Altimmune Announces Third Quarter 2022 Financial Results and Provides a Business Update

November 10, 2022

Topline 24-week data from Phase 1b trial in subjects with non-alcoholic fatty liver disease (NAFLD) expected mid-December 2022

Interim 24-week readout from MOMENTUM Phase 2 obesity trial expected Q1 2023

GAITHERSBURG, Md., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three and nine months ended September 30, 2022, and provided a business update.

"We continue on course in our advancement of pemvidutide for two important clinical indications, obesity and non-alcoholic steatohepatitis (NASH), and look forward to data readouts from our NAFLD trial extension in mid-December 2022 and from our interim 24-week readout on approximately 160 subjects from our MOMENTUM Phase 2 obesity trial in Q1 2023," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune.

"We believe that the promising reductions in liver fat content and alanine aminotransferase (ALT) levels observed in our recently completed 12-week Phase 1b NAFLD trial should translate into success on the approvable NASH endpoints, including NASH resolution and fibrosis improvement, in late-phase biopsy trials. The magnitude of the effects on the liver combined with meaningful reductions in body weight could represent important points of differentiation from other drugs in development for NASH."

Dr. Garg added, "Turning to our MOMENTUM obesity trial, we believe that the level of weight loss we expect to see at 48 weeks will be similar to the leading drugs in the class. The trial is being conducted in a typical obesity population at established obesity trial sites and employs lifestyle interventions that are standard in obesity trials. We believe the absence of dose titration, together with the favorable tolerability profile, reductions in serum lipids and reductions in liver fat content observed in clinical trials to date, could translate into greater ease of administration, improved adherence to therapy and greater potential for cardiovascular benefit in this patient population."

Recent Highlights and Anticipated Milestones:

Pemvidutide

- *Topline data readout from 12-week Phase 1b NAFLD trial in September 2022*
  - This trial was conducted in the U.S., with Dr. Stephen A. Harrison, Director, Pinnacle Research and University of Oxford, serving as Principal Investigator.
  - A total of 94 subjects were randomized and dosed, with approximately 80% being of Hispanic ethnicity, and with a median liver fat content of approximately 22%.
  - A 68.5% relative reduction in liver fat content was achieved at the 1.8 mg dose at Week 12, with 94.4% of subjects achieving a 30% reduction of liver fat and 55.6% achieving normalization of liver fat, defined as 5% or less on MRI-PDFF, at Week 12.
  - As announced in a late-breaking abstract presented on November 7, 2022, at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, DC, greater than 83% of subjects who received pemvidutide and who participated in a corrected T1 (cT1) imaging sub-study achieved an 80 millisecond (ms) or more reduction in cT1 relaxation times at Week 12 at each pemvidutide dose. Elevated cT1 scores have been correlated with hepatic and cardiovascular events in clinical studies. An 80 ms reduction has been shown to correlate with a 2-point improvement in NAFLD Activity Score on liver biopsies.

- *Topline 24-week data from NAFLD trial (12-week extension) expected mid-December 2022*
  - This extension trial provides 12 weeks of additional treatment to subjects with NAFLD who completed the 12-week Phase 1b trial, allowing subjects to receive a total of 24 weeks of treatment.
  - Although the extension trial was initiated several months after the start of the original 12-week Phase 1b NAFLD trial, a total of 66 of 94 subjects (70%) rolled over into this trial.

- *Randomization and first dosing of all subjects is complete in 48-week Phase 2 MOMENTUM obesity trial – 24-week interim analysis of approximately 160 subjects expected in Q1 2023*
  - This Phase 2 trial is being conducted at 30 sites across the U.S., with Dr. Lou Aronne, Professor of Clinical Medicine, Weill Cornell Medical College, a leading authority in obesity and obesity clinical trials, serving as the Principal Investigator.
  - The trial was designed to enroll approximately 320 non-diabetic subjects with obesity, or overweight with at least one co-morbidity. 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. Baseline characteristics of the study population include median body weight and body mass index (BMI) of approximately 101 kg and 36 kg/m^2, respectively, and median liver fat content of approximately 5%, as measured in approximately 100 subjects participating in a body composition sub-study. The study population is approximately 75% female, and approximately 20% of subjects are of Hispanic ethnicity.

- The primary endpoint is the relative (percent) change in body weight at 48 weeks compared to baseline. Additional readouts include metabolic and lipid profiles, cardiovascular measures and glucose homeostasis.
- A 24-week interim analysis on approximately 160 subjects is planned in Q1 2023.

- *Enrollment complete in Phase 1b trial of subjects with type 2 diabetes*
  - This 12-week safety trial will evaluate the effects of pemvidutide in approximately 48 subjects with type 2 diabetes and obesity or overweight.
  - Data readout is expected in Q1 2023.

HepTcell™

- *Enrollment continuing in the Phase 2 clinical trial in chronic hepatitis B*
  - Endpoints include virological markers of hepatitis B infection and functional cure.
  - Data readout is expected in H2 2023.

Financial Results for the Three Months Ended September 30, 2022

- Altimmune had cash, cash equivalents and short-term investments totaling $201.9 million at September 30, 2022.
- Revenue was minimal for the three months ended September 30, 2022 compared to $0.2 million in the same period in 2021. The change in revenue quarter over quarter was primarily due to the discontinuation of development activities for the T-COVID and NasoShield programs in 2021.
- Research and development expenses were $20.3 million for the three months ended September 30, 2022, compared to $29.2 million in the same period in 2021. The expenses for the quarter ended September 30, 2022 included $14.0 million in direct costs related to development activities for pemvidutide and $1.8 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were $4.5 million for the three months ended September 30, 2022, compared to $4.2 million in the same period in 2021. The change was primarily attributable to increased stock compensation expense.
- Net loss for the three months ended September 30, 2022 was $23.5 million, or $0.48 net loss per share, compared to a net loss of $33.5 million, or $0.81 net loss per share, in the same period in 2021.

Conference Call Information:

Date:	Thursday, November 10, 2022
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.

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. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability. In a 12-week Phase 1b clinical trial, NAFLD subjects treated with pemvidutide demonstrated promising reductions in liver fat content, serum ALT levels and body weight.

About HepTcell

HepTcell is a novel, investigational, immunotherapeutic comprised of nine synthetic peptides representing conserved hepatitis B (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 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 readout of the NAFLD trial, diabetic subject trial, drug-drug interaction trial and the Phase 2 obesity clinical trial of pemvidutide, the timing of the data readouts for the Phase 2 clinical trial of HepTcell, and the prospects for regulatory approval, use, 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 COVID-19, 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 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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ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 127,465	$ 190,301
Restricted cash	34	34
Total cash, cash equivalents and restricted cash	127,499	190,335
Short-term investments	74,362	—
Accounts receivable	633	429
Income tax and R&D incentive receivables	3,720	5,410
Prepaid expenses and other current assets	4,790	7,952
Total current assets	211,004	204,126
Property and equipment, net	1,172	1,448
Intangible assets, net	12,419	12,419
Other assets	682	872
Total assets	$ 225,277	$ 218,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,419	$ 2,034
Contingent consideration	—	6,090
Accrued expenses and other current liabilities	14,323	10,152
Total current liabilities	15,742	18,276
Other long-term liabilities	4,506	1,454
Total liabilities	20,248	19,730
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 49,161,637 and 40,993,768 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	5	4
Additional paid-in capital	566,551	497,342
Accumulated deficit	(356,224)	(293,171)
Accumulated other comprehensive loss, net	(5,303)	(5,040)
Total stockholders' equity	205,029	199,135

Total liabilities and stockholders' equity	$ 225,277	$ 218,865

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues	$ 2	$ 158	$ 42	$ 1,133
Operating expenses:				
Research and development	20,262	29,206	51,359	54,356
General and administrative	4,492	4,156	13,329	11,636
Impairment loss on construction-in-progress	—	—	—	8,070
Total operating expenses	24,754	33,362	64,688	74,062
Loss from operations	(24,752)	(33,204)	(64,646)	(72,929)
Other income (expense):				
Interest expense	(64)	(33)	(191)	(67)
Interest income	1,053	13	1,402	88
Other income (expense), net	50	(286)	185	(293)
Total other income (expense), net	1,039	(306)	1,396	(272)
Net loss before income taxes	(23,713)	(33,510)	(63,250)	(73,201)
Income tax benefit	197	—	197	—
Net loss	(23,516)	(33,510)	(63,053)	(73,201)
Other comprehensive income — unrealized (loss) gain on short-term investments	(143)	(2)	(263)	4
Comprehensive loss	$ (23,659)	$ (33,512)	$ (63,316)	$ (73,197)
Net loss per share, basic and diluted	$ (0.48)	$ (0.81)	$ (1.37)	$ (1.79)
Weighted-average common shares outstanding, basic and diluted	49,286,535	41,370,768	45,881,547	40,843,905

Source: Altimmune, Inc