Altimmune Announces Positive Lean Mass Preservation Data for Pemvidutide and Reports Fourth Quarter and Full Year 2023 Financial Results

March 27, 2024 at 7:00 AM EDT

Body composition study showed lean mass preservation, with only 25.5% of weight loss derived from lean mass

Enrollment ongoing in IMPACT Phase 2b trial of pemvidutide in Metabolic Dysfunction-Associated Steatohepatitis (MASH), with topline 24-week data expected Q1 2025

Preclinical study results showed a direct anti-fibrotic effect of pemvidutide in a non-steatotic model of liver fibrosis

Cash, cash equivalents and short-term investments of $198.0 million at December 31, 2023

Webcast to be held today, March 27, 2024, at 8:30 am ET

GAITHERSBURG, Md., March 27, 2024 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2023, and provided a business update.

“We are extremely pleased with the results of the body composition analysis from our recently completed MOMENTUM 48-week Phase 2 obesity trial of pemvidutide. Our data show that 74.5% of weight loss was derived from adipose tissue and only 25.5% from lean mass, comparable to the effects historically associated with weight loss from diet and exercise programs,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “Based on compelling weight loss, a clean safety profile, robust reductions in serum lipids and blood pressure, and now preservation of lean mass observed in our clinical trials, we believe that pemvidutide has the potential to distinguish itself broadly from other therapies for the treatment of obesity. We also remain excited about the outcome of our ongoing IMPACT Phase 2b MASH trial with topline 24-week data on the key endpoints of MASH resolution or fibrosis improvement anticipated in the first quarter of 2025. The results from a recently completed preclinical study demonstrating direct anti-fibrotic activity of pemvidutide only adds to our optimism about achieving a positive outcome in this trial.”

“Preservation of lean mass during weight loss is critical, since excessive loss of lean mass has been associated with negative outcomes, such as sarcopenia and bone fractures, especially in women and the elderly,” said Scott Harris, Chief Medical Officer, Altimmune. “There is a growing appreciation that the quality of weight loss is as important as the quantity of weight loss. Given these new body composition data, the robust reductions in serum lipids, and the class-leading reduction of hepatic fat content, we believe that pemvidutide, if approved, could stand out as an attractive option for weight loss and weight maintenance.”

Recent Highlights and Anticipated Milestones:

Pemvidutide

- *Positive lean mass preservation in body composition analysis from MOMENTUM trial*
    - Body composition analysis from MOMENTUM showed only 25.5% of weight loss derived from lean mass, with 74.5% of weight loss from adipose tissue, comparable to the effects historically associated with diet and exercise.
    - Complete analysis of the data to be presented at an upcoming scientific meeting.
- *Positive top-line data readout from MOMENTUM 48-week Phase 2 obesity trial in November 2023*
    - 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 the 2.4 mg dose.
    - Robust reductions of triglycerides (55.8%), total cholesterol (20.0%) and LDL cholesterol (17.4%) on 2.4 mg dose in patients with elevated baseline lipids.
    - Up to 78.6% of subjects with excess liver fat normalized their liver fat content.
    - Improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate.
- *Enrollment ongoing in IMPACT biopsy-driven Phase 2b MASH trial*
    - The FDA granted Fast Track designation to pemvidutide for the treatment of MASH.
    - Approximately 190 subjects with and without diabetes are being randomized 1:2:2 to 1.2 mg, 1.8 mg pemvidutide or placebo.
    - The key endpoints are MASH resolution or fibrosis improvement after 24 weeks of treatment, with subjects to be followed for an additional 24 weeks of dosing for assessment of safety and additional biomarker responses.
    - Top-line results after 24 weeks of treatment are expected in the first quarter of 2025.

- *Demonstration of the direct anti-fibrotic effects of pemvidutide in a preclinical model of hepatic fibrosis*
    - Significant improvement observed in a model of chemically-induced hepatic fibrosis after 14 days of treatment with pemvidutide.
    - The model excluded the effects of liver fat reduction, providing evidence for a direct effect of pemvidutide in reducing liver fibrosis.

- *Demonstration of improved cholesterol elimination in a preclinical model of dyslipidemia*
    - Pemvidutide stimulated reverse cholesterol transport and increased cholesterol elimination.
    - These data provide evidence for a potential additional mechanism of reducing cardiovascular risk beyond the effects of pemvidutide on serum lipids and liver fat content.

HepTcell ™

The Phase 2 clinical trial evaluating the efficacy of HepTcell in reducing virological markers in patients chronically infected with the hepatitis B virus has been completed. The overall response in the trial was deemed to be insufficient to warrant further advancement. As a result, any further development related to HepTcell has been stopped.

Financial Results for the Three Months Ended December 31, 2023

- Altimmune had cash, cash equivalents and short-term investments totaling $198.0 million at December 31, 2023.
- Research and development expenses were $16.9 million for the three months ended December 31, 2023, compared to $19.2 million in the same period in 2022. The expenses for the quarter ended December 31, 2023 included $10.3 million in direct costs related to development activities for pemvidutide and $1.1 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were $4.3 million for the three months ended December 31, 2023, compared to $3.8 million in the same period in 2022. The increase was primarily due to $0.3 million increase in professional fees and $0.2 million increase in stock compensation.
- Impairment loss on intangible asset of $12.4 million was recognized during the three months ended December 31, 2023 related to the acquired In-Process Research and Development asset associated with HepTcell. The overall response in the Phase 2 trial was deemed to be insufficient to warrant further advancement. As a result, any further development related to HepTcell has been stopped.
- Interest income for the three months ended December 31, 2023 was $2.0 million as compared to $1.5 million in the same period in 2022, primarily due to an increase in interest income earned on cash equivalents and short-term investments.
- Net loss for the three months ended December 31, 2023 was $31.6 million, or $0.54 net loss per share, compared to a net loss of $21.7 million, or $0.43 net loss per share, in the same period in 2022. The net loss for 2023 included the $12.4 million noncash impairment charge described above.

Conference Call Information:

Date:	Wednesday, March 27, 2024
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.

Following the conclusion of the call, the webcast will be available for replay on the Investor Relations (IR) 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.

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, leading to rapid reductions in levels of liver fat and serum lipids. In clinical trials, once-weekly pemvidutide has shown compelling weight loss, robust reductions in triglycerides, LDL cholesterol, liver fat content and blood pressure with a clean safety profile to date. The U.S. FDA has granted Fast Track designation to pemvidutide for the treatment of MASH. Pemvidutide has recently completed the MOMENTUM Phase 2 obesity trial and is being studied in the 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 key milestones for 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.

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

Media Contact:
Danielle Cantey
Inizio Evoke, Biotech
Phone: 619-826-4657
Danielle.cantey@inizioevoke.com

ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per-share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,117	$ 111,097
Restricted cash	41	34
Total cash, cash equivalents and restricted cash	135,158	111,131
Short-term investments	62,698	73,783
Accounts and other receivables	1,111	173
Income tax and R&D incentive receivables	3,742	2,368
Prepaid expenses and other current assets	6,917	5,358
Total current assets	209,626	192,813
Property and equipment, net	651	1,081
Indefinite-lived intangible asset	—	12,419
Other assets	363	615
Total assets	$ 210,640	$ 206,928
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,070	$ 4,804
Accrued expenses and other current liabilities	10,073	12,250
Total current liabilities	12,143	17,054
Noncurrent liabilities	4,398	4,581
Total liabilities	16,541	21,635
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 70,677,400 and 49,199,845 shares issued and outstanding as of December 31, 2023 and 2022, respectively	7	5
Additional paid-in capital	665,427	568,399

Accumulated deficit	(466,331)	(377,884)
Accumulated other comprehensive loss, net	(5,004)	(5,227)
Total stockholders' equity	194,099	185,293
Total liabilities and stockholders' equity	$ 210,640	$ 206,928

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per-share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues	$ 37	$ (110)	$ 426	$ (68)
Operating expenses:				
Research and development	16,909	19,179	65,799	70,538
General and administrative	4,332	3,805	18,137	17,134
Impairment loss on intangible asset	12,419	—	12,419	—
Total operating expenses	33,660	22,984	96,355	87,672
Loss from operations	(33,623)	(23,094)	(95,929)	(87,740)
Other income (expense):				
Interest expense	(2)	183	(35)	(8)
Interest income	1,964	1,468	7,351	2,870
Other income (expense), net	20	(217)	166	(32)
Total other income (expense), net	1,982	1,434	7,482	2,830
Net loss before income taxes	(31,641)	(21,660)	(88,447)	(84,910)
Income tax expense (benefit)	—	—	—	(197)
Net loss	(31,641)	(21,660)	(88,447)	(84,713)
Other comprehensive income — unrealized gain (loss) on short-term investments	120	76	223	(187)
Comprehensive loss	$ (31,521)	$ (21,584)	$ (88,224)	$ (84,900)
Net loss per share, basic and diluted	$ (0.54)	$ (0.43)	$ (1.66)	$ (1.81)
Weighted-average common shares outstanding, basic and diluted	58,442,779	50,026,686	53,246,937	46,926,349

Source: Altimmune, Inc