziu, MD, PhD, Professor of Hepatology at Sorbonne University and Pitié-Salpêtrière Hospital in Paris, France. “It is exciting to see this technology being used to accelerate the development of potential new therapies for MASH.”

Highlights from the AI-based analysis of biopsies from patients in the IMPACT Phase 2b trial include:

- Data for total fibrosis showed 31% of patients in the pemvidutide 1.8 mg group (n = 85), and 12% of patients in the pemvidutide 1.2 mg group (n = 41) achieved a ≥ 60% reduction in the area of fibrosis compared to 8% of placebo-treated patients (n = 86, p = 0.0003 and p = 0.5, respectively).
- Data for early fibrosis showed 34% of patients in the pemvidutide 1.8 mg group (n = 85), and 24% of patients in the pemvidutide 1.2 mg group (n = 41) achieved ≥ 60% reduction in the area of fibrosis compared to 9% of placebo-treated patients (n = 86, p < 0.0001 and p = 0.017, respectively).
- Data for advanced fibrosis showed 27% of patients in the pemvidutide 1.8 mg group (n = 85), and 5% of patients in the pemvidutide 1.2 mg group (n = 41) achieved ≥ 60% reduction in the area of fibrosis compared to 11% of placebo-treated patients (n = 86, p = 0.0063 and p = 0.32, respectively).

Additional analyses showed significant reductions in non-invasive tests (NITs) of liver fibrosis with pemvidutide compared to placebo, including in the PRO-C3:CTX-III ratio, consistent with fibrosis regression, and in PRO-C6, a fibrosis marker that may be linked to cardiovascular risk.

“In our 24-week IMPACT MASH Trial, we achieved MASH resolution in up to 58% of patients, suggesting that the balanced 1:1 ratio of glucagon/GLP-1 in pemvidutide can lead to rapid MASH resolution,” said Christophe Arbet-Engels, M.D., Ph.D., Chief Medical Officer of Altimmune. “Using this powerful AI-based technology to examine liver biopsies, we found compelling reductions in total liver fibrosis as well, with statistically significant reductions in both early and advanced fibrosis (for 1.8 mg pemvidutide) at 24-weeks. We look forward to the upcoming 48-week IMPACT trial readout which will include longer-term NIT and weight loss data.”

About the IMPACT Phase 2b Study
The randomized, placebo-controlled, double-blind IMPACT Phase 2b trial (NCT05989711) enrolled 212 participants with biopsy-confirmed metabolic dysfunction-associated steatohepatitis (MASH) and fibrosis stages F2 or F3, with and without diabetes. Study participants were randomized 1:2:2 to receive weekly subcutaneous pemvidutide doses at either 1.2 mg, 1.8 mg or placebo for 48 weeks. Key efficacy endpoints, measured at 24 weeks, were MASH resolution without worsening of fibrosis, or fibrosis improvement without worsening of MASH. Secondary endpoints included non-invasive tests of fibrosis and weight loss. Participants will receive a total of 48 weeks of treatment, and a final readout of longer-term NITs and weight loss is anticipated in the fourth quarter of 2025.

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 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.

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 fourth quarter 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.

Forward Looking Statements
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, the timing of key milestones for the Company's clinical assets, future plans or expectations for pemvidutide for the treatment of MASH, AUD and ALD, 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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