Altimmune Initiates PERFORMA Phase 3 Trial of Pemvidutide in Patients with MASH

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Global registrational study designed to evaluate pemvidutide on fibrosis improvement, MASH resolution, and clinical outcomes

Initiation marks advancement of Altimmune's lead program into late-stage development following positive IMPACT Phase 2b data

GAITHERSBURG, Md., Aug. 03, 2026 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a late clinical-stage biopharmaceutical company focused on serious liver diseases, today announced that the company has begun enrolling patients in the PERFORMA Phase 3 trial evaluating the efficacy and safety of pemvidutide in patients with metabolic dysfunction-associated steatohepatitis (MASH). Pemvidutide is an investigational balanced glucagon/GLP-1 dual receptor agonist also in development for the treatment of alcohol use disorder (AUD) and alcohol-associated liver disease (ALD).

The PERFORMA trial is a global, Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy, safety, and clinical outcomes of pemvidutide in MASH patients with moderate to advanced fibrosis. PERFORMA is Altimmune's registrational study for pemvidutide in MASH and will assess the effects of treatment on fibrosis improvement and MASH resolution as well as clinical outcomes. The trial follows positive findings from the IMPACT Phase 2b study and incorporates feedback from the U.S. Food and Drug Administration (FDA) and European regulatory agencies. The 52-week data readout from the trial is anticipated in 2029.

"The body of evidence, including favorable safety and tolerability, generated from the IMPACT Phase 2 trial supports the potential of pemvidutide as we advance into the PERFORMA Phase 3 trial," said Christophe Arbet-Engels, M.D., Ph.D., Chief Medical Officer of Altimmune. "With the balanced one-to-one glucagon/GLP-1 receptor agonism providing direct effects on the liver, as well as metabolic benefits, pemvidutide may offer an important new treatment option for patients with MASH and serious liver diseases. We look forward to evaluating pemvidutide in a registrational setting."

“Initiating the PERFORMA Phase 3 trial is a key milestone for Altimmune and for the advancement of MASH treatment. We’re building momentum across our pemvidutide program in multiple indications, including the recently announced positive RECLAIM Phase 2 data in AUD. We remain focused on pemvidutide’s potential differentiation as we advance our franchise,” said Jerry Durso, Chief Executive Officer and Chairman of the Board of Altimmune. “In just three months, we moved from securing funding for PERFORMA to initiating the trial, reinforcing Altimmune’s commitment to execute with speed and efficiency.”

In the IMPACT Phase 2b study, pemvidutide demonstrated statistically significant MASH resolution rates, improvements in non-invasive measures of fibrosis and liver health, meaningful weight loss, and a generally favorable tolerability profile. The FDA granted Fast Track Designation and Breakthrough Therapy Designation to pemvidutide for the treatment of MASH.

MASH affects millions of individuals worldwide and is a leading cause of liver fibrosis, cirrhosis, liver transplantation, and liver-related mortality. More than 80% of patients with MASH are overweight or obese, highlighting the importance of therapies that address both liver disease and underlying metabolic dysfunction.

“MASH is a complex disease, and as clinicians, we need therapies that can effectively address both liver disease and the broader metabolic dysfunction that contributes to long-term health risks,” said Naim Alkhouri, MD, Chief Medical Officer, Summit Clinical Research and a principal investigator of the PERFORMA trial. “The initiation of PERFORMA is exciting because it will allow us to evaluate whether the broad improvements observed with pemvidutide in earlier studies can translate into meaningful outcomes for a larger population of patients with MASH.”

About the PERFORMA Phase 3 Study

The PERFORMA trial is a global, randomized, double-blind, placebo-controlled, parallel-group Phase 3 study evaluating the efficacy and safety of pemvidutide in adults with metabolic dysfunction-associated steatohepatitis (MASH) and confirmed moderate to advanced liver fibrosis (F2–F3). The study is an event-driven study with an interim analysis to support the accelerated approval. The study includes two parallel cohorts; Cohort 1 will enroll approximately 990 patients and is designed to support the accelerated approval pathway based on a biopsy-assessed primary efficacy endpoint of MASH resolution and/or fibrosis improvement at 52 weeks. A second cohort will enroll approximately 800 patients with fibrosis as evidenced through non-invasive tests (NITs) to add to the safety dataset. The study incorporates a simple, 1- or 2- step monthly dose titration from 1.2mg to the 1.8mg or 2.4mg trial doses, respectively, to further improve tolerability. The PERFORMA trial will integrate the FDA-qualified AIM-MASH AI Assist tool to help standardize histological assessment of liver biopsy samples. Both cohorts will support the final regulatory approval which will be based on liver-related events at ~60 months.

About Pemvidutide

Pemvidutide is a novel, investigational peptide with balanced 1:1 glucagon/GLP-1 dual receptor agonist activity that has an effect on reducing liver fat, inflammation, and fibrosis, 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, while GLP-1 receptors mediate metabolic effects such as appetite suppression and weight loss and are involved in pathways related to craving and reward.

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 topline 48-week data from the IMPACT Phase 2b trial in MASH. In July 2026, the Company announced topline results from the RECLAIM Phase 2 trial in AUD. The RESTORE trial in ALD was initiated in July 2025, and enrollment completion is expected in the third quarter 2026. The PERFORMA Phase 3 trial, a global, randomized, double-blind, placebo-controlled, parallel-group study of pemvidutide in patients with MASH was initiated in August 2026.

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 investigational 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 Statements

This press release has been prepared by Altimmune, Inc. ("we," "us," "our," "Altimmune" or the "Company") and includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the timing of key milestones for our clinical assets, the performance of our drug candidates in ongoing and future clinical trials including the RECLAIM trial, the ongoing RESTORE trial and PERFORMA trial, evaluating pemvidutide in patients with MASH, AUD and ALD, the potential benefits of Fast Track and Breakthrough Therapy Designations and the prospects for regulatory approval, commercializing, market size, market potential, competitive landscape, or selling any product or drug candidates. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential", "suggest" and similar expressions and their variants, as they relate to the Company 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 such as 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; patient baseline characteristics which may vary and impact the success of future trials; 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; whether the FDA will agree with the Company's proposed development and regulatory strategy for pemvidutide in AUD, including following any End-of-Phase 2 meeting; the risk that results from the RECLAIM trial may not be predictive of results in the RESTORE trial, the PERFORMA trial, or any other future or larger clinical trial; the Company's need for substantial additional capital to complete development of pemvidutide, which may not be available on acceptable terms or at all; competition from other companies developing treatments for MASH, AUD and ALD; and the success of future product advancements, including the success of current and 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 latest annual report on Form 10-K, quarterly report on Form 10-Q and our other filings with the SEC, which are available at www.sec.gov.

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