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

November 7, 2024 at 7:30 AM EST

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) -- Altimmune, 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 Altimmune. "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 Altimmune 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 Altimmune
Altimmune 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.

Follow @Altimmune, Inc. on LinkedIn
Follow @AltimmuneInc on Twitter

Forward-Looking Statement
Any statements made in this press release related to the development or commercialization of product candidates and other 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.

Company Contact:
Vipin Garg
President and Chief Executive Officer
Phone: 240-654-1450
ir@altimmune.com

Investor Contact:
Lee Roth
Burns McClellan
Phone: 646-382-3403
lroth@burnsmc.com

Julia Weilman
Burns McClellan
Phone: 646-732-4443
jweilman@burnsmc.com

Media Contact:
Danielle Cantey
Inizio Evoke, Biotech
Phone: 619-826-4657
Danielle.cantey@inizioevoke.com

This press release was published by a CLEAR® Verified individual.

Source: Altimmune, Inc