Altimmune Announces Positive Topline Results from the IMPACT Phase 2b Trial of Pemvidutide in the Treatment of MASH

June 26, 2025 at 7:00 AM EDT

First product candidate to demonstrate significant MASH effects and weight loss at 24 weeks

Trial met its primary endpoint with statistically significant MASH resolution without worsening of fibrosis in up to 59.1% of participants in an ITT analysis

Fibrosis improvement without worsening of MASH in up to 34.5% of participants in an ITT analysis

Supplemental AI-based analysis demonstrated statistically significant reductions in liver fibrosis at 24 weeks

Weight loss of up to 6.2% at 24 weeks with no plateauing

Potentially best-in-class tolerability, with less than 1% treatment discontinuations due to adverse events in pemvidutide-treated participants

Conference call to be held on June 26, 2025 at 8:30 am ET

GAITHERSBURG, Md., June 26, 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 positive topline results from the IMPACT Phase 2b trial of pemvidutide in metabolic dysfunction-associated steatohepatitis (MASH).

The Phase 2b trial enrolled 212 participants with biopsy-confirmed MASH and fibrosis stages F2/F3 with and without diabetes randomized 1:2:2 to receive either weekly subcutaneous pemvidutide at 1.2 mg or 1.8 mg doses or placebo for 24 weeks. Treatment discontinuation rates were low, with only 9% of participants prematurely discontinuing treatment. In an intent-to-treat (ITT) analysis, in which participants with missing biopsies were considered non-responders, the proportions of participants achieving MASH resolution without worsening of fibrosis at 24 weeks were 59.1% and 52.1% for pemvidutide 1.2 mg and 1.8 mg, respectively versus 19.1% for placebo ($p< 0.0001$ both doses). The effects on fibrosis improvement without worsening of MASH in an ITT analysis were 31.8% and 34.5% for pemvidutide 1.2 mg and 1.8 mg, respectively compared with 25.9% for placebo (differences not statistically significant). A supplemental AI-based analysis demonstrated statistically significant reductions in fibrosis, including 30.6% of participants receiving pemvidutide 1.8 mg achieving a 60% or more reduction in fibrosis compared to 8.2% receiving placebo ($p< 0.001$). Statistically significant changes in well-established non-invasive tests (NITs) of fibrosis, including Enhanced Liver Fibrosis score (ELF) and Vibration-Controlled Transient Elastography (VCTE) were also observed compared with placebo at both doses. Together, these data suggest strong evidence of anti-fibrotic activity of pemvidutide in the MASH population. At 24 weeks, mean weight loss in pemvidutide-treated participants was 5.0% and 6.2% at the 1.2 mg and 1.8 mg doses, respectively, versus 1.0% in the placebo arm ($p< 0.001$, both doses). Pemvidutide also demonstrated favorable safety and tolerability, with 0.0% and 1.2% adverse events (AE) related discontinuations in the pemvidutide 1.2 mg and 1.8 mg groups versus 2.4% in the placebo group, and there were no serious adverse events (SAEs) related to study medication.

“These data represent an important step forward in the development of pemvidutide for the treatment of MASH and reinforce our conviction in its potential to disrupt the treatment paradigm in this serious and rapidly growing disease,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “Despite a prevalence expected to exceed 27 million by 2030 in the United States alone, current treatment options are limited. We are excited to continue our efforts to bring this potentially transformative therapy to MASH patients.”

Dr. Mazen Noureddin, Professor of Medicine at the Houston Methodist Hospital and Co-Chairman of the Board for Summit and Pinnacle Clinical Research, commented, “The combination of MASH resolution and weight loss achieved at only 24 weeks is unique among drugs in development for MASH. The tolerability of pemvidutide was also impressive, with one of the lowest rates of AE-related drug discontinuations observed in any MASH clinical trial to date. The significant reduction in fibrosis in AI-based readings and its corroboration with established NITs suggest that pemvidutide has potent anti-fibrotic activity and that statistical significance on the fibrosis improvement endpoint could be achieved with longer durations of treatment.”

Dr. Scott Harris, Chief Medical Officer of Altimmune, emphasized that “Based on the results generated in the IMPACT trial, pemvidutide demonstrated significant MASH resolution and encouraging evidence of fibrosis improvement at 24 weeks. Additionally, when one considers the weight loss and favorable tolerability associated with pemvidutide, we believe that there is a clear path to a successful End of Phase 2 meeting with the FDA in the fourth quarter of 2025, enabling rapid progression to Phase 3.”

Highlights from the 24-week Topline Results

- In an ITT analysis, MASH resolution without worsening of fibrosis was achieved in 59.1% and 52.1% of participants treated with pemvidutide 1.2 mg and 1.8 mg, respectively, vs. 19.1% of participants treated with placebo ($p< 0.0001$, both doses).
- In an additional ITT analysis, fibrosis improvement without worsening of MASH was achieved in 31.8% and 34.5% of participants treated with pemvidutide 1.2 mg and 1.8 mg vs. 25.9% of participants treated with placebo (differences not significant).
- A supplemental AI-based analysis demonstrated statistically significant reductions in fibrosis, which included 30.6% of participants receiving pemvidutide 1.8 mg achieving a 60% or more reduction in fibrosis compared to 8.2% receiving placebo ($p< 0.001$).
- Pemvidutide-treated participants also achieved statistically significant reductions in non-invasive tests of fibrosis (ELF and VCTE) and inflammation (alanine aminotransferase, ALT).
- A total of 25.8% and 24.1% of participants receiving pemvidutide 1.2 mg and 1.8 mg, respectively, achieved the stringent

endpoint of MASH resolution and fibrosis improvement versus 13.5% in participants receiving placebo (differences not significant).

- Participants receiving pemvidutide 1.2 mg and 1.8 mg achieved weight loss of 5.0% and 6.2% vs. 1.0% in placebo ($p< 0.001$), with the trajectory showing no plateauing at 24 weeks.
- Liver fat reductions of 58.0% and 62.8% were achieved in participants who received pemvidutide 1.2 mg and 1.8 mg, respectively, vs. 16.2% in participants who received placebo ($p< 0.001$, both doses).
- AEs leading to treatment discontinuation were 0.0% and 1.2% for pemvidutide 1.2 mg and 1.8 mg, respectively, vs. 2.4% in participants on placebo.
- No SAEs related to study drug or arrhythmias were reported at 24 weeks.
- Glycemic control was maintained with minimal changes in HbA1C regardless of diabetic status.

Primary Endpoint (ITT analyses)	**Placebo (N=85)**	**Pemvidutide 1.2 mg (N=42)**	**Pemvidutide 1.8 mg (N=85)**
MASH resolution without worsening of fibrosis (%; LSM, *Chi-Square Test*)	19.1	59.1****	52.1****
Fibrosis improvement without worsening of MASH (%; LSM, *Chi-Square Test*)	25.9	31.8	34.5

**** $p< 0.0001$ vs. placebo; LSM, least squares mean

Secondary Endpoints	**Placebo (N=85)**	**Pemvidutide 1.2 mg (N=42)**	**Pemvidutide 1.8 mg (N=85)**
Proportion of participants achieving the composite of both MASH resolution and improvement of liver fibrosis at 24 weeks (%; LSM, *Chi-Square Test*)	13.5	25.8	24.1
Relative change in body weight at 24 weeks (%; LSM, *MMRM*)	-1.0	-5.0***	-6.2***

*** $p< 0.001$ vs. placebo; LSM, least square mean; MMRM, mixed model for repeated measures

Other Secondary Endpoints	**Placebo**	**Pemvidutide 1.2 mg**	**Pemvidutide 1.8 mg**
Relative reduction in liver fat content by MRI-PDFF (%; LSM, *ANCOVA*)	16.2 N=75	58.0*** N=40	62.8*** N=79
Absolute change in alanine aminotransferase (ALT) (IU/L; LSM, *MMRM*)	-10.0 N=85	-34.6*** N=42	-34.4*** N=85
Absolute change in Enhanced Liver Fibrosis (ELF) score (LSM, *ANCOVA*)	0.03 N=73	-0.6*** N=40	-0.5*** N=76
Absolute change in Vibration-Controlled Transient Elastography (VCTE) (kPa; LSM, *ANCOVA*)	-0.5 N=75	-3.3** N=38	-2.0* N=78
Proportion of participants with reduction of > 0.5 ELF + 25% VCTE, (%; *CMH*)	5.9 N=85	38.1†††† N=42	20.0† N=85

* $p< 0.05$, ** $p< 0.005$, *** $p< 0.001$ vs. placebo (ANCOVA or MMRM)

† $p< 0.05$, †††† $p< 0.0001$ vs. placebo; LSM, least square mean; CMH, Cochran-Mantel-Haenszel; ANCOVA, analysis of co-variance

AI-based Fibrosis Analysis (ITT analyses)	**Placebo (N=85)**	**1.2 mg (N=42)**	**1.8 mg (N=85)**
Proportion of participants with a 30% reduction (%; *CMH*)	21.2	38.1†	49.4†††
Proportion of participants with a 40% reduction (%; *CMH*)	17.6	31.0	43.5†††
Proportion of participants with a 50% reduction (%; *CMH*)	12.9	19.0	35.3†††
Proportion of participants with a 60% reduction (%; *CMH*)	8.2	11.9	30.6†††

† p< 0.05, ††† p< 0.001 vs. placebo; CMH, Cochran-Mantel-Haenszel

Adverse Events (AEs)	Placebo (N=85)	1.2 mg (N=42)	1.8 mg (N=85)
Serious AEs, n (%)	3 (3.5)	1 (2.4)	3 (3.5)
Serious AEs related to study med, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Severe AEs, n (%)	2 (2.4)	1 (2.4)	4 (4.7)
AEs leading to treatment discontinuation, n (%)	2 (2.4)	0 (0.0)	1 (1.2)
AEs of Special Interest, n (%)	0 (0.0)	0 (0.0)	0 (0.0)

Conference Call and Webcast
Altimmune will host a conference call and webcast on Thursday, June 26, 2025 at 8:30 am ET to review the Topline IMPACT data. In addition to remarks from Altimmune management, the call will include a discussion of the data and its implications with IMPACT Principal Investigator, Mazen Noureddin, M.D., MHSc.

The event will be available via the Events section of the Altimmune website.

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

About Pemvidutide
Pemvidutide is a novel, investigational, peptide-based 1:1 GLP-1/glucagon dual receptor agonist in development for the treatment of MASH, obesity, Alcohol Use Disorder (AUD) and Alcohol-associated Liver Disease (ALD). Activation of the GLP-1 and glucagon receptors is believed to mimic the complementary effects of diet and exercise on weight loss, with GLP-1 suppressing appetite and glucagon increasing energy expenditure. Glucagon is also recognized as having direct effects on hepatic fat metabolism, which is believed to lead to rapid reductions in levels of liver fat and serum lipids. In clinical trials to date, once-weekly pemvidutide has demonstrated statistically significant MASH resolution and positive trends in liver fibrosis improvement, compelling weight loss with class-leading lean mass preservation, and robust reductions in liver fat content, triglycerides, LDL cholesterol and blood pressure. The U.S. FDA has granted Fast Track designation to pemvidutide for the treatment of MASH. Pemvidutide completed the MOMENTUM Phase 2 obesity trial in 2024 and is being studied in the ongoing IMPACT Phase 2b MASH trial. IND applications in AUD and ALD have received FDA clearance, with a Phase 2 trial in AUD underway and a Phase 2 trial in ALD scheduled to commence in the third quarter of 2025.

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, AUD and ALD. For more information, please visit www.altimmune.com.

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

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, including the results of the IMPACT Phase 2b Trial and statements relating to fibrosis improvement and the achievement of statistical significance on the fibrosis improvement endpoint, the timing of key milestones for the Company's clinical assets, future plans or expectations for pemvidutide for the treatment of MASH, 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.

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 Comms
Phone: 619-849-5383
jake.robison@inizioevoke.com

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

Source: Altimmune, Inc