Altimmune Presents Data at EASL International Liver Congress™ 2024 Supporting the Disease Modifying Potential and Differentiated Therapeutic Profile of Pemvidutide in Metabolic Dysfunction-Associated Steatohepatitis (MASH)

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Follow-on analyses of non-invasive tests from Phase 1 trials in Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) suggest the potential for meaningful histologic improvements with MASH biopsy readouts in Q1 2025

Based on a quantitative systems pharmacology (QSP) computational model, pemvidutide's GLP-1/glucagon dual agonism could have additive effects on MASH resolution and fibrosis improvement compared with GLP-1 alone

Lipidomic profiling reinforces the disease modifying potential of pemvidutide on MASH and MASH-associated co-morbidities, including cardiovascular disease

Pemvidutide is currently being evaluated in the ongoing Phase 2b IMPACT trial in subjects with MASH

GAITHERSBURG, Md., June 05, 2024 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today presented new data on the potential anti-inflammatory and anti-fibrotic properties of pemvidutide in Metabolic Dysfunction-Associated Steatohepatitis (MASH) at the EASL International Liver Congress™ 2024 in MilanJItaly.

"These data, coupled with MOMENTUM Phase 2 obesity trial results that showed class-leading lean mass preservation in body composition, further reinforce the opportunity for pemvidutide to distinguish itself broadly from approved therapies and other clinical candidates targeting MASH and obesity," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "The balanced GLP-1 and glucagon dual agonism of pemvidutide represents a potentially differentiated approach to achieving clinically meaningful reductions in body weight, liver fat, and lipids to ameliorate MASH and address the many MASH-associated co-morbidities."

The data presented are summarized below:

WED-212 (Abstract #3002): *Pemvidutide treatment is associated with improvement in non-invasive tests indicating greater likelihood of histologic response in subjects with metabolic dysfunction-associated steatotic liver disease: a 24-week, randomized, double-blind, placebo-controlled trial*

- 64 subjects who participated in the Phase 1 study of pemvidutide in MASLD were evaluated for changes in FibroScan®-AST (FAST) over 24 weeks of treatment. A subset of subjects with baseline ALT ≥ 30 IU/L were also evaluated for changes in MRI-PDFF and ALT scores.
- Up to 75% of subjects with intermediate-to-high risk of MASH progression (FAST ≥ 0.35) at baseline who received pemvidutide had their risk reduced to low (FAST < 0.35) at Week 24 vs 25% in subjects receiving placebo.
- Up to 60% of subjects achieved a reduction of both MRI-PDFF (≥ 30%) and ALT (≥ 17 IU/L) at Week 24 compared with 0% in subjects receiving placebo. Simultaneous reductions in MRI-PDFF and ALT have been shown in other MASH clinical trials to be associated with a significantly greater likelihood of achieving MASH resolution.

WED-219 (Abstract #2881): *Pemvidutide, a glucagon-like peptide 1/glucagon dual receptor agonist, improves metabolic dysfunction-associated steatohepatitis activity and fibrosis in a clinical quantitative systems pharmacology model*

- A quantitative systems pharmacology (QSP) computational model was used to predict the effects of pemvidutide and the relative contributions of GLP-1 and glucagon receptor agonism on MASH outcomes. Data from a completed clinical trial of pemvidutide in metabolic dysfunction-associated steatotic liver disease (MASLD) subjects were used to calibrate the quantitative effects of pemvidutide 1.8 mg once weekly dosing over 24 weeks.
- A strong correlation was observed between clinically reported and QSP predicted effects of pemvidutide on weight loss and liver fat content.
- The QSP model predicted pemvidutide 1.8 mg would result in complete resolution of MASH and a 1-point median improvement in fibrosis by Week 24.
- Adding glucagon receptor agonism to GLP-1 receptor agonism was also predicted to result in additional reductions in liver fat content and median NAFLD activity score (NAS) compared to GLP-1 receptor agonism alone. GLP-1 receptor monotherapy was predicted to have no effect on fibrosis within the 24-week timeframe.
- Taken together, these results suggest that glucagon receptor agonism could have potent effects on MASH fibrosis, over and above GLP-1 monotherapy.

WED-251 (Abstract #2985): *Plasma lipidomic profiling of subjects with overweight or obesity following treatment with the glucagon-like peptide 1/glucagon dual receptor agonist pemvidutide: an investigation of lipid signatures associated with metabolic dysfunction-associated steatohepatitis*

- Plasma lipidomic profiling was performed on samples collected during Phase 1 studies of pemvidutide in subjects with overweight or obesity, with or without MASLD.
- Subjects treated with pemvidutide had significantly decreased serum lipids from baseline, including glycophospholipids,

sphingolipids and other inflammatory lipid subspecies associated with MASH and cardiovascular disease.

- Pemvidutide treatment was also associated with reduced bile acid dysregulation. Obesity and insulin resistance, two key risk factors for MASH and MASLD, contribute to bile acid dysregulation. Evidence has shown that bile acid dysregulation worsens as MASLD progresses.
- These findings support the disease modifying potential of pemvidutide on MASH and MASH-associated co-morbidities, including cardiovascular disease.

The posters presented at the EASL International Liver Congress™ 2024 are accessible on the Events section of the Altimmune website.

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. 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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