Altimmune Announces Publication of Clinical Study of Pemvidutide in Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) in Journal of Hepatology

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Weekly subcutaneous doses of pemvidutide resulted in up to 68.5% relative reduction in liver fat content (LFC), with up to 55.6% of subjects achieving LFC normalization after 12 weeks of treatment

LFC changes were accompanied by significant improvements in body weight and non-invasive markers of liver inflammation

Pemvidutide is currently being evaluated in the Phase 2b IMPACT trial in subjects with metabolic dysfunction-associated steatohepatitis (MASH), with data readout expected in Q1 2025

GAITHERSBURG, Md., July 25, 2024 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced the data from its 12-week clinical trial of pemvidutide, an investigational GLP-1/glucagon dual receptor agonist, in metabolic dysfunction-associated steatotic liver disease (MASLD) has been published in the Journal of Hepatology.

"MASLD is estimated to affect 25% of adults globally, with between 20% and 30% of patients progressing to MASH, making this an area of great unmet medical need," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "With nearly all subjects achieving 30% or more reductions in liver fat content after only 12 weeks of treatment, this study demonstrates the potential of pemvidutide to achieve class-leading effects in the treatment of MASH. We look forward to sharing results from our ongoing biopsy-driven Phase 2b IMPACT trial of pemvidutide in MASH early next year."

In the study, 94 subjects with obesity or overweight and LFC ≥10% were randomized and dosed 1:1:1:1 to pemvidutide (1.2mg, 1.8mg and 2.4mg) or placebo administered once-weekly subcutaneously for 12 weeks. The study did not include diet or exercise interventions. Relative reductions in LFC from baseline, the study's primary efficacy endpoint, were up to 68.5% in subjects receiving pemvidutide compared to 4.4% in subjects receiving placebo. Responder analyses showed that up to 94.4% of subjects receiving pemvidutide achieved ≥30% relative reduction in LFC, an important predictor of MASH resolution and fibrosis improvement, compared to only 4.2% receiving placebo ($p < 0.0001$ vs. placebo, respectively). Moreover, up to 55.6% of subjects receiving pemvidutide achieved LFC normalization, defined as an LFC ≤5%, compared to 0% of subjects receiving placebo. Significant reductions in body weight and established markers of MASH inflammatory activity, including alanine aminotransferase (ALT) and corrected T1 (cT1) MRI imaging, were also observed. Pemvidutide was well-tolerated, with a 2.9% rate of adverse event discontinuations in subjects receiving pemvidutide, and no severe or serious adverse events.

"We're excited to publish the results of this study that demonstrate pemvidutide's ability to significantly reduce liver fat, body weight, and hepatic inflammatory activity, supporting its potential as a treatment for MASH and obesity," said Scott Harris, M.D., Chief Medical Officer of Altimmune. "Unlike other incretin-based therapies that lack glucagon activity, pemvidutide has a direct effect on hepatic fat metabolism, providing a mechanism for potentially more potent reductions in liver fat than that achieved through weight loss alone. Although not reported in this publication, the Phase 1 trial was extended for an additional 12 weeks, which resulted in up to 76.4% relative reduction in liver fat and further improvement in hepatic inflammation, and we look forward to the publication of these data in the near future."

About Pemvidutide
Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and MASH. 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 compelling weight loss, robust reductions in triglycerides, LDL cholesterol, liver fat content and blood pressure. The U.S. FDA has granted Fast Track designation to pemvidutide for the treatment of MASH. Pemvidutide recently completed the MOMENTUM Phase 2 obesity trial and is being studied in the ongoing IMPACT Phase 2b MASH trial.

About Altimmune
Altimmune is a clinical-stage biopharmaceutical company focused on developing innovative next-generation peptide-based therapeutics. The Company is developing pemvidutide, a GLP-1/glucagon dual receptor agonist for the treatment of obesity and MASH. For more information, please visit www.altimmune.com.

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Any statements made in this press release 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, and the prospects for the utility of, regulatory approval, 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 and our other filings with the SEC, which are available at www.sec.gov.

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