Altimmune Granted Fast Track Designation by FDA for Pemvidutide for the Treatment of Non-Alcoholic Steatohepatitis (NASH)

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GAITHERSBURG, Md., Oct. 26, 2023 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to its clinical program investigating pemvidutide for the treatment of NASH.

NASH is a serious, potentially life-threatening condition that is a leading cause of liver failure and liver transplantation globally. NASH is a growing public health concern, and there are currently no approved treatments. The Fast Track designation is designed to facilitate the development and expedite the review of new drugs intended to treat serious conditions and address unmet medical needs.

"The FDA's decision was informed by the results of Altimmune's studies including its Phase 1b randomized, placebo-controlled study of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD), which showed class-leading relative reductions in liver fat and non-invasive markers of hepatic inflammation and a favorable safety and tolerability profile," said Vipin K. Garg, Ph.D., President and CEO of Altimmune. "The Fast Track designation reflects Altimmune's commitment to patients with NASH and efforts to find safe and effective treatments for this condition."

The efficacy and safety of pemvidutide in NASH are being evaluated in IMPACT, a Phase 2b randomized, placebo-controlled biopsy-driven trial that is being conducted at approximately 60 sites in the U.S. Approximately 190 subjects with and without diabetes are being enrolled. Key efficacy endpoints are NASH resolution and fibrosis improvement at 24 weeks of treatment, with subjects followed for an additional 24 weeks to a total of 48 weeks for safety and biomarker responses. In addition to IMPACT, the efficacy and safety of pemvidutide in obesity is being evaluated in MOMENTUM, a Phase 2b, randomized, placebo-control trial that is being conducted at approximately 30 sites in the U.S. An interim analysis of 160 subjects completing 24 weeks of treatment was reported in Q1 2023, and full results of 391 subjects receiving up to 48 weeks of treatment are expected later this quarter.

About Pemvidutide

Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and NASH. 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, leading to rapid reductions in levels of liver fat. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while likely slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability.

About Altimmune

Altimmune is a clinical-stage biopharmaceutical company focused on developing innovative next-generation therapeutics for the treatment of obesity and liver diseases. The Company's lead product candidate, pemvidutide, is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and NASH. In addition, Altimmune is developing HepTcell ™, an immunotherapeutic designed to achieve a functional cure for chronic hepatitis B. For more information, please visit www.altimmune.com.

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Forward-Looking Statement

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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