# Altimmune Announces FDA Clearance of Pemvidutide (ALT-801) IND for Obesity

January 31, 2022

**Enrollment in 48-week Phase 2 clinical trial expected to begin in Q1 2022**

GAITHERSBURG, Md., Jan. 31, 2022 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for its Phase 2 clinical trial of pemvidutide for obesity. Pemvidutide is an investigational GLP-1/glucagon dual receptor agonist under development for the treatment of obesity and non-alcoholic steatohepatitis (NASH). Altimmune expects to initiate the Phase 2 trial in obesity in the first quarter of 2022. The Company previously received IND clearance for pemvidutide in NASH and is currently enrolling subjects with nonalcoholic fatty liver disease (NAFLD) in a Phase 1b trial.

"This Phase 2 trial in obesity represents an important milestone toward developing a safe and effective treatment option for people with obesity," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "Results from a recently completed Phase 1 study of pemvidutide in Australia showed that 12 weekly subcutaneous doses of pemvidutide at the 1.8 mg dose level resulted in an average weight loss of 10.3% in overweight and obese subjects. Importantly, there were no study discontinuations due to adverse events. We believe these results rank among the best in terms of the rate and magnitude of weight loss and tolerability among drugs in development for obesity."

The Phase 2 clinical trial will enroll approximately 320 individuals with obesity or who are overweight with at least one obesity-related complication. Subjects will be randomized 1:1:1:1 to receive either 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks. The primary endpoint of the study 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.

**About Pemvidutide**

Pemvidutide (proposed INN, formerly known as ALT-801) 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 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 study, 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.

**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 and timing of the Phase 2 clinical trial of pemvidutide in Q1 2022, the timing of the data readouts for the Phase 2 clinical trial of pemvidutide, and the prospects for 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. (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 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 and quarterly report on Form 10-Q for the quarter ended September 30, 2021 filed with the SEC, which are available at www.sec.gov.

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**Investor & Media Contacts:**

Richard Eisenstadt
Chief Financial Officer
Phone: 240-654-1450

reisenstadt@altimmune.com

Source: Altimmune, Inc