



## Altimune Announces Successful Completion of End-of-Phase 2 Meeting with FDA for Pemvidutide in the Treatment of Obesity

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*Company and Agency aligned on key efficacy and safety measures to be studied in Phase 3 program*

*Pivotal Phase 3 trials designed to leverage the differentiated attributes of pemvidutide and potential benefits of balanced GLP-1/glucagon dual agonism*

GAITHERSBURG, Md., Nov. 07, 2024 (GLOBE NEWSWIRE) -- [Altimune, Inc.](#) (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced the successful completion of its End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) and agreement on the design of a Phase 3 registrational program for its product candidate, pemvidutide, in the treatment of obesity.

"Our interactions with the FDA regarding the Phase 3 development program have been incredibly productive, and this regulatory alignment represents a major accomplishment for our team," said Vipin K. Garg, Ph.D., Chief Executive Officer of Altimune. "As the metabolic landscape continues to evolve, we believe that the ability of a drug to address both obesity and its underlying comorbidities will become increasingly important, and we are confident that this is where pemvidutide has an opportunity to excel. Achieving this regulatory milestone is especially important as we advance our partnering efforts, approach the data readout from our Phase 2b IMPACT Trial in MASH and prepare IND submissions for additional indications."

The interaction with the FDA included an extensive review of the preclinical and clinical data generated to date, including data from six completed clinical trials of pemvidutide. The planned registrational program will include four Phase 3, randomized, double-blind, placebo-controlled, parallel-group trials, each evaluating treatment with pemvidutide over a 60-week period. The Phase 3 program is expected to enroll approximately 5,000 subjects across the four trials. The safety and efficacy of pemvidutide doses of 1.2 mg, 1.8 mg, and 2.4 mg will be evaluated with the intention of obtaining approval for all three doses.

The Phase 3 program is designed to leverage the key attributes of pemvidutide, including the effects of balanced GLP-1/glucagon dual agonism in subjects with overweight and obesity.

- **VELOCITY-1:** This trial will assess the effects of pemvidutide on body weight in patients with obesity or overweight without diabetes. Other endpoints will include reductions in waist circumference, serum lipids, and blood pressure.
- **VELOCITY-2:** This trial will assess the effects of pemvidutide on body weight and serum lipids in subjects with obesity or overweight and elevated LDL cholesterol levels. The study population will include a subset of subjects with elevated LDL cholesterol levels despite ongoing statin therapy. A large proportion of patients taking statins fail to achieve target LDL levels, and in a previous Phase 2 clinical trial in subjects with overweight or obesity, pemvidutide appeared to enhance LDL-lowering effects in subjects receiving concomitant statin therapy.
- **VELOCITY-3:** This trial will assess the effects of pemvidutide on body weight in subjects with obesity or overweight and elevated liver fat. Excess liver fat is highly prevalent in patients with obesity and is associated with an increased risk of cardiovascular disease.
- **VELOCITY-4:** This trial will assess the effects of pemvidutide on body weight and body composition, including in an elderly population, with emphasis on individuals entering the study with sarcopenia at baseline. Functional measures and activities of daily living will also be assessed in this patient population.

Scott Harris, M.D., Chief Medical Officer of Altimune added, "We are pleased with the successful outcome of the End-of-Phase 2 meeting with the FDA. We continue to believe that pemvidutide is highly differentiated from other incretin-based agents currently available and in development. The Phase 3 obesity program is designed to maximize the unique attributes of pemvidutide beyond weight loss, including its potential for lipid lowering effects, liver fat reduction and lean mass preservation."

### 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 with class-leading lean mass preservation, and 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 Altimune

Altimune 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](http://www.altimmune.com).

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Any statements made in this press release related to the development or commercialization of product candidates and other business matters,

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