Altimmune Announces Initiation of 48-week Phase 2 MOMENTUM Trial of Pemvidutide in Obesity

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The Company also announces completion of enrollment in 12-week, Phase 1b trial of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD)

GAITHERSBURG, Md., April 01, 2022 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that it has enrolled the first subject in the 48-week Phase 2 MOMENTUM trial evaluating the safety and efficacy of pemvidutide[1] in subjects with obesity or overweight. Pemvidutide is a novel, investigational GLP-1/glucagon dual receptor agonist under development for the treatment of obesity and non-alcoholic steatohepatitis (NASH). The Company also today announced the completion of enrollment in its 12-week Phase 1b clinical trial of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD).

The 48-week MOMENTUM trial is being conducted at approximately 25 sites in the United States with Dr. Lou Aronne, a leading authority in obesity and obesity clinical trials, serving as the Principal Investigator. The randomized, placebo-controlled trial is expected to enroll approximately 320 non-diabetic subjects randomized 1:1:1:1 to receive either 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo weekly for 48 weeks. The primary endpoint of the trial is the relative (percent) change in body weight at 48-weeks compared to baseline, with additional readouts including metabolic and lipid profiles, cardiovascular measures and glucose homeostasis. An interim analysis is planned to assess changes in body weight after 24 weeks of treatment, with an expected readout in Q4 2022.

“Initiation of the Phase 2 MOMENTUM obesity trial marks an important milestone in the development of pemvidutide,” stated Dr. Scott Harris, Chief Medical Officer at Altimmune. “Built on a foundation of compelling Phase 1 clinical data, we see a great potential for pemvidutide to address the serious and widespread disease of obesity and its debilitating consequences.”

Results from a Phase 1 trial of pemvidutide in individuals with obesity or overweight showed that 12 weekly subcutaneous doses of pemvidutide resulted in an average weight loss of 10.3%, or approximately 20 pounds, without diet or lifestyle modification. If these effects continue over the 48-week study as anticipated, weight loss approaching or equaling those of bariatric surgery may be achieved. Side effects were mild to moderate, with no serious or severe treatment-emergent adverse events, even without the dose-titration schedules commonly used by other therapeutics in this class.

Significant progress has also been made in the development of pemvidutide for the treatment of NASH, including the completion of enrollment in a 12-week Phase 1b trial in subjects with NAFLD, and the initiation of a blinded, 12-week NAFLD extension trial. The 12-week Phase 1b NAFLD trial is designed to assess the effects of pemvidutide on liver fat in subjects with obesity or overweight and liver fat content of 10% or greater as measured by MRI-PDFF. Approximately 72 subjects with or without diabetes are being randomized 1:1:1:1 to receive pemvidutide 1.2 mg, 1.8 mg, 2.4 mg or placebo weekly over the 12 weeks of treatment. The primary endpoint of the trial is the reduction in liver fat by MRI-PDFF, but a key secondary endpoint is percent weight loss at the end of 12 weeks of treatment, reflecting the fact that obesity is a key driver of NAFLD and its more advanced form, NASH. A data readout from the 12-week trial is expected in Q3 2022, and it is expected that the cumulative weight loss at 24 weeks in combination with the extension trial will be reported out in Q4 2022.

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. By combining GLP-1 and glucagon activity in a single peptide, pemvidutide has the potential to achieve weight loss comparable to bariatric surgery. Pemvidutide also has been shown to increase the breakdown of fat and its mobilization within the liver, which may have beneficial effects on not only fat-related liver diseases like NASH, but also insulin resistance, a common problem in people with obesity. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability. In a Phase 1 clinical trial, pemvidutide demonstrated striking reductions in body weight, liver fat and serum lipids.

About Altimmune

Altimmune is a clinical-stage biopharmaceutical company focused on the development of novel peptide-based therapeutics for the treatment of obesity and liver diseases. The company’s lead product candidate, pemvidutide (ALT-801), 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, the 12-week study readout of the Phase 1b NAFLD trial in the third quarter of 2022, the interim analysis of body weight in the obesity trial of pemvidutide in the fourth quarter of 2022, the readout of weight loss in the extension trial of pemvidutide in the fourth quarter of 2022, the potential therapeutic effects of pemvidutide, the safety and tolerability of pemvidutide, the prospects for regulatory approval, and our ability to manufacture pemvidutide for our clinical trials and commercial needs, 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, 2021 filed with the SEC, which is available at www.sec.gov.

Altimmune Investor & Media Contact:

Rich Eisenstadt
Chief Financial Officer
Phone: 240-654-1450
reisenstadt@altimmune.com

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