Altimmune Announces Positive Topline Results from MOMENTUM 48-Week Phase 2 Obesity Trial of Pemvidutide

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- *Achieved mean weight loss of 15.6% on 2.4 mg dose of pemvidutide at Week 48, with weight loss continuing at the end of treatment*
- *Over 30% of subjects achieved 20% or more weight loss on 2.4 mg dose at 48 weeks*
- *Robust reductions in BMI and serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate*

Altimmune to host conference call tomorrow at 8:30 am EST

GAITHERSBURG, Md., Nov. 30, 2023 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company (the "Company"), today announced topline results from its 48-week MOMENTUM Phase 2 obesity trial of pemvidutide. The trial enrolled 391 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. The 1.2 mg and 1.8 mg doses were administered without dose titration, while a short 4-week titration period was employed for the 2.4 mg dose. At baseline, subjects had a mean age of approximately 50 years, mean body mass index (BMI) of approximately 37 kg/m^2 and mean body weight of approximately 104 kg. Approximately 75% of subjects were female.

At Week 48, subjects receiving pemvidutide achieved mean weight losses of 10.3%, 11.2%, 15.6% and 2.2% at the 1.2 mg, 1.8 mg, and 2.4 mg doses and placebo, respectively, with a near-linear trajectory of continued weight loss observed on the 2.4 mg dose at the end of treatment. Over 50% of subjects achieved at least 15% weight loss and over 30% of subjects achieved at least 20% weight loss on the 2.4 mg dose. As in prior clinical trials, pemvidutide resulted in robust reductions in serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate. Glucose homeostasis was maintained, with no significant changes in fasting glucose or HbA1c.

More subjects receiving pemvidutide stayed on study compared to those receiving placebo, with 74.1% of pemvidutide subjects completing the trial compared to 61.9% of placebo subjects. Nausea and vomiting comprised the majority of adverse events (AEs) and were predominantly mild to moderate in severity. Only one (1.0%) subject experienced a drug-related serious adverse event (SAE), a case of vomiting at the 2.4 mg dose. Rates of AEs leading to treatment discontinuation were 6.2% in subjects receiving placebo and 5.1%, 19.2%, and 19.6% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively. Study discontinuations related to study drug occurred in 2.1% of placebo subjects and 4.1%, 16.2% and 15.5% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively, with most discontinuations due to AEs in the pemvidutide groups occurring in the first 16 weeks of treatment. No AEs of special interest or major adverse cardiac events (MACE) were observed, and there were low rates of cardiac AEs, including arrhythmias, with no imbalance across pemvidutide or placebo groups.

"The level of weight loss achieved at 48 weeks in this trial has been shown to reverse the key complications of obesity. Moreover, the trajectory of weight loss at the end of treatment with the 2.4 mg dose suggests the potential for greater weight loss with continued treatment," said Dr. Scott Harris, Chief Medical Officer of Altimmune. Dr. Harris added, "It is also important to recognize the safety profile of pemvidutide observed to date, especially cardiac-related safety, considering that many obesity patients are at risk for cardiovascular events such as arrhythmias and major adverse cardiac events."

"This is an important day for Altimmune and we couldn't be more pleased with these results," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "To put these results in context, the 15.6% mean weight loss observed with the 2.4 mg dose was associated with a mean weight loss of 32.2 lbs at 48 weeks. The impact of this level of weight loss on patients can be significant. For example, 48% of subjects on the 2.4 mg dose with baseline obesity no longer had obesity at the end of the 48-week trial." Dr. Garg continued, "We believe the magnitude of weight loss, robust reductions in triglycerides, LDL cholesterol and blood pressure, together with the safety profile observed in this trial, could potentially differentiate pemvidutide from the other incretin-based therapies. If approved, we believe pemvidutide could offer an important option for obesity patients, including those with risk factors for cardiovascular disease."

Summary of Efficacy Findings

Primary Endpoint: Body weight		**Placebo (N=97)**	**1.2 mg (N=98)**	**1.8 mg (N=99)**	**2.4 mg (N=97)**
Δ Bodyweight, all subjects	%, LSM (SE)[1]	-2.2 (1.4)	-10.3 (1.4)***	-11.2 (1.4)***	-15.6 (1.4)***

Responder Analyses		**Placebo (N=51)**	**1.2 mg (N=70)**	**1.8 mg (N=63)**	**2.4 mg (N=56)**
% Subjects w/ ≥5% weight loss	%[2]	17.6%	68.6%****	76.2%****	83.9%****
% Subjects w/ ≥10% weight loss		3.9%	42.9%****	49.2%****	71.4%****
% Subjects w/ ≥15% weight loss		2.0%	21.4%**	28.6%***	51.8%****
% Subjects w/ ≥20% weight loss		2.0%	10.0%	9.5%	32.1%****

Secondary Endpoints		**Placebo(N=50)**	**1.2 mg (N=69)**	**1.8 mg (N=58)**	**2.4 mg (N=55)**
Δ Total cholesterol	%,	-2.8 (2.0)	-11.6 (1.7)**	-13.1 (1.9)***	-15.1 (2.0)***

Δ LDL cholesterol	LSM (SE)[3]	-2.8 (4.1)	-6.2 (3.5)	-11.2 (3.8)	-9.9 (3.9)
Δ Triglycerides		+7.3 (4.6)	-21.7 (3.9)***	-22.3 (4.3)***	-34.9 (4.4)***

Blood Pressure and Heart Rate		**Placebo (N=97)**	**1.2 mg (N=98)**	**1.8 mg (N=99)**	**2.4 mg (N=97)**
Δ Systolic BP	mm Hg, LSM (SE)[1]	+3.5 (2.3)	-2.3 (2.2)	-1.6 (2.2)	-4.6 (2.3)
Δ Diastolic BP		+1.8 (1.4)	-2.1 (1.3)	-1.0 (1.3)	-2.9 (1.4)
Δ Heart rate	bpm, LSM (SE)[1]	-1.4 (1.6)	0.1 (1.5)	3.1 (1.5)	2.5 (1.6)

[1] MMRM (mixed model for repeated measures), [2] CMH (Cochran Mantel Haenszel), [3] ANCOVA (analysis of covariance)

*p < 0.05; ** p < 0.005, *** p < 0.001, ****p < 0.0001 compared with placebo

Summary of Safety and Tolerability

Adverse events (AEs)		**Placebo (N=97)**	**1.2 mg (N=98)**	**1.8 mg (N=99)**	**2.4 mg (N=97)**
SAEs related to study drug	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)[4]
All AEs leading to discontinuation	N (%)	6 (6.2%)	5 (5.1%)	19 (19.2%)	19 (19.6%)
Drug-related AEs leading to discontinuation	N (%)	2 (2.1%)	4 (4.1%)	16 (16.2%)	15 (15.5%)
Gastrointestinal AEs—mainly mild to moderate					
Nausea	N (%)	11 (11.3%)	25 (25.5%)	59 (59.6%)	50 (51.5%)
Vomiting	N (%)	3 (3.1%)	6 (6.1%)	27 (27.3%)	27 (27.8%)
Diarrhea	N (%)	5 (5.2%)	8 (8.2%)	10 (10.1%)	18 (18.6%)
Constipation	N (%)	8 (8.2%)	17 (17.3%)	13 (13.1%)	22 (22.7%)
Major Adverse Cardiac Events (MACE)	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiac AEs including arrhythmias	N (%)	4 (4.1%)	3 (3.1%)	4 (4.0%)	3 (3.1%)

[4] Vomiting

Summary of Glycemic Control		**Placebo (N=50)**	**1.2 mg (N=68)**	**1.8 mg (N=58)**	**2.4 mg (N=55)**
Fasting glucose					
Baseline, mg/dL	mean (SE)	95.5 (1.5)	99.4 (1.4)	101.6 (1.4)	101.5 (1.6)
Week 48, mg/dL	mean (SE)	95.2 (1.5)	98.6 (1.7)	100.6 (1.6)	99.4 (2.0)
HbA1c					
Baseline, %	mean (SE)	5.6 (0.0)	5.5 (0.0)	5.5 (0.1)	5.6 (0.0)
Week 48, %	mean (SE)	5.5 (0.0)	5.5 (0.0)	5.6 (0.1)	5.5 (0.1)

About Pemvidutide

Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and metabolic dysfunction-associated steatohepatitis (MASH), formerly known as non-alcoholic steatohepatitis (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 beginning at 8:30 am E.T. tomorrow. 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:	Friday, December 1
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 developing treatments for obesity and liver diseases. The Company's lead product candidate, pemvidutide, is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and MASH, formerly known as 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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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 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 (the "SEC"), including under the heading "Risk Factors" in the Company's most recent annual report on Form 10-K and its other filings with the SEC, which are available at www.sec.gov.

Investor Contact:
Rich Eisenstadt
Chief Financial Officer
Phone: 240-654-1450
reisenstadt@altimmune.com

Media Contact:
Danielle Duchene
Evoke Canale
Phone: 619-826-4878
Danielle.Duchene@canalecomm.com

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