Altimmune Completes Enrollment in Phase 2b IMPACT Trial of Pemvidutide in Metabolic Dysfunction-Associated Steatohepatitis (MASH)

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IMPACT trial is evaluating the safety and efficacy of pemvidutide in approximately 190 subjects with MASH; top-line efficacy data expected in Q2 2025

End-of-Phase 2 Meeting for the obesity program with U.S. Food and Drug Administration (FDA) has been scheduled for early November 2024

Company plans to submit Investigational New Drug (IND) applications for pemvidutide in up to three additional indications beginning in Q4 2024

GAITHERSBURG, Md., Sept. 30, 2024 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced completion of patient enrollment in IMPACT, its Phase 2b biopsy-driven trial evaluating pemvidutide in metabolic dysfunction-associated steatohepatitis (MASH) and provided an update on additional development and regulatory initiatives related to pemvidutide.

“We continue to make important advancements in the development of pemvidutide and are excited to have completed enrollment in the IMPACT trial, with top-line efficacy data expected in the second quarter of 2025,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “We are also excited to have received FDA confirmation of the End-of-Phase 2 meeting for our obesity program, which is scheduled for early November. Furthermore, we are planning to file INDs for Phase 2 studies of pemvidutide in up to three additional indications. These initiatives are expected to expand the differentiation of pemvidutide in the metabolic disease space and enhance its long-term value proposition.”

“IMPACT will be the first incretin-based study to read out on a biopsy-driven fibrosis endpoint at only 24 weeks. I believe the combination of direct liver effects and weight loss conferred by pemvidutide offers an important advantage over other approaches to the treatment of MASH and I look forward to the results of the IMPACT trial with great optimism,” said Dr. Mazen Noureddin, M.D., MHSc, Professor of Medicine at Houston Methodist Hospital, Director, Houston Research Institute and Principal Investigator on the IMPACT trial.

“We look forward to aligning with the FDA on our Phase 3 clinical development plan for pemvidutide in obesity at our End-of-Phase 2 meeting in early November,” added Dr. Garg. “Our proposed registrational program leverages the unique attributes of pemvidutide, which we believe will benefit patients with obesity, excess liver fat and elevated serum lipids while preserving lean mass.”

Altimmune also expects to file IND applications for pemvidutide in up to three additional indications with the first of these IND submissions in Q4 2024. The company plans to disclose details on these indications following alignment with the FDA. Preparations for the first trial are underway, with initiation planned for H1 2025.

“We believe we have strong scientific rationale to support the development of pemvidutide in these additional indications, all of which are areas of high unmet medical need, where we believe its balanced GLP-1/glucagon dual agonism could allow for differentiation from other approaches,” said Scott Harris, M.D., Chief Medical Officer of Altimmune.

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, robust reductions in triglycerides, LDL cholesterol, liver fat content and blood pressure, while preserving lean mass.
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.

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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 the IMPACT trial data readout, the timing of the planned End-of-Phase 2 FDA meeting, the timing of the planned IND submissions for pemvidutide, the timing of key milestones for any of 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.

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