Altimmune Announces Positive Results from Week 24 Interim Analysis of Pemvidutide MOMENTUM Phase 2 Obesity Trial and 12-Week Phase 1b Type 2 Diabetes Safety Trial

March 21, 2023

MOMENTUM Phase 2 Obesity Trial (Week 24 Interim Analysis of 160 Subjects)

- *Mean weight loss of 10.7% (placebo-adjusted 9.7%) at 2.4 mg dose at Week 24*
- *Mean weight loss of 11.9% (placebo-adjusted 11.1%) in subjects weighing 115 kg or less at baseline at 2.4 mg dose at Week 24*
- *Approximately 50% of subjects achieved 10% or more weight loss and approximately 20% of subjects achieved 15% or more weight loss at the 1.8 mg and 2.4 mg doses at Week 24*
- *Robust reductions in waist circumference, serum lipids and blood pressure without meaningful increases in heart rate*
- *Rates of gastrointestinal (GI) adverse events (AEs) similar to earlier pemvidutide trials*

Phase 1b Type 2 Diabetes Safety Trial (Week 12 End-of-Study Analysis)

- *7.7% (placebo-adjusted 8.5%) weight loss at 2.4 mg dose at Week 12*
- *Glycemic homeostasis maintained, with no significant changes in fasting glucose or HbA1c, and no hyperglycemia AEs*
- *Excellent tolerability with low rates of gastrointestinal AEs*

Altimmune to host conference call today at 8:30 am ET

GAITHERSBURG, Md., March 21, 2023 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company (the "Company"), today announced topline results from a Week 24 interim analysis of 160 subjects in its 48-week MOMENTUM Phase 2 obesity trial of pemvidutide along with the results of the 12-week Phase 1b safety trial of pemvidutide in subjects with obesity or overweight and type 2 diabetes.

MOMENTUM Phase 2 Obesity Trial – Week 24 Interim Analysis

The MOMENTUM Phase 2 obesity trial is being conducted at 30 sites across the U.S., with Dr. Louis Aronne, Professor of Metabolic Research and Professor of Clinical Medicine, Weill Cornell Medicine, a leading authority in obesity and obesity clinical trials, serving as the Principal Investigator. The trial was designed to enroll approximately 320 subjects with obesity or overweight with at least one co-morbidity and without diabetes. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks in conjunction with diet and exercise. A pre-specified interim analysis was conducted after 160 subjects completed 24 weeks of treatment. Subjects in the interim analysis had a demographic composition similar to the full study population previously announced, with a median age of approximately 48 years, a median body mass index of approximately 36 kg/m^2, and a median body weight of approximately 100 kg. Approximately 75% of subjects were female, and approximately 20% of subjects were of Hispanic ethnicity.

At Week 24, subjects receiving pemvidutide achieved mean weight losses of 7.3%, 9.4% and 10.7% at the 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, with the placebo group experiencing a mean weight loss of 1.0% ($p < 0.001$ at all three doses vs placebo, efficacy estimand using a mixed model of repeated measures [MMRM] analysis). An impact of baseline body weight was observed, where subjects with baseline body weight less than or equal to 115 kg (75% of the study population) achieved mean weight losses of 8.2%, 10.6%, 11.9% and 0.8% at the 1.2 mg, 1.8 mg, 2.4 mg and placebo groups, respectively ($p < 0.001$ at all three doses vs placebo). Approximately 50% of subjects achieved 10% or more weight loss and approximately 20% of subjects achieved 15% or more weight loss at Week 24 at the 1.8 mg and 2.4 mg doses. Robust reductions in waist circumference (a measure of visceral fat) and serum lipids were also observed, and clinically meaningful reductions in blood pressure were achieved without meaningful increases in heart rate. Glucose homeostasis was also maintained, with no significant changes in fasting glucose or HbA1c.

Regarding safety, upper GI events of nausea and vomiting comprised the majority of AEs. These events were predominantly mild and moderate in severity, dose-related and similar in frequency to those observed in prior trials of pemvidutide. Rates of lower GI AEs including diarrhea and constipation were notably low. This AE profile was observed in the absence of dose titration at the 1.2 mg and 1.8 mg doses and with a limited 4-week dose titration at the 2.4 mg dose. One subject (2.4%) experienced a serious adverse event of nausea and vomiting requiring rehydration at the 2.4 mg dose. Treatment discontinuation rates were 28.2% in subjects receiving placebo and 24.0% in subjects receiving pemvidutide. The majority of placebo discontinuations were due to withdrawal of consent, while approximately half of the withdrawals across the pemvidutide dose groups were attributed to GI AEs. These discontinuations occurred almost entirely in the first 16 weeks of treatment. The protocol did not allow for dose reduction due to intolerability as employed in other incretin trials.

"The weight loss achieved was impressive and bodes well for the effects that could be achieved at the completion of 48 weeks of therapy," said Louis Aronne, M.D., Sanford I. Weill Professor of Metabolic Research and Professor of Clinical Medicine, Weill Cornell Medicine, and a paid scientific advisory board member for Altimmune, Inc. "I believe that the reductions in total and LDL cholesterol, blood pressure and waist circumference have the potential to be compelling product attributes, if approved, for patients with risk factors for cardiovascular disease. The impact of baseline weight, which was likewise observed with semaglutide above 115 kg, suggests that higher doses could be an effective strategy in the population with more severe degrees of obesity."

"We regard these results as extremely promising," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "The ability to achieve robust reductions in body weight, waist circumference, blood pressure, and serum lipids, together with the previously demonstrated best-in-class effects on liver fat reduction, suggest that pemvidutide has the potential to be an important treatment option for patients with obesity, especially those who are at risk for liver disease, dyslipidemia and related conditions." Dr. Garg added, "We believe that the 1.2 mg and 1.8 mg doses used without dose titration would be attractive options for primary care physicians and that we have the opportunity to improve further upon the profile of pemvidutide by utilizing higher doses in patients with more severe degrees of obesity, by allowing dose reduction and by employing a more prolonged titration for doses higher than 1.8 mg in our future trials. We look forward to completing our 48-week MOMENTUM obesity trial in the fourth quarter of 2023 and initiating a Phase 2 biopsy NASH trial in mid-2023."

MOMENTUM Week 24 Interim Analysis—Summary of Efficacy Findings

Primary Endpoint: Body weight		**Placebo (n=39)**	**1.2 mg (n=40)**	**1.8 mg (n=40)**	**2.4 mg (n=41)**
Δ Body weight, all subjects	%, LSM (SE)[1]	-1.0 (0.8)	-7.3 (0.8)***	-9.4 (0.8)***	-10.7 (0.9)***
Impact of Baseline Body Weight on Efficacy		**Placebo (n=28)**	**1.2 mg (n=30)**	**1.8 mg (n=31)**	**2.4 mg (n=31)**
Δ Body weight, subjects with baseline weight ≤ 115 kg	%, LSM (SE)[1]	-0.8 (1.0)	-8.2 (1.1)***	-10.6 (1.1)***	-11.9 (1.1)***
Responder Analyses		**Placebo (n=28)**	**1.2 mg (n=33)**	**1.8 mg (n=33)**	**2.4 mg (n=26)**
% Subjects w/ ≥5% weight loss	%	25.0%	66.7%**	66.7%***	84.6%****
% Subjects w/ ≥10% weight loss	%	0.0%	30.3%**	48.5%****	50.0%****
% Subjects w/ ≥15% weight loss	%	0.0%	6.1%	18.2%*	23.1%*
Secondary Endpoints		**Placebo (n=39)**	**1.2 mg (n=40)**	**1.8 mg (n=40)**	**2.4 mg (n=41)**
Δ Waist circumference	cm, LSM (SE)[1]	-4.0 (1.5)	-8.2 (1.5)**	-8.8 (1.5)***	-10.2 (1.6)***
Δ Total cholesterol	mg/dl. mean (SE)[2]	-2.5 (4.7)	-13.0 (4.7)**	-14.5 (4.9)***	-16.5 (5.1)***
Δ LDL cholesterol		-1.1 (7.9)	-5.5 (7.9)	-10.3 (8.3)	-12.7 (8.5)
Δ Triglycerides		-3.3 (9.4)	-25.1 (9.6)**	-14.4 (9.9)	-25.0 (10.3)**
Δ Systolic BP	mm Hg, LSM (SE)[1]	-0.5 (2.6)	-2.9 (2.5)	-3.1 (2.7)	-5.5 (2.8)
Δ Diastolic BP		0.5 (1.6)	-0.1 (1.5)	-1.4 (1.6)	-1.8 (1.7)
Δ Heart rate	bpm, LSM (SE)[1]	-2.4 (1.9)	0.0 (1.8)	1.0 (1.9)	0.6 (2.0)

[1] MMRM, [2]ANCOVA, *p < .05; ** p < 0.05, *** p < 0.001, ****p < 0.0001 compared with placebo

MOMENTUM Week 24 Interim Analysis—Summary of Safety Findings

		Placebo (n=39)	**1.2 mg (n=40)**	**1.8 mg (n=40)**	**2.4 mg (n=41)**
Adverse events (AEs)					
Serious AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)[1]
Discontinuations due to AE	n (%)	1 (2.6%)	3 (7.5%)	4 (10.0%)	11 (26.8%)
Gastrointestinal AEs					
Nausea AEs	Mild, n (%)	2 (5.1%)	5 (12.5%)	9 (22.5%)	12 (29.3%)
	Moderate, n (%)	0 (0.0%)	3 (7.5%)	13 (32.5%)	9 (22.0%)
	Severe, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)
Vomiting AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	2 (5.0%)	5 (12.2%)
	Moderate, n (%)	0 (0.0%)	2 (5.0%)	3 (7.5%)	4 (9.8%)
	Severe, n (%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.4%)
Diarrhea AEs	Mild, n (%)	0 (0.0%)	3 (7.5%)	2 (5.0%)	4 (9.8%)
	Moderate, n (%)	2 (5.1%)	0 (0.0%)	0 (0.0%)	2 (4.9%)
Constipation AEs	Mild, n (%)	0 (0.0%)	3 (7.5%)	1 (2.5%)	5 (12.2%)
	Moderate, n (%)	2 (5.1%)	2 (5.0%)	1 (2.5%)	1 (2.4%)
Glycemic Control					
Fasting glucose					
Baseline, mg/dL	mean (SD)	96.1 (9.8)	97.0 (12.2)	103.1 (12.1)	100.3 (12.9)
Week 24, mg/dL	mean (SD)	97.7 (11.4)	96.0 (11.2)	103.9 (14.4)	102.5 (18.4)
HbA1c					
Baseline, %	mean (SD)	5.5 (0.4)	5.6 (0.3)	5.5 (0.4)	5.5 (0.4)

Week 24, %	mean (SD)	5.5 (0.3)	5.5 (0.3)	5.6 (0.5)	5.6 (0.5)

[1] Rehydration for nausea and vomiting

Phase 1b Type 2 Diabetes Safety Trial

The Phase 1b trial, which was conducted to evaluate the safety profile of pemvidutide in subjects with overweight or obesity and type 2 diabetes, was comprised of 54 subjects randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. No caloric restrictions or lifestyle interventions were employed. Subjects were required to be 18-65 years of age with BMI ≥ 28 kg/m^2 and type 2 diabetes on a stable regimen of diet and exercise, metformin with absent or mild GI symptoms, or SGLT-2 therapy for at least 3 months.

Subjects receiving pemvidutide achieved mean weight losses of 4.4%, 6.1% and 7.7% at the 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, over only 12 weeks of treatment, with the placebo group experiencing a mean weight gain of 0.8% (efficacy estimand using MMRM analysis).

Glucose homeostasis was maintained throughout the 12 weeks of treatment, with no significant changes in fasting glucose or HbA1c and no hyperglycemic AEs. No SAEs were observed in patients treated with pemvidutide. Rates of GI AEs were low, and there were no AEs leading to study discontinuation.

Phase 1b Type 2 Diabetes Safety Trial—Summary of Efficacy Findings

Body weight		**Placebo (n=14)**	**1.2 mg (n=14)**	**1.8 mg (n=13)**	**2.4 mg (n=13)**
Δ Body weight, all subjects	%, LSM (SE)[1]	+0.8 (0.7)	-4.4 (1.1)***	-6.1 (1.6)***	-7.7 (1.4)***

[1] MMRM, *** p < 0.001 compared with placebo

Phase 1b Type 2 Diabetes Safety Trial—Summary of Safety Findings

		Placebo (n=14)	**1.2 mg (n=14)**	**1.8 mg (n=13)**	**2.4 mg (n=13)**
Glycemic Control					
Fasting glucose					
Baseline, mg/dL	mean (SD)	140.9 (41.6)	132.6 (25.0)	124.9 (31.0)	128.2 (22.8)
Week 12, mg/dL	mean (SD)	140.4 (45.4)	132.0 (32.8)	126.2 (15.7)	140.6 (28.7)
HbA1c					
Baseline, %	mean (SD)	6.6 (1.3)	6.5 (1.0)	6.6 (0.7)	6.9 (0.7)
Week 12, %	mean (SD)	7.0 (1.4)	6.5 (0.5)	6.7 (0.8)	7.0 (0.6)
Adverse events (AEs)					
Serious AEs	n (%)	1 (7.1%)[2]	0 (0.0%)	0 (0.0%)	0 (0.0%)
Discontinuations due to AE	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperglycemia AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gastrointestinal AEs					
Nausea AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
Vomiting AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation AEs	Mild, n (%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[2] Cervical radiculopathy

About Pemvidutide

Pemvidutide 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. Glucagon is also recognized as having direct effects on hepatic fat metabolism, leading to rapid reductions in levels of liver fat. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while likely slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability.

Conference Call Information

Altimmune management will host a conference call and webcast with a slide presentation presented by Dr. Scott Harris, Chief Medical Officer, and Dr. Louis Aronne, Principal Investigator, beginning at 8:30 am E.T. today. Following the conclusion of the call, the webcast will be available for replay on the Investor Relations page of the Company's website at www.altimmune.com. The Company has used, and intends to continue to use, the IR portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

Conference Call Details:

Date: Tuesday, March 21

Time:	8:30 am Eastern Time
Webcast:	To listen, the conference call will be webcast live on Altimmune's Investor Relations website at https://ir.altimmune.com/investors.
Dial-in:	To participate or dial-in, register here to receive the dial-in numbers and unique PIN to access the call.

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 (formerly 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.

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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 key milestones for the Company's clinical assets, such as the completion of the Company's 48-week MOMENTUM obesity trial and initiation of the Phase 2 biopsy NASH 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," "look forward," "plan," "potential," "predict" and similar expressions and their variants, as they relate to 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 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 impact of base line characteristics, such as body weight, and demographics on the success of future trials; the reliability of the results of trials 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 (the "SEC"), including under the heading "Risk Factors" in the Company's annual report on Form 10-K for the most recent fiscal year and the Company's other filings with the SEC, which are available at www.sec.gov.

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