Altimmune Announces that Pemvidutide Achieved Key Measures of Success at 48 Weeks in IMPACT Phase 2b MASH Trial

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Improvements observed in key non-invasive markers of fibrosis across treatment arms versus placebo, with continued reductions from 24-week timepoint

Additional weight loss from 24 to 48 weeks with 1.8 mg dose, without plateauing

Favorable tolerability profile of pemvidutide preserved at 48 weeks, reinforced by low treatment-related discontinuation rate

End-of-Phase 2 meeting with FDA supports advancing to registrational Phase 3 trial in MASH patients with moderate to advanced liver fibrosis

Conference call to be held today at 8:00 a.m. ET

GAITHERSBURG, Md., Dec. 19, 2025 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company developing therapies that address serious liver diseases, today announced positive topline results from the IMPACT Phase 2b trial of pemvidutide, a balanced 1:1 glucagon/GLP-1 dual receptor agonist, in patients with metabolic dysfunction-associated steatohepatitis (MASH) at 48 weeks.

Topline 48-week data from the IMPACT trial showed that treatment with pemvidutide achieved statistically significant improvements across treatment arms in key non-invasive tests (NITs), including Enhanced Liver Fibrosis (ELF) and Liver Stiffness Measurement (LSM), versus placebo. Importantly, these data exhibited continued reductions from week 24 and provide evidence of continued improvement in antifibrotic activity with both treatment doses. These are well-established markers of fibrosis and hepatic inflammation and are strongly associated with histological changes and liver related events. Additional weight loss was observed with the 1.8 mg dose compared to the IMPACT 24-week data, with no evidence of plateauing. The 48-week data also maintained the favorable tolerability profile seen at 24 weeks, including a lower discontinuation rate due to adverse events than placebo.

“The magnitude of response versus placebo on measures such as ELF and LSM at 48 weeks makes these data particularly compelling, as these noninvasive markers have been shown to correlate with histologic fibrosis stage. These results reinforce that pemvidutide may address both liver-specific and metabolic drivers of MASH without compromising tolerability – three critical elements of a potential effective treatment for this patient population,” said 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. “I am encouraged by the dose response observed and the performance of the 1.8 mg arm and I am eager to see this differentiated therapeutic candidate advance into Phase 3 evaluation.”

Highlights from the 48-Week Topline Results

- Pemvidutide-treated participants achieved statistically significant reductions in primary non-invasive markers of fibrosis, including Enhanced Liver Fibrosis (ELF) and Liver Stiffness Measurement (LSM).
  - ELF: 1.2 mg and 1.8 mg doses achieved a mean reduction from baseline of -0.49 and -0.58 respectively, vs. +0.16 in placebo-treated patients ($p<0.0001$, both doses).
  - LSM: 1.2 mg and 1.8 mg doses achieved a mean reduction from baseline of -3.04 ($p<0.05$) and -3.97 ($p<0.001$), respectively, vs. -0.03 in placebo-treated participants.
  - The proportion of participants receiving pemvidutide 1.2 mg and 1.8 mg that achieved both a ≥0.5 reduction in ELF and a 30% reduction in LSM were 27.8% ($p<0.001$) and 32.4% ($p<0.0001$) respectively, vs. 3.2% in placebo-treated participants.
- Pemvidutide-treated participants also achieved statistically significant reductions in key non-invasive measures of liver health and hepatic inflammation, including liver fat content, alanine aminotransferase (ALT) and corrected T1 (cT1).
  - Liver fat content: 1.2 mg and 1.8 mg doses achieved a mean reduction from baseline of 45.2% and 54.7% respectively, compared to 8.2% in participants who received placebo ($p<0.0001$).
  - ALT: 1.2 mg and 1.8 mg achieved a mean reduction from baseline of -37.8 IU/L and -37.4 IU/L respectively, vs. -10.3 IU/L in placebo-treated participants ($p<0.0001$, both doses).
  - cT1: 1.2 mg and 1.8 mg achieved a mean reduction from baseline of -124 and -140 milliseconds (ms) respectively, vs. -21 ms in placebo-treated participants ($p<0.0001$, both doses).
- Participants receiving pemvidutide 1.2 mg and 1.8 mg achieved weight loss of 4.5% and 7.5%, respectively, vs. 0.2% of placebo-treated participants ($p<0.0001$, both doses), with no plateauing at 48 weeks with the 1.8 mg dose.
- Adverse events leading to treatment discontinuation occurred in 0% and 1.2% of patients treated with pemvidutide 1.2 mg and 1.8 mg, respectively, vs. 3.5% of participants on placebo.
- No serious or severe AEs related to treatment were reported.

Additionally, the Company announced that it held a productive End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) which resulted in alignment on the parameters for a registrational Phase 3 trial of pemvidutide for MASH patients with moderate to advanced liver fibrosis. With the FDA’s recent qualification of AIM-MASH AI Assist, the Agency was open to the Company’s intent to integrate use of this AI tool into the Phase

3 trial. AIM-MASH AI Assist is intended to help standardize histologic assessment and reduce the time and resources needed for MASH drug development.

“With the benefit of FDA feedback and these 48-week data now in hand, we are greatly looking forward to progressing pemvidutide to a Phase 3 program which we intend to initiate in 2026. Strong evidence of antifibrotic improvements based upon non-invasive tests, combined with an attractive tolerability profile, highlight pemvidutide’s differentiation and potential to be a meaningful treatment option for the MASH patient community,” said Vipin Garg, Ph.D., Chief Executive Officer of Altimmune.

Conference Call and Webcast
Altimmune will host a conference call and webcast on Friday, December 19, 2025 at 8:00 am ET to review the IMPACT Phase 2b topline 48-week data. The conference call will be webcast live on Altimmune’s Investor Relations 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 Altimmune’s Investor Relations website.

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 measured at 24 and 48 weeks.

About MASH
Metabolic dysfunction-associated steatohepatitis (MASH) is a progressive liver disease marked by fat accumulation, inflammation, and fibrosis in the liver. Without treatment, it can progress to cirrhosis, liver failure, or liver cancer, and is one of the most common reasons for liver transplantation in the U.S. Management relies largely on lifestyle changes, and currently approved treatment options may not fully address both the metabolic drivers and fibrosis that can pose long-term risk.

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.

The FDA granted Fast Track designations to pemvidutide for the treatment of MASH and AUD, both areas of significant unmet medical need. In December 2025, the Company announced 48-week data from the IMPACT Phase 2b trial in MASH. 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 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 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 Statement
Any statements made in this press release related to the clinical trial results, development or commercialization of pemvidutide, an investigational product candidate, and other business, regulatory and financial matters including without limitation, trial results and data, including the data and results from the 48-week IMPACT trial, and statements related to ELF, LSM, ALT and cT1, the timing of key milestones for the Company’s clinical assets, future plans or expectations for pemvidutide for the treatment of MASH, any meetings with the FDA, 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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