Altimmune Announces Publication of IMPACT Phase 2b Trial Data in The Lancet and Concurrent Late-Breaking Oral Presentation at AASLD The Liver Meeting® 2025

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24-week data demonstrated significant MASH resolution and weight loss, and strong evidence of anti-fibrotic activity with a favorable tolerability profile

Significant improvements observed in secondary endpoints, including reductions in liver fat, inflammation and biomarkers of fibrosis

GAITHERSBURG, Md., Nov. 11, 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 publication in *The Lancet* of 24-week efficacy and safety data from the ongoing IMPACT Phase 2b trial of pemvidutide in patients with metabolic dysfunction-associated steatohepatitis (MASH) in a paper titled "**Safety and efficacy of weekly pemvidutide versus placebo for metabolic dysfunction-associated steatohepatitis (IMPACT): 24-week results from a multicentre, randomised, double-blind, phase 2b study**".

Dr. Mazen Noureddin, M.D., IMPACT trial principal investigator, Professor of Medicine at Houston Methodist Hospital and Co-Chairman of the Board for Summit and Pinnacle Clinical Research will present these data in a late-breaking oral presentation at The Liver Meeting® 2025, hosted by the American Association for the Study of Liver Diseases (AASLD) in Washington, D.C.

Topline 24-week data from the IMPACT Phase 2b trial were previously announced in June 2025, demonstrating that pemvidutide, Altimmune's 1:1 glucagon/GLP-1 agonist, achieved statistically significant MASH resolution without worsening of fibrosis, meaningful reductions in fibrosis, liver fat, and clinically relevant weight loss with favorable tolerability.

The Lancet publication describes changes across key non-invasive tests (NITs) from blood-based biomarkers (ELF, PRO-C3, and AST), imaging modalities (MRI-PDFF, FibroScan®, and cT1), and combined measures such as FAST score – all markers that offer consistent evidence of fibrosis reduction and improvement in liver inflammation.

"As the primary goal of treatment for patients with MASH is to reverse liver fibrosis to prevent progression to cirrhosis and other serious and life-threatening complications, the totality of the 24-week clinical data from the IMPACT trial is very encouraging," said Dr. Mazen Noureddin. "Given the significant resolution of MASH that occurred after only 24 weeks of treatment, along with strong evidence of anti-fibrotic activity and weight loss, the profile of pemvidutide suggests it has the potential to meaningfully alter the course of this disease."

Highlights from the Published IMPACT 24-Week Results

Endpoint	Placebo (N=86)	1.2 mg (N=41)	1.8 mg (N=85)
Primary Endpoint: Histology (ITT Analysis)			
MASH resolution without worsening of fibrosis, LSM % patients (SE)	20 (4.3)	58 (7.9) ****	52 (5.6) ****
Fibrosis improvement without worsening of MASH, LSM % patients (SE)	28 (4.9)	33 (7.5)	36 (5.3)
Secondary Endpoints			
Change in liver stiffness measurement, kPa (SE)	-0.7 (0.5)	-3.7 (0.7) ***	-2.2 (0.5) *
Change in Enhanced Liver Fibrosis score (SE)	0.03 (0.1)	-0.6 (0.1) ***	-0.5 (0.1) ***
Change in corrected T1 relaxation time, ms (SE)	-14.7 (11.9)	-124.6 (16.1) ***	-134.7 (11.9) ***
Normalization of liver fat content (≤ 5%), n (%) patients	3/76 (4%)	12/39 (31%) ****	35/79 (44%) ****
Body weight relative reduction, % (SE)	−0.5 (0.3)	−4.8 (0.5) ***	−5.8 (0.3) ***
Adverse Events (AEs)			
Adverse event leading to the discontinuation of treatment, n (%)	2 (2%)	0 (0%)	1 (1%)
Any serious adverse event, n (%)	3 (3%)	1 (2%)	3 (4%)
Serious adverse event considered by the investigator to be related to assigned treatment, n (%)	0 (0%)	0 (0%)	0 (0%)

Data are presented as least squares mean (SE) unless indicated otherwise. A treatment policy estimand was applied with missing outcomes due either to missing biopsies or treatment discontinuations treated as non-responders (composite estimand). Comparisons versus placebo for the primary endpoints were made using the Chi-square test; **** p <0.0001 vs. placebo. The Cochran-Mantel-Haenszel test was applied to endpoints that were categorical in nature; **** p <0.0001 vs. placebo. Comparisons versus placebo were made using mixed models for repeated measures for endpoints measured at multiple time points and analysis of covariance for endpoints measured at baseline and week 24; * p <0.05, *** p <0.001 vs. placebo.

"The dual glucagon and GLP-1 receptor agonism of pemvidutide, which has a unique, balanced 1:1 activity ratio, was intentionally designed to target both the hepatic and metabolic drivers of MASH. The strength of these IMPACT 24-week results, particularly the rapid resolution of MASH in 24 weeks, provides strong evidence for a reduction in fibrosis and significant reductions in other NITs, reinforcing our belief in the differentiated mechanism of pemvidutide and its potential to become an important treatment for patients with MASH," said Christophe Arbet-Engels, M.D., Ph.D., Chief Medical Officer of Altimmune. "We also look forward to providing a final readout of longer-term NITs and weight loss from the IMPACT trial in the fourth quarter of 2025."

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. The primary 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 the fourth quarter of 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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