Altimmune Receives FDA Breakthrough Therapy Designation for Pemvidutide in MASH

January 5, 2026 at 7:30 AM EST

Alignment on Phase 3 registrational trial parameters confirmed following receipt of minutes from end-of-phase 2 meeting with U.S. FDA

GAITHERSBURG, Md., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company developing therapies that address serious liver diseases, today announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for pemvidutide, a balanced 1:1 glucagon/GLP-1 dual receptor agonist, for the treatment of patients with metabolic dysfunction-associated steatohepatitis (MASH).

Breakthrough Therapy Designation is intended to expedite the development and review of medicines that are intended to treat a serious or life-threatening condition and have shown preliminary clinical evidence indicating the potential for substantial improvement over available therapies on a clinically significant endpoint.

“The FDA’s Breakthrough Therapy Designation for pemvidutide in MASH reinforces the promise of its clinical profile and potential to address significant unmet needs in this serious, progressive liver disease,” said Jerry Durso, President and Chief Executive Officer of Altimmune. “As I step into the CEO role, this designation represents an important validation for pemvidutide. Phase 2b data support its differentiated profile and the meaningful role it could play in MASH, and potentially other serious liver diseases. With this breakthrough designation and alignment with the FDA on registrational Phase 3 trial parameters, we are laser-focused on strengthening the foundation of Altimmune to advance pemvidutide through late-stage development – guided by our commitment to serve patients and create value for our stakeholders.”

Breakthrough Therapy Designation for pemvidutide in MASH was granted based on submission of 24-week data from the IMPACT Phase 2b trial demonstrating statistically significant MASH resolution without worsening of fibrosis, along with early and substantial improvements in liver fat and non-invasive tests of fibrosis and hepatic inflammation. In December 2025, Altimmune reported 48-week topline IMPACT data showing that continued treatment with pemvidutide resulted in statistically significant improvements versus placebo in key non-invasive tests, including Enhanced Liver Fibrosis (ELF) and Liver Stiffness Measurement (LSM), with additional reductions from week 24 across both dose levels, supporting ongoing antifibrotic activity. At 48 weeks, patients receiving the 1.8 mg dose achieved further weight loss with no evidence of plateauing, and pemvidutide maintained the favorable tolerability profile observed at 24 weeks, including a lower discontinuation rate due to adverse events compared with placebo.

Altimmune completed a productive end-of-phase 2 meeting with the FDA last month, resulting in alignment on parameters for a registrational Phase 3 trial of pemvidutide in MASH patients with moderate to advanced liver fibrosis as reflected in the final meeting minutes. The Company plans to initiate a Phase 3 trial evaluating multiple pemvidutide doses over a 52-week treatment period. The trial is expected to incorporate biopsy-based endpoints to support a potential accelerated approval and the use of AIM-MASH AI Assist, the first AI pathology tool qualified by the FDA for use in MASH clinical trials. As previously disclosed, the Company also will be seeking scientific advice from European regulators, which will be considered when finalizing the Phase 3 protocol.

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. Currently approved treatment options may not fully address both the metabolic drivers and fibrosis that can pose long-term risk for patients living with MASH.

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, 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. 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 in development 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 potential benefits of Breakthrough Therapy Designation, including regulatory timeline and approval benefits, the clinical trial results, 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, 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.

Investor Contact:
Lee Roth
Burns McClellan
Phone: 646-382-3403
lroth@burnsmc.com

Media Contact:
Savannah Valade
Real Chemistry
Altimmune@realchemistry.com

Source: Altimmune, Inc