Altimmune Announces Initiation of 12-week Phase 1b Trial of Pemvidutide in Subjects with Non-Alcoholic Fatty Liver Disease

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- *First patient has been enrolled in 12-week non-alcoholic fatty liver disease (NAFLD) study*
- *Dr. Stephen Harrison will be serving as Principal Investigator for the study*
- *Topline data readout expected in the first half of 2022*

GAITHERSBURG, Md., Oct. 04, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has enrolled the first patient in a Phase 1b clinical trial of pemvidutide (proposed INN, formerly known as ALT-801) in subjects with non-alcoholic fatty liver disease (NAFLD). Pemvidutide is a novel, investigational GLP-1/glucagon dual receptor agonist under development for the treatment of obesity and non-alcoholic steatohepatitis (NASH), the most severe form of NAFLD.

The trial is being conducted at multiple sites in the United States with Dr. Stephen Harrison, a renowned expert in the field of NASH and liver diseases, serving as the Principal Investigator. This double-blind, randomized, placebo-controlled study will enroll approximately 72 diabetic and non-diabetic overweight and obese adult patients with a liver fat content greater than 10% as measured by MRI-PDFF. Pemvidutide will be administered weekly at one of three dose levels versus placebo over 12 weeks. The primary efficacy endpoint is change in liver fat content from baseline, as measured by MRI-PDFF. Secondary efficacy endpoints include weight loss, serum lipid profile, hemoglobin A1c, adiponectin, and inflammatory and fibrosis markers. The study is expected to read out topline results in the first half of 2022. Based on the findings of the NAFLD study, the Company intends to initiate a 52-week biopsy driven Phase 2 NASH study in 2022.

“We are excited to initiate this NAFLD trial as we build on our recent clinical trial results in overweight and obese subjects, where we saw 10.3% weight loss at the 1.8 mg dose and positive effects on blood pressure, serum lipids and insulin resistance in only 12-weeks,” said Dr. Scott Harris, Chief Medical Officer of Altimmune. “Studies show that sustained weight loss greater than 10% leads to NASH resolution and fibrosis improvement. Meaningful weight loss, combined with the potent effects of glucagon agonism on liver fat, as observed in animal models, make a compelling case for pemvidutide in the treatment of NASH.”

NAFLD is a precursor to NASH, characterized by the buildup of excess fat in liver cells, usually as a consequence of obesity. It is estimated that more than 100 million people in the United States have NAFLD, and it is now the most common form of liver disease in children. If unaddressed, the condition may progress to NASH, where the liver is chronically inflamed and becomes fibrotic, and eventually cirrhosis. The World Hepatitis Alliance recently reported that NASH is now the most common reason for a liver transplant in women, older patients and people receiving Medicare insurance in the United States.

Altimmune believes the treatment of obesity is the cornerstone of treating NASH and its co-morbidities and views the treatment of obesity and NASH as significant unmet medical needs that can be addressed through significant weight loss. In a 12-week Phase 1 study in Australia, subjects receiving pemvidutide achieved mean weight losses of 4.9%, 10.3%, and 9.0% at 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, with the placebo group experiencing a mean weight loss of 1.6%. Weight loss occurred rapidly and consistently over 12-weeks. Side effects were mild to moderate, with no serious or severe treatment-emergent adverse events. Importantly, pemvidutide was well-tolerated without the need for dose titration, and no discontinuations due to adverse events were reported.

Pemvidutide development plan
An Investigational New Drug (IND) application in NASH recently cleared the U.S. Food and Drug Administration (FDA) review, enabling this 12-week Phase 1b trial in subjects with NAFLD. The Company has also commenced a drug-drug interaction trial in Australia and plans to initiate a trial of glucose control in patients with type 2 diabetes in the U.S. later this year. Topline data from all three trials are expected in the first half of 2022.

The Company intends to file a second IND application in obesity in 2021 with plans to initiate a 48-week, Phase 2 obesity trial in H1 2022.

About Altimmune

Altimmune is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver diseases. Our pipeline includes next generation peptide therapeutics for obesity, NASH (pemvidutide), and chronic hepatitis B (HepTcell™). For more information on Altimmune, 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, the initiation of the Type 2 diabetes trial in 2021, 12-week study readout of the Phase 1b NAFLD trial in the first half of 2022, the initiation of a 52-week NASH clinical trial in 2022, the timing of topline data for the drug-drug interaction trial and type 2 diabetes trial in the first half of 2022, the timing of the filing of an additional IND for obesity in Q4 2021, initiation of a 48-week Phase 2 obesity trial in H1 2022, the potential therapeutic effects of pemvidutide, the prospects for regulatory approval, our ability to manufacture pemvidutide for our clinical trials and commercial needs, and 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. (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 relating to: potential impacts due to the COVID-19 pandemic 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; 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 and commercial supply 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 annual report on Form 10-K for the fiscal year ended December 31, 2020 filed with the SEC, which is available at www.sec.gov.

Altimmune Investor & Media Contact:

Will Brown
Chief Financial Officer
Phone: 240-654-1450
wbrown@altimmune.com

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