Altimmune Announces First Quarter 2023 Financial Results and Provides a Business Update

May 11, 2023 at 7:00 AM EDT

Initiation of the IMPACT Phase 2b trial of pemvidutide in non-alcoholic steatohepatitis (NASH) expected mid-2023

Top-line 48-week results from the MOMENTUM Phase 2 obesity trial expected Q4 2023

Top-line results from the Phase 2 trial of HepTcell™ in chronic hepatitis B (CHB) expected Q1 2024

Webcast to be held today, May 11, 2023, at 8:30 am EDT

GAITHERSBURG, Md., May 11, 2023 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three months ended March 31, 2023, and provided a business update.

"We are on course for mid-year initiation of IMPACT, our Phase 2b biopsy trial of pemvidutide in subjects with NASH," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "In our previous trials in subjects with non-alcoholic fatty liver disease (NAFLD), we observed remarkable reductions in liver fat content and markers of liver inflammation that occurred rapidly after treatment. This leads us to believe that the IMPACT trial has the potential to show a statistically significant impact on the key endpoints of NASH resolution and fibrosis improvement. We also believe pemvidutide may distinguish itself from other candidates in development for NASH because of its demonstrated reductions in both liver fat content and body weight. This is important, because many NASH patients suffer not only from the complications of liver disease but also from the underlying obesity, a principal driver of NASH. In addition, we eagerly await top-line 48-week results from our MOMENTUM obesity trial anticipated in the fourth quarter of 2023, which we expect will demonstrate continued weight loss beyond the robust levels reported at the 24-week interim analysis. We believe pemvidutide could be an important treatment option for patients with obesity, if approved, particularly those with NAFLD and dyslipidemia, conditions that are highly prevalent in these patients. We also look forward to the top-line results of our Phase 2 trial of HepTcell in CHB, which we expect to announce in the first quarter of 2024."

Recent Highlights and Anticipated Milestones

Pemvidutide

- *Positive interim data readout from 24-week MOMENTUM Phase 2 obesity trial in March 2023*
  - Mean weight loss of 10.7% and 9.4% at the 2.4 mg and 1.8 mg doses, respectively, at Week 24, compared to mean weight loss of 1.0% in the placebo group.
  - Approximately 50% of subjects achieved 10% or more weight loss and approximately 20% of subjects achieved 15% or more weight loss at both the 2.4 mg and 1.8 mg doses at Week 24.
  - Robust reductions in waist circumference, serum lipids and blood pressure, surrogates of reduced cardiovascular risk.
  - Higher adverse event discontinuation rates observed at the 2.4 mg dose can be mitigated by allowance for dose reduction in Phase 3 trials.
- *Initiation of IMPACT Phase 2b NASH trial expected mid-2023*
  - This Phase 2b biopsy-driven NASH trial will be conducted at approximately 60 sites in the U.S., with Dr. Stephen Harrison, Medical Director, Pinnacle Research, and Adjunct Professor of Medicine, Oxford University, serving as the principal investigator.
  - 190 subjects with and without diabetes are planned to be randomized 1:2:2 to pemvidutide 1.2 mg, pemvidutide 1.8 mg, or placebo.
  - The key endpoints will be NASH resolution and fibrosis improvement after 24 weeks of treatment, with subjects followed for an additional 24 weeks to a total of 48 weeks for assessment of safety and additional biomarker responses.
  - Dose reduction will be allowed for subjects who experience GI intolerance.
  - The trial is expected to commence mid-2023 with top-line results expected in the first quarter of 2025.

HepTcell™

- *Completed enrollment in the Phase 2 clinical trial in CHB*
  - The multicenter clinical trial, which is being conducted at 26 sites in North America, Europe and Southeast Asia, enrolled approximately 80 previously untreated subjects with inactive CHB and low levels of hepatitis B surface antigen (HBsAg).
  - Subjects were randomized 1:1 to HepTcell or placebo.
  - The primary endpoint is virological response, defined as a 1-log or greater reduction or clearance of HBsAg; secondary endpoints include changes in the levels of hepatitis B virus (HBV) DNA, pre-genomic RNA and other markers of virologic response.
  - Data readout is expected in the first quarter of 2024 after all subjects complete the 6-month course of treatment.

Financial Results for the Three Months Ended March 31, 2023

- Cash, cash equivalents and short-term investments totaled $165.8 million as of March 31, 2023.
- Research and development expenses were $17.2 million for the three months ended March 31, 2023, compared to $15.1 million in the same period in 2022. The expenses for the quarter ended March 31, 2023 included $8.7 million in direct costs related to development activities for pemvidutide and $2.1 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were consistent period-over-period at $4.5 million and $4.4 million for the three months ended March 31, 2023 and March 31, 2022, respectively.
- Interest income for the three months ended March 31, 2023 was $1.7 million as compared to a negligible amount in the three months ended March 31, 2022.
- Net loss for the three months ended March 31, 2023 was $20.1 million, or $0.40 net loss per share, compared to a net loss of $19.4 million, or $0.44 net loss per share, in the same period in 2022.

Conference Call Information:

Date:	Thursday, May 11, 2023
Time:	8:30 am EDT
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 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 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.

About HepTcell
HepTcell is a novel, investigational, immunotherapeutic comprised of nine synthetic peptides representing conserved HBV sequences formulated with IC31®, a TLR9-based adjuvant from Valneva SE. The HBV-directed peptides are designed to drive T cell responses against all HBV genotypes towards a functional cure for chronic HBV in patients of diverse genetic backgrounds.

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 CHB. 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 Phase 2 trial of HepTcell in CHB and the Phase 2 MOMENTUM trial of pemvidutide in obesity, the timing of the initiation and the data readout of the Phase 2b IMPACT trial of pemvidutide in NASH 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.

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

	March 31, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 104,690	$ 111,097
Restricted cash	34	34
Total cash, cash equivalents and restricted cash	104,724	111,131
Short-term investments	61,039	73,783
Accounts receivable	252	173
Income tax and R&D incentive receivables	3,118	2,368
Prepaid expenses and other current assets	3,978	5,358
Total current assets	173,111	192,813
Property and equipment, net	1,007	1,081
Indefinite-lived intangible asset	12,419	12,419
Other assets	546	615
Total assets	$ 187,083	$ 206,928
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,238	$ 4,804
Accrued expenses and other current liabilities	9,713	12,250
Total current liabilities	14,951	17,054
Other long-term liabilities	4,400	4,581
Total liabilities	19,351	21,635
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 49,286,710 and 49,199,845 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	570,786	568,399
Accumulated deficit	(397,958)	(377,884)
Accumulated other comprehensive loss, net	(5,101)	(5,227)
Total stockholders' equity	167,732	185,293
Total liabilities and stockholders' equity	$ 187,083	$ 206,928

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

	Three Months Ended March 31,	
	2023	2022
Revenues	$ 21	$ 32
Operating expenses:		
Research and development	17,249	15,104
General and administrative	4,531	4,427
Total operating expenses	21,780	19,531
Loss from operations	(21,759)	(19,499)
Other income (expense):		
Interest expense	(2)	(62)
Interest income	1,668	21

Other income (expense), net	19	110
Total other income (expense), net	1,685	69
Net loss	(20,074)	(19,430)
Other comprehensive income — unrealized gain on short-term investments	126	—
Comprehensive loss	$ (19,948)	$ (19,430)
Net loss per share, basic and diluted	$ (0.40)	$ (0.44)
Weighted-average common shares outstanding, basic and diluted	50,125,685	43,969,481

Source: Altimmune, Inc