Altimmune Announces Significant Reductions in Liver Fat Content and Body Weight in 12-Week Phase 1b Clinical Trial of Pemvidutide in Subjects with NAFLD

September 14, 2022 at 7:00 AM EDT

- *All 3 pemvidutide dosing groups (1.2 mg, 1.8 mg, 2.4 mg) achieved the primary endpoint of relative and absolute reductions in liver fat, with a 68.5% relative reduction in liver fat content in subjects receiving 1.8 mg dose at 12 weeks of treatment*
- *Mean weight loss of 4.9% (placebo-adjusted 4.7%) in subjects without diabetes receiving 1.8 mg dose at 12 weeks of treatment*
- *Altimmune to host conference call today at 8:30 am ET*

GAITHERSBURG, Md., Sept. 14, 2022 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced positive topline results from its 12-week Phase 1b study of pemvidutide[1] in subjects with non-alcoholic fatty liver disease (NAFLD).

The trial was a randomized, double-blind, placebo-controlled study, with Dr. Stephen A. Harrison, Medical Director, Pinnacle Research, serving as the Principal Investigator. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. No dose titration was used with 1.2 mg or 1.8 mg dose, while a short 4-week dose titration was employed at the 2.4 mg dose. The primary efficacy endpoint was the percent (%) reduction in liver fat content from baseline, and the key secondary efficacy endpoint was the % weight loss from baseline, both at 12 weeks of treatment. The trial was conducted without adjunctive diet and exercise interventions that are the standard for obesity trials.

Ninety-four (94) subjects were randomized and treated at 13 sites across the U.S. Mean BMI at baseline was approximately 36 kg/m^2 and mean liver fat content (LFC), as measured by MRI-PDFF, was approximately 22%. Twenty-seven (29%) subjects had type 2 diabetes at baseline, and approximately 75% of study subjects were of Hispanic ethnicity.

The trial met its primary endpoint in all pemvidutide treatment groups. At the 1.8 mg dose (with and without diabetes), pemvidutide achieved a mean reduction of liver fat content of 68.5%, with 94.4% of subjects achieving a 30% reduction in liver fat, 72.2% achieving a 50% reduction in liver fat, and 55.6% of subjects achieving normalization of liver fat, defined as liver fat fraction of 5% or less. In addition, mean serum alanine aminotransferase (ALT) levels declined in all subjects, and in subjects with baseline serum ALT above 30 IU/L, levels declined more than 17 IU/L at all dose levels and 27.0 IU/L in the 2.4 mg dose cohort.

The trial also met its key secondary endpoint in all pemvidutide treatment groups. Employing an efficacy estimand, mean weight losses of 4.9% (placebo-adjusted 4.7%) in subjects without diabetes and 4.4% in subjects with diabetes (placebo-adjusted 3.9%) were achieved at the 1.8 and 2.4 mg doses, respectively.

Pemvidutide was reported to be generally well tolerated. Gastrointestinal events comprised the majority of the adverse events (AEs). Even without dose titration, the symptoms experienced by subjects were predominantly mild and transient in nature, consistent with known GLP-1 class effects. No serious or severe AEs were reported. Two subjects treated with pemvidutide discontinued treatment due to AEs [1 (4.3%) at 1.8 mg and 1 (4.2%) at 2.4 mg], both secondary to gastrointestinal intolerability. No clinically significant ALT elevations (defined as an increase to 3-fold or greater the upper limit of normal) were observed. Glycemic control was unaffected, with no clinically meaningful changes in HbA1c or fasting glucose. Clinically meaningful reductions in systolic blood pressure were observed, along with the 2-3 beat per minute increase in heart rate typical for GLP-1 class of drugs.

“We are pleased with the results of this trial, including the extent of liver fat and serum ALT reductions. Weight loss was within our target range, and good tolerability was observed without the need for dose titration. In addition, no clinically significant ALT elevations were observed,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “With these positive results in hand, we look forward to reporting data from the 24-week NAFLD trial, as well as 24-week interim data from our MOMENTUM obesity trial.”

Dr. Stephen Harrison, Principal Investigator, remarked, “Significant reductions in the liver fat fraction and serum ALT have been shown to correlate with improvement of non-alcoholic steatohepatitis (NASH) in clinical trials. The marked decreases in both liver fat and serum ALT, together with approximately 5% weight loss in just 12 weeks in this NAFLD patient population, highlight pemvidutide as potentially a promising therapeutic for both NASH and obesity.” Dr. Harrison also noted, “It is important to recognize that the baseline liver fat content and demographics in this study diverged substantially from a typical obesity study population.”

Baseline Study Demographics

Characteristic		Treatment			
		Placebo (n = 24)	1.2 mg (n=23)	1.8 mg (n=23)	2.4 mg (n=24)
Age, years	mean (SD)	47.9 (14)	48.6 (11)	50.3 (9)	48.8 (8)
Sex	female, n (%)	14 (58.3%)	9 (39.1%)	12 (52.2%)	15 (62.5%)
Race	white, n (%)	21 (87.5%)	21 (91.3%)	20 (87.0%)	24 (100%)
	other, n (%)	3 (12.5%)	2 (8.7%)	3 (13.0%)	0 (0.0%)
Ethnicity	Hispanic, n (%)	14 (58.3%)	20 (87.0%)	19 (82.6%)	18 (75.0%)

	Non-Hispanic, n (%)	10 (41.7%)	3 (13.0%)	4 (17.4%)	6 (25.0%)
BMI, kg/m2	mean (SD)	36.9 (4.7)	36.3 (5.6)	35.4 (3.9)	35.3 (5.0)
Body weight, kg	mean (SD)	105.1 (20.8)	102.4 (14.6)	98.9 (19.7)	98.2 (18.9)
Diabetes status	T2D, n (%)	6 (25.0%)	7 (30.4%)	7 (30.4%)	7 (33.3%)
LFC, %	mean (SD)	23.8 (9.2)	21.6 (7.3)	21.8 (8.0)	20.2 (7.0)

Reduction of Liver Fat Content (MRI-PDFF)—All Subjects

Endpoint		**Treatment**			
		Placebo (n = 24)	**1.2 mg (n=20)**	**1.8 mg (n=18)**	**2.4 mg (n=20)**
Absolute reduction, %	mean (SE)	0.2 (1.7)	8.9 (1.8)**	14.7 (1.7)**	11.3 (2.0)**
Relative reduction, %	mean (SE)	4.4 (8.7)	46.6 (8.1)**	68.5 (9.7)**	57.1 (8.0)**
30% reduction	n (%)	1 (4.2%)	13 (65.0%)**	17 (94.4%)**	17 (85.0%)**
50% reduction	n (%)	0 (0.0%)	8 (40.0%)**	13 (72.2%)**	14 (70.0%)**
Normalization (≤ 5% LFC)	n (%)	0 (0.0%)	4 (20.0%)*	10 (55.6%)**	10 (50.0%)**

**p < .05, **p<.001 compared to placebo*

Reductions in Body Weight—Efficacy Estimand

Population		**Treatment**			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
No diabetes, (% change)	LSM (SE)	-0.2 (0.7)	-3.4** (0.8)	-4.9** (0.8)	-3.5** (0.8)
Diabetes, (% change)	LSM (SE)	-0.5 (1.3)	-3.3* (1.1)	-3.8* (1.2)	-4.4* (1.3)
All subjects (% change)	LSM (SE)	-0.2 (0.7)	-3.4** (0.7)	-4.3** (0.7)	-3.7** (0.7)

*LSM, least square mean; *p < .05, **p<.001 compared to placebo*

Summary of Safety Findings

Characteristic		**Treatment**			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
Severe AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SAEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs leading to treatment discontinuation	n (%)	0 (0.0%)	0 (0.0%)	1 (4.3%)	1 (4.2%)
Nausea	mild, n (%)	3 (12.5%)	3 (13.0%)	6 (26.1%)	6 (25.0%)
	mod, n (%)	0 (0.0%)	1 (4.3%)	6 (26.1%)	3 (12.5%)
Vomiting	mild, n (%)	0 (0.0%)	3 (13.0%)	2 (8.7%)	2 (8.3%)
	mod, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea	mild, n (%)	4 (16.7%)	3 (13.0%)	5 (21.7%)	1 (4.2%)
	mod, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation	Mild, n (%)	0 (0.0%)	3 (13.0%)	4 (17.4%)	1 (4.2%)
	mod, n (%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)

[1] *proposed INN*

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. 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. In a 12-week Phase 1 clinical trial, pemvidutide-treated subjects demonstrated substantial reductions in body weight, liver fat and serum lipids commonly associated with cardiovascular disease.

Conference Call Information

Altimmune management will host a conference call and webcast with a slide presentation presented by Dr. Stephen A. Harrison beginning at 8:30 am E.T. 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 Information:

Date:	Wednesday, September 14
Time:	8:30 am Eastern Time
Webcast:	The conference call will be webcast live on Altimmune's Investor Relations website at https://ir.altimmune.com/investors.
Dial-in:	Participants who would like to join the call may 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, 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 our clinical assets, the timing of the data readouts of the NAFLD trials, the Phase 2 obesity clinical 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," "plan," "predict" and similar expressions and their variants, as they relate to Altimmune, Inc. (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 from the ongoing conflict in Ukraine and the COVID-19 pandemic, 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 liver fat content and demographics in the Phase 1b NAFLD study on the success of future trials; 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 annual report on Form 10-K for the fiscal year ended December 31, 2021 and our other filings with the SEC, which are available at www.sec.gov.

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