



Altimmune Announces Third Quarter 2021 Financial Results and Provides a Corporate Update

November 9, 2021

Exploratory MRI-PDFF analysis of subjects with hepatic steatosis in recently completed Phase 1 study of pemvidutide shows reduction of liver fat to undetectable levels after 6 weeks of treatment

Approximately \$200 Million in cash and short-term investments to advance pipeline

GAITHERSBURG, Md., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three- and nine-months ending September 30, 2021 and provided a corporate update.

"The third quarter was a momentous time for our pemvidutide (ALT-801) program, as we delivered on positive topline data for the 12-week Phase 1 trial, cleared an IND in non-alcoholic steatohepatitis (NASH) with the FDA and initiated a 12-week Phase 1b study in non-alcoholic fatty liver disease (NAFLD)," remarked Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimmune. "In addition to the previously announced 12-week data showing double-digit weight loss in the 1.8 mg arm without the need for dose titration, we now have MRI-PDFF data in a subset of subjects with hepatic steatosis, or fatty liver, from that study demonstrating a remarkable reduction in liver fat to undetectable levels after only 6 weeks of pemvidutide treatment. These findings show the potential of pemvidutide in the treatment of both obesity and NASH, and we look forward to sharing the data from our ongoing Phase 1b trial in NAFLD and initiating Phase 2 trials for obesity and NASH in 2022."

Program Highlights:

Pemvidutide¹ (ALT-801)

- *Announced weight loss data from 12-week Phase 1 clinical trial of pemvidutide in overweight and obese subjects*
 - Subjects achieved mean weight losses of 4.9%, 10.3%, and 9.0% at 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively
 - Once-weekly dosing regimen was well-tolerated without dose titration
 - Clinically meaningful reductions in serum lipids and blood pressure
 - No discontinuations due to adverse events
- *Obesity program advancing towards 48-week Phase 2 trial in the first half of 2022*
 - Investigational New Drug application (IND) for obesity expected to be submitted by year end 2021
 - 48-week Phase 2 obesity study expected to commence in the first half of 2022

¹ proposed INN

- *Reduction in liver fat by MRI-PDFF exploratory analysis in recently completed Phase 1 study*
 - MRI-PDFF data on liver fat content have now been analyzed through 6 weeks of treatment. While the trial inclusion criteria did not pre-specify a minimum liver fat content, the study did enroll a number of subjects with hepatic steatosis or fatty liver, defined as liver fat content greater than or equal to 5%. Five subjects had baseline hepatic steatosis (liver fat content ranging from 5.5 to 19.5%) and received pemvidutide at 1.8 mg or 2.4 mg dose levels. In each of these subjects, liver fat levels fell to undetectable levels within 6 weeks of treatment, representing a greater than 90% reduction in the liver fat content. These findings reinforce the results from preclinical studies of pemvidutide, which demonstrated statistically greater reductions in liver fat than an equivalent dose of semaglutide and confirm the combined beneficial effects of weight loss and glucagon on liver fat metabolism.
- *Pemvidutide IND application for NASH cleared and enrollment initiated in Phase 1b clinical trial in NAFLD, with topline data expected in the first half of 2022*
 - The Phase 1b, 12-week NAFLD trial is being conducted in the US, with Dr. Stephen A. Harrison serving as Principal Investigator
 - The study will include diabetic and non-diabetic subjects, with a primary efficacy end point of the change in liver fat as measured by MRI-PDFF, and a key secondary endpoint of weight loss at Week 12
 - A 52-week biopsy driven Phase 2 NASH trial is expected to follow the conclusion of the NAFLD trial
- *Additional activities for continued development of pemvidutide*
 - Drug-drug interaction trial of pemvidutide has been initiated in Australia, with results expected in the first half of

2022

- o A 12-week study to be initiated in Q1 2022 in the US to further characterize safety and pharmacokinetics of pemvidutide in diabetic subjects

HepTcell

- Enrollment progressing in international Phase 2 clinical trial in chronic hepatitis B subjects, with topline data expected in the second half of 2022
- Study readouts to include virological markers of hepatitis B infection

Financial Results for the Three and Nine Months Ended September 30, 2021

- Altimmune had cash, cash equivalents, short-term investments and restricted cash totaling \$199.9 million at September 30, 2021 compared to \$216.0 million at December 31, 2020.
- Revenue was \$0.2 million for the three months ended September 30, 2021 compared to \$2.9 million in the same period in 2020. The change in revenue quarter over quarter was primarily due to a decrease in MTEC/DoD revenue during the current period due to the timing of clinical trials and development activities for T-COVID.
- Research and development expenses were \$29.2 million for the three months ended September 30, 2021, compared to \$17.0 million in the same period in 2020. The change was primarily the result of increased expenses related to development activities for the Company's COVID-19 programs, offset by a decrease in the fair value of contingent consideration liability connected with the acquisition and development of pemvidutide.
- General and administrative expenses were consistent period-over-period with \$4.2 million recognized for the three months ended September 30, 2021 and \$4.2 million in the same period in 2020.
- Net loss for the three months ended September 30, 2021 was \$33.5 million, or \$0.81 net loss per share, compared to \$17.8 million in the same period in 2020, or \$0.54 net loss per share. Net loss for the nine months ended September 30, 2021 was \$73.2 million, or \$1.79 net loss per share, compared to \$38.4 million in the same period in 2020, or \$1.74 net loss per share.

Conference Call Information

Date: Wednesday, November 10
Time: 8:30 am Eastern Time
Domestic Dial-in: (844) 615-6509
International Dial-in: (918) 922-3148
Conference ID: 5783655
Webcast: <https://edge.media-server.com/mmc/p/zgrmubx>

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 (proposed INN, formerly known as ALT-801) is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist for obesity and non-alcoholic steatohepatitis (NASH). Altimmune believes the treatment of obesity is the cornerstone of treating NASH and its co-morbidities and views these conditions as significant unmet medical needs.

About HepTcell

HepTcell is a novel 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 developing treatments for obesity and liver diseases. Our pipeline includes next generation peptide therapeutics for obesity, NASH (pemvidutide), and chronic hepatitis B (HepTcell™). For more information on Altimmune, 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 our Investigational New Drug application (IND) for obesity expected by year end, the commencement of a 48-week Phase 2 obesity study expected to commence in the first half of 2022, the timing of the data readout from the pemvidutide 12-week Phase 1b NAFLD trial in the first half of 2022, the timing of the data

readout of the pemvidutide drug/drug interaction trial in the first half of 2022, the commencement of a 52-week, Phase 2, biopsy-trial based on NASH endpoints following the conclusion of the NAFLD trial, the timing of a 12-week Phase 1 study to further characterize safety, pharmacokinetics of pemvidutide subjects in diabetic expected to be initiated in Q1 2022, the timing of the data readout from the HepTcell Phase 2 trial in the second half of 2022, the prospects for regulatory approval of our product candidates and 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 due to 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 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 and commercial supply 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, 2020 filed with the SEC, which is available at www.sec.gov.

Investor & Media Contacts:

Will Brown
 Chief Financial Officer
 Phone: 240-654-1450
wbrown@altimmune.com

ALTIMMUNE, INC. CONSOLIDATED BALANCE SHEETS

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 174,863,565	\$ 115,917,807
Restricted cash	34,174	34,174
Total cash, cash equivalents and restricted cash	174,897,739	115,951,981
Short-term investments	25,020,738	100,005,558
Accounts receivable	1,573,760	4,610,202
Income tax receivable	9,476,435	7,762,793
Prepaid expenses and other current assets	7,294,360	1,926,675
Total current assets	218,263,032	230,257,209
Property and equipment, net	4,718,146	1,056,920
Intangible assets, net	12,993,575	12,823,846
Other assets	931,904	977,238
Total assets	\$ 236,906,657	\$ 245,115,213
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,083	\$ 612,293
Accrued expenses and other current liabilities	19,120,902	11,408,154
Total current liabilities	19,126,985	12,020,447
Contingent consideration	6,950,000	5,390,000
Other long-term liabilities	1,565,611	1,828,443
Total liabilities	27,642,596	19,238,890
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 39,702,768 and 37,142,946 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	3,959	3,697
Additional paid-in capital	483,582,367	417,337,742
Accumulated deficit	(269,282,102)	(186,420,599)
Accumulated other comprehensive loss, net	(5,040,163)	(5,044,517)
Total stockholders' equity	209,264,061	225,876,323
Total liabilities and stockholders' equity	\$ 236,906,657	\$ 245,115,213

ALTIMMUNE, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues	\$ 157,559	\$ 2,937,991	\$ 1,132,698	\$ 5,872,321
Operating expenses:				
Research and development	29,205,739	17,041,975	54,356,051	40,823,756
General and administrative	4,155,928	4,220,238	11,636,001	9,097,511
Impairment loss on construction-in-progress	—	—	8,070,000	—
Total operating expenses	33,361,667	21,262,213	74,062,052	49,921,267
Loss from operations	(33,204,108)	(18,324,222)	(72,929,354)	(44,048,946)
Other income (expense):				
Interest expense	(32,866)	(2,275)	(66,763)	(7,468)
Interest income	12,485	45,127	87,847	278,154
Other (expense) income, net	(286,199)	29,218	(293,233)	48,882
Total other (expense) income, net	(306,580)	72,070	(272,149)	319,568
Net loss before income tax benefit	(33,510,688)	(18,252,152)	(73,201,503)	(43,729,378)
Income tax benefit	—	482,017	—	5,306,678
Net loss	(33,510,688)	(17,770,135)	(73,201,503)	(38,422,700)
Other comprehensive (loss) income — unrealized (loss) gain on short-term investments	(1,923)	(10,569)	4,354	(22,116)
Comprehensive loss	\$ (33,512,611)	\$ (17,780,704)	\$ (73,197,149)	\$ (38,444,816)
Net loss per share, basic and diluted	\$ (0.81)	\$ (0.54)	\$ (1.79)	\$ (1.74)
Weighted-average common shares outstanding, basic and diluted	41,370,768	33,056,971	40,843,905	22,058,424



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Source: Altimune, Inc