## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

### FORM 8-K

#### CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 30, 2023

# ALTIMMUNE, INC.

(Exact name of registrant as specified in its charter)

001-32587

Delaware (State or other jurisdiction of incorporation)

910 Clopper Road, Suite 201S Gaithersburg, Maryland (Address of principal executive offices) 20-2726770 (IRS Employer Identification No.)

20878 (Zip Code)

Registrant's telephone number including area code: (240) 654-1450

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	ALT	The NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

### Item 7.01 Regulation FD Disclosure.

On November 30, 2023, Altimmune, Inc. (the "Company") issued a press release (the "Press Release") announcing the topline results from its 48-week MOMENTUM Phase 2 obesity trial of pemvidutide, a copy of which is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company intends to host a conference call and live webcast to discuss the results on December 1, 2023 at 8:30 a.m. EST. The Company has made available a slide presentation to accompany the call, a copy of which is being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

#### Item 8.01 Other Events

On November 30, 2023, the Company announced topline results from its 48-week MOMENTUM Phase 2 obesity trial of pemvidutide. The trial enrolled 391 subjects with obesity or overweight with at least one co-morbidity and without diabetes.

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. The 1.2 mg and 1.8 mg doses were administered without dose titration, while a short 4-week titration period was employed for the 2.4 mg dose. At baseline, subjects had a mean age of approximately 50 years, mean body mass index (BMI) of approximately 37 kg/m² and mean body weight of approximately 104 kg. Approximately 75% of subjects were female.

At Week 48, subjects receiving perovidutide achieved mean weight losses of 10.3%, 11.2%, 15.6% and 2.2% at the 1.2 mg, 1.8 mg, and 2.4 mg doses and placebo, respectively, with a near-linear trajectory of continued weight loss observed on the 2.4 mg dose at the end of treatment. Over 50% of subjects achieved at least 15% weight loss on over 30% of subjects achieved at least 20% weight loss on the 2.4 mg dose. As in prior clinical trials, perovidutide resulted in robust reductions in serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate. Glucose homeostasis was maintained, with no significant changes in fasting glucose or HIBA1c

More subjects receiving pemvidutide stayed on study compared to those receiving placebo, with 74.1% of pemvidutide subjects completing the trial compared to 61.9% of placebo subjects. Nausea and vomiting comprised the majority of adverse events (AEs) and were predominantly mild to moderate in severity. Only one (1.0%) subject experienced a drug-related serious adverse event (SAE), a case of vomiting at the 2.4 mg dose. Rates of AEs leading to treatment discontinuation were 6.2% in subjects receiving placebo and 5.1%, 19.2%, and 19.6% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively. Study discontinuations related to study drug occurred in 2.1% of placebo subjects and 4.1%, 16.2% and 15.5% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively, with most discontinuations due to AEs in the pemvidutide groups occurring in the first 16 weeks of treatment. No AEs of special interest or major adverse cardiac events (MACE) were observed, and there were low rates of cardiac AEs, including arrhythmias, with no imbalance across pemvidutide or placebo groups.

 $The \ tables \ below \ summarize \ the \ efficacy \ findings \ as \ well \ as \ safety \ and \ tolerability \ findings \ of \ the \ trial.$ 

## Summary of Efficacy Findings

Primary Endpoint: Body weight		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
Δ Body weight, all subjects	%, LSM (SE) <sup>1</sup>	-2.2 (1.4)	-10.3 (1.4)***	-11.2 (1.4)***	-15.6 (1.4)***
Responder Analyses		Placebo (N=51)	1.2 mg (N=70)	1.8 mg (N=63)	2.4 mg (N=56)
% Subjects w/≥5% weight loss		17.6%	68.6%****	76.2%****	83.9%****
% Subjects w/≥10% weight loss	% <sup>2</sup>	3.9%	42.9%****	49.2%****	71.4%****
% Subjects w/≥15% weight loss	70-	2.0%	21.4%**	28.6%***	51.8%****
% Subjects w/ ≥20% weight loss		2.0%	10.0%	9.5%	32.1%****
Secondary Endpoints		Placebo (N=50)	1.2 mg (N=69)	1.8 mg (N=58)	2.4 mg (N=55)
Δ Total cholesterol		-2.8 (2.0)	-11.6 (1.7)**	-13.1 (1.9)***	-15.1 (2.0)***
Δ LDL cholesterol	%, LSM (SE) <sup>3</sup>	-2.8 (4.1)	-6.2 (3.5)	-11.2 (3.8)	-9.9 (3.9)
Δ Triglycerides	ESW (SE)	+7.3 (4.6)	-21.7 (3.9)***	-22.3 (4.3)***	-34.9 (4.4)***
Blood Pressure and Heart Rate		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
Δ Systolic BP	mm Hg,	+3.5 (2.3)	-2.3 (2.2)	-1.6 (2.2)	-4.6 (2.3)
Δ Diastolic BP	LSM (SE) <sup>1</sup>	+1.8 (1.4)	-2.1 (1.3)	-1.0 (1.3)	-2.9 (1.4)
Δ Heart rate	bpm, LSM (SE) <sup>1</sup>	-1.4 (1.6)	0.1 (1.5)	3.1 (1.5)	2.5 (1.6)

 $<sup>\</sup>label{eq:main_control} $^{+}$ MMRM (mixed model for repeated measures), $^{2}$ CMH (Cochran Mantel Henszel), $^{3}$ ANCOVA (analysis of covariance) $^{+}$ $^{0}$ 0.005, $^{*}$ $^{+}$ $^{0}$ 0.001, $^{*}$ $^{+}$ $^{0}$ 0.001 compared with placebo$ 

### Summary of Safety and Tolerability

Adverse events (AEs)		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
SAEs related to study drug	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)4
All AEs leading to discontinuation	N (%)	6 (6.2%)	5 (5.1%)	19 (19.2%)	19 (19.6%)
Drug-related AEs leading to discontinuation	N (%)	2 (2.1%)	4 (4.1%)	16 (16.2%)	15 (15.5%)
Gastrointestinal AEs—mainly mild to moderate		•		•	
Nausea	N (%)	11 (11.3%)	25 (25.5%)	59 (59.6%)	50 (51.5%)
Vomiting	N (%)	3 (3.1%)	6 (6.1%)	27 (27.3%)	27 (27.8%)
Diarrhea	N (%)	5 (5.2%)	8 (8.2%)	10 (10.1%)	18 (18.6%)
Constipation	N (%)	8 (8.2%)	17 (17.3%)	13 (13.1%)	22 (22.7%)
Major Adverse Cardiac Events (MACE)	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiac AEs including arrhythmias	N (%)	4 (4.1%)	3 (3.1%)	4 (4.0%)	3 (3.1%)

<sup>&</sup>lt;sup>4</sup> Vomiting

Summary of Glycemic Control		Placebo	1.2 mg	1.8 mg	2.4 mg
		(N=50)	(N=68)	(N=58)	(N=55)
Fasting glucose					
Baseline, mg/dL	mean (SE)	95.5 (1.5)	99.4 (1.4)	101.6 (1.4)	101.5 (1.6)
Week 48, mg/dL	mean (SE)	95.2 (1.5)	98.6 (1.7)	100.6 (1.6)	99.4 (2.0)
HbA1c					
Baseline, %	mean (SE)	5.6 (0.0)	5.5 (0.0)	5.5 (0.1)	5.6 (0.0)
Week 48, %	mean (SE)	5.5 (0.0)	5.5 (0.0)	5.6 (0.1)	5.5 (0.1)

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Altimmune, Inc. dated November 30, 2023
<b>77.1</b>	riess release of Arthinitune, inc. dated rovember 30, 2023
99.2	Slide Presentation of Altimmune, Inc. dated November 30, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALTIMMUNE, INC.

By:

/s/ Richard Eisenstadt Name: Richard Eisenstadt Title: Chief Financial Officer

Dated: November 30, 2023





### Altimmune Announces Positive Topline Results from MOMENTUM 48-Week Phase 2 Obesity Trial of Pemvidutide

- Achieved mean weight loss of 15.6% on 2.4 mg dose of permidutide at Week 48, with weight loss continuing at the end of treatment
- Over 30% of subjects achieved 20% or more weight loss on 2.4 mg dose at 48 weeks
- Robust reductions in BMI and serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate

#### Altimmune to host conference call tomorrow at 8:30 am EST

GAITHERSBURG, MD, – November 30, 2023 – Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company (the "Company"), today announced topline results from its 48-week MOMENTUM Phase 2 obesity trial of permidutide. The trial enrolled 391 subjects with obesity or overweight with at least one co-morbidity and without diabetes. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg penvidutide or placebo administered weekly for 48 weeks in conjunction with diet and exercise. The 1.2 mg and 1.8 mg doses were administered without dose titration, while a short 4-week titration period was employed for the 2.4 mg dose. At baseline, subjects had a mean age of approximately 50 years, mean body mass index (BMI) of approximately 37 kg/m² and mean body weight of approximately 104 kg. Approximately 75% of subjects were female.

At Week 48, subjects receiving pemvidutide achieved mean weight losses of 10.3%, 11.2%, 15.6% and 2.2% at the 1.2 mg, 1.8 mg, and 2.4 mg doses and placebo, respectively, with a near-linear trajectory of continued weight loss observed on the 2.4 mg dose at the end of treatment. Over 50% of subjects achieved at least 15% weight loss ond over 30% of subjects achieved at least 20% weight loss on the 2.4 mg dose. As in prior clinical trials, pemvidutide resulted in robust reductions in serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate. Glucose homeostasis was maintained, with no significant changes in fasting glucose or HbA1c.

More subjects receiving pemvidutide stayed on study compared to those receiving placebo, with 74.1% of pemvidutide subjects completing the trial compared to 61.9% of placebo subjects. Nausea and vomiting comprised the majority of adverse events (AEs) and were predominantly mild to moderate in severity. Only one (1.0%) subject experienced a drug-related serious adverse event (SAE), a case of vomiting at the 2.4 mg dose. Rates of AEs leading to treatment discontinuation were 6.2% in subjects receiving placebo and 5.1%, 19.2%, and 19.6% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively. Study discontinuations related to study drug occurred in 2.1% of placebo subjects and 4.1%, 16.2% and 15.5% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively, with most



discontinuations due to AEs in the pemvidutide groups occurring in the first 16 weeks of treatment. No AEs of special interest or major adverse cardiac events (MACE) were observed, and there were low rates of cardiac AEs, including arrhythmias, with no imbalance across pemvidutide or placebo groups.

"The level of weight loss achieved at 48 weeks in this trial has been shown to reverse the key complications of obesity. Moreover, the trajectory of weight loss at the end of treatment with the 2.4 mg dose suggests the potential for greater weight loss with continued treatment," said Dr. Scott Harris, Chief Medical Officer of Altimmune. Dr. Harris added, "It is also important to recognize the safety profile of penvidutide observed to date, especially cardiac-related safety, considering that many obesity patients are at risk for cardiovascular events such as arrhythmias and major adverse cardiac events."

"This is an important day for Altimmune and we couldn't be more pleased with these results," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "To put these results in context, the 15.6% mean weight loss observed with the 2.4 mg dose was associated with a mean weight loss of 32.2 lbs at 48 weeks. The impact of this level of weight loss on patients can be significant. For example, 48% of subjects on the 2.4 mg dose with baseline obesity no longer had obesity at the end of the 48-week trial." Dr. Garg continued, "We believe the magnitude of weight loss, robust reductions in triglycerides, LDL cholesterol and blood pressure, together with the safety profile observed in this trial, could potentially differentiate perwidutide from the other incretin-based therapies. If approved, we believe perwidutide could offer an important option for obesity patients, including those with risk factors for cardiovascular disease."

#### **Summary of Efficacy Findings**

Primary Endpoint: Body weight		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
Δ Body weight, all subjects	%, LSM (SE)1	-2.2 (1.4)	-10.3 (1.4)***	-11.2 (1.4)***	-15.6 (1.4)***
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% Subjects w/ ≥15% weight loss	762	2.0%	21.4%**	28.6%***	51.8%****
% Subjects w/ ≥20% weight loss		2.0%	10.0%	9.5%	32.1%****
Secondary Endpoints		Placebo (N=50)	1.2 mg (N=69)	1.8 mg (N=58)	2.4 mg (N=55)
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Blood Pressure and Heart Rate		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
Δ Systolic BP	mm Hg,	+3.5 (2.3)	-2.3 (2.2)	-1.6 (2.2)	-4.6 (2.3)
Δ Diastolic BP	LSM (SE) <sup>1</sup>	+1.8 (1.4)	-2.1 (1.3)	-1.0 (1.3)	-2.9 (1.4)
Δ Heart rate	bpm, LSM (SE) <sup>1</sup>	-1.4 (1.6)	0.1 (1.5)	3.1 (1.5)	2.5 (1.6)

<sup>&</sup>lt;sup>1</sup> MMRM (mixed model for repeated measures), <sup>2</sup> CMH (Cochran Mantel Haenszel), <sup>3</sup> ANCOVA (analysis of covariance)

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Gastrointestinal AEs—mainly mild to moderate		•	•	•	
Nausea	N (%)	11 (11.3%)	25 (25.5%)	59 (59.6%)	50 (51.5%)
Vomiting	N (%)	3 (3.1%)	6 (6.1%)	27 (27.3%)	27 (27.8%)
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Major Adverse Cardiac Events (MACE)	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiac AEs including arrhythmias	N (%)	4 (4.1%)	3 (3.1%)	4 (4.0%)	3 (3.1%)

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Summary of Glycemic Control		Placebo (N=50)	1.2 mg (N=68)	1.8 mg (N=58)	2.4 mg (N=55)
Fasting glucose					
Baseline, mg/dL	mean (SE)	95.5 (1.5)	99.4 (1.4)	101.6 (1.4)	101.5 (1.6)
Week 48, mg/dL	mean (SE)	95.2 (1.5)	98.6 (1.7)	100.6 (1.6)	99.4 (2.0)
HbA1c	•	•			•
Baseline, %	mean (SE)	5.6 (0.0)	5.5 (0.0)	5.5 (0.1)	5.6 (0.0)
Week 48, %	mean (SE)	5.5 (0.0)	5.5 (0.0)	5.6 (0.1)	5.5 (0.1)

<sup>\*</sup>p < 0.05; \*\*p < 0.005, \*\*\*p < 0.001, \*\*\*\*p < 0.0001 compared with placebo



#### **About Pemvidutide**

Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and metabolic dysfunction-associated steatohepatitis (MASH), formerly known as non-alcoholic steatohepatitis (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.

#### **Conference Call Information**

Altimmune management will host a conference call and webcast with a slide presentation presented by Dr. Scott Harris, Chief Medical Officer beginning at 8:30 am E.T. tomorrow. 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 Details:**

Date: Friday, December 1
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.

#### **About Altimmune**

Altimmune is a clinical-stage biopharmaceutical company focused on developing treatments for 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 MASH, formerly known as 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.

# Follow @Altimmune, Inc. on LinkedIn Follow @AltimmuneInc on Twitter

#### **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 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 (the "SEC"), including under the heading "Risk Factors" in the Company's most recent annual report on Form 10-K and its 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 Duchene Evoke Canale Phone: 619-826-4878

Danielle.Duchene@canalecomm.com



# Forward-looking statements

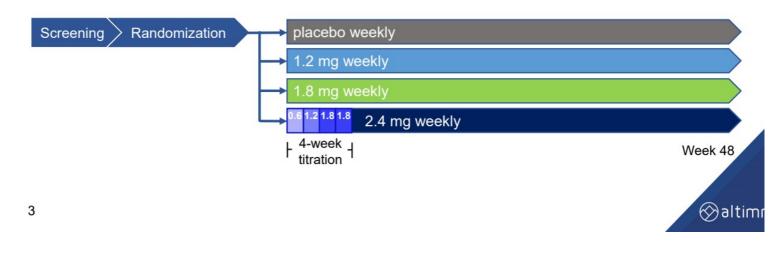
#### Safe-Harbor Statement

This presentation has been prepared by Altimmune, Inc. ("we," "us," "our," "Altimmune" or the "Company") and includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements 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 results of the Phase 2 obesity clinical trial of pemvidutide, the performance of our drug candidates in ongoing and future clinical trials and the prospects for regulatory approval, commercializing or selling any product or drug candidates. 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 the Company may identify forward-looking statements. The Company cautions that these forwardlooking 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 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 subject baseline characteristics, including body weight, 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 latest annual report on Form 10-K and our other filings with the SEC, which are available at www.sec.gov.



# **MOMENTUM Trial**

- Phase 2, 48-week trial of pemvidutide, a balanced (1:1) GLP-1/glucagon dual receptor agonist, in 391 subjects with overweight or obesity
- Randomized 1:1:1:1 to 1 of 4 treatment arms, stratified by gender and baseline BMI, with standard lifestyle interventions
- No or rapid (4 week) dose titration; dose reduction due to intolerability was not allow



# Study Population—Key Eligibility Criteria

- · Men and women ages 18-75 years
- BMI ≥ 30 kg/m² or BMI ≥ 27 kg/m² with at least one obesity-related comorbidity
  - History of cardiovascular disease
  - Hypertension
  - Dyslipidemia
  - Pre-diabetes
  - Obstructive sleep apnea
- Non-diabetes: HbA1c ≤ 6.5% and fasting glucose ≤ 125 mg/dL
- At least one unsuccessful weight loss attempt
- · A minimum of approximately 25% of subjects were to be male



# **Study Endpoints**

# **Efficacy**

- · Primary endpoint
  - Relative change from baseline in body weight (%)
- · Key secondary endpoints
  - Proportions (%) of subjects achieving weight loss of ≥ 5%, ≥ 10%, ≥ 15% and ≥ 20% body weight
  - · Change from baseline in serum lipids and blood pressure

## Safety

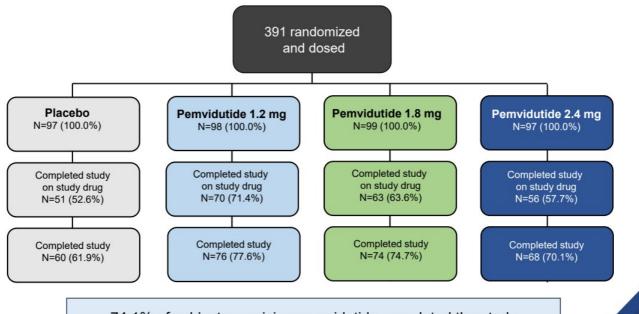
- · Adverse events (AEs)
  - Serious AEs
  - · Adverse Events of Special Interest (AESI)
  - Cardiac AEs and Major Adverse Cardiac Events (MACE)
- · Heart rate
- · Glucose homeostasis

# **Tolerability**

- · AEs leading to discontinuation
- · Gastrointestinal (GI) AEs



# **Disposition of Subjects**



74.1% of subjects receiving pemvidutide completed the study



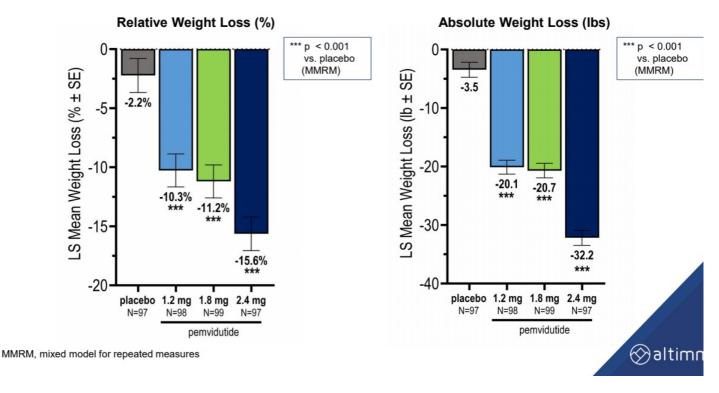
# **Baseline Characteristics of Subjects**

			Treat	ment	
Cha	aracteristic	Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
Age, years	mean (SD)	50.3 (13.6)	49.6 (12.3)	50.1 (13.3)	48.5 (13.6)
Gender	female, N (%)	72 (74.2%)	75 (76.5%)	76 (76.8%)	74 (76.3%)
	White, N (%)	76 (78.4%)	86 (87.8%)	72 (72.7%)	77 (79.4%)
Race	African-American, N (%)	13 (13.4%)	8 (8.2%)	19 (19.2%)	16 (16.5%)
	Asian, N (%)	5 (5.2%)	1 (1.0%)	2 (2.0%)	0 (0.0%)
	Native or American Indian, N (%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)
	Other, N (%)	3 (3.1%)	3 (3.1%)	5 (5.1%)	4 (4.1%)
	Hispanic, N (%)	19 (19.6%)	19 (19.4%)	18 (18.2%)	24 (24.7%)
Ethnicity	not Hispanic, N (%)	78 (80.4%)	77 (78.6%)	79 (79.8%)	73 (75.3%)
	not reported, N (%)	0 (0.0%)	2 (2.0%)	2 (2.0%)	0 (0.0%)
BMI, kg/m <sup>2</sup>	mean (SD)	37.8 (7.2)	37.4 (6.1)	37.4 (7.4)	37.1 (5.9)
Body weight, kg	mean (SD)	105.7 (22.5)	104.5 (22.7)	103.8 (23.8)	104.0 (19.7)
	systolic, mean (SD)	122.2 (12.8)	121.6 (12.9)	124.0 (12.8)	124.7 (13.0)
Blood pressure, mm Hg	diastolic, mean (SD)	76.4 (8.1)	77.9 (7.5)	78.2 (7.6)	80.0 (7.7)

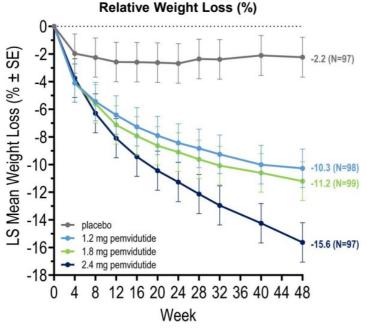


# Weight Loss of 15.6% Achieved at Week 48 on 2.4 mg

MEAN WEIGHT LOSS OF 32.2 LBS AND MAXIMAL WEIGHT LOSS OF 87.1 LBS



# Weight Loss Continuing at Week 48

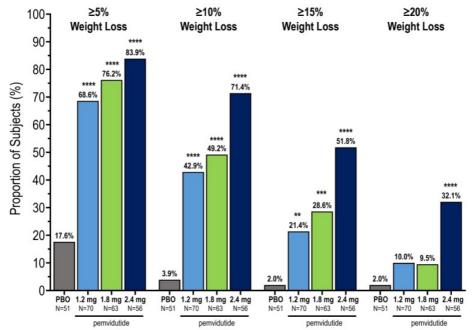


- Near linear trajectory of weight loss on 2.4 mg at 48 weeks
- Greater weight loss could potentially be realized with longer durations of treatment



MMRM, mixed model for repeated measures

# Majority of Subjects Lost ≥ 15% Body Weight on 2.4 mg

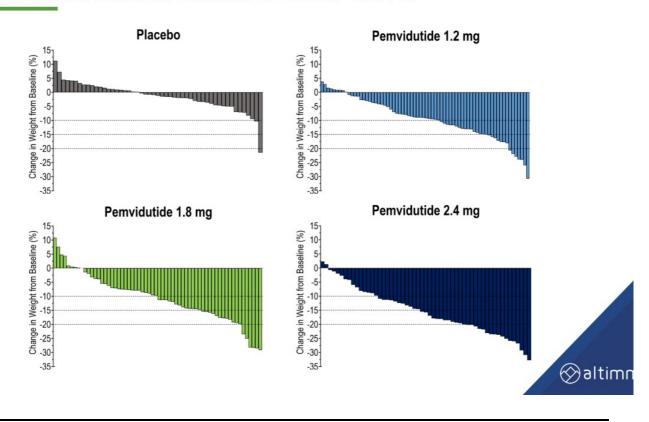


\*\* p < 0.005 \*\*\* p < 0.001 \*\*\*\* p < 0.0001 vs. placebo (CMH)

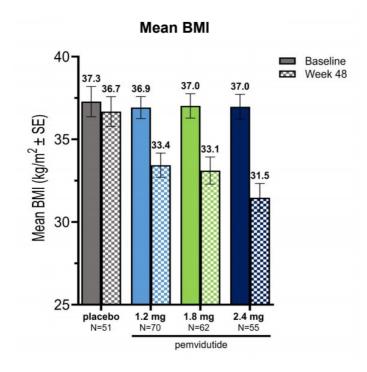


CMH, Cochran-Mantel-Haenszel

# Robust Weight Loss at All Pemvidutide Doses OVER 30% OF SUBJECTS LOST 20% OR MORE BODY WEIGHT ON 2.4 MG



# Significant Reductions in BMI at Week 48



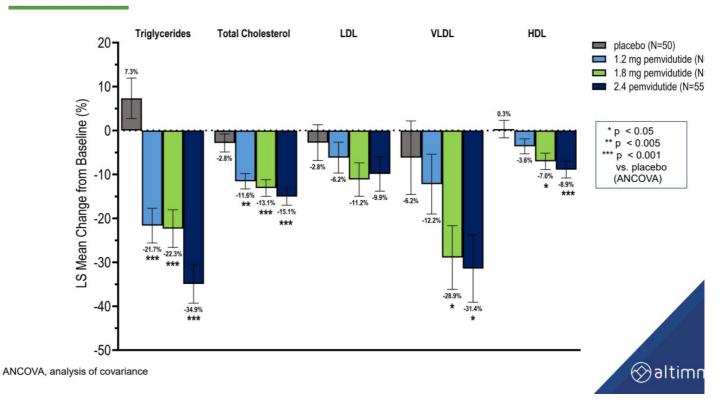
## **BMI Classes**

Normal	Over-	Obesity	Obesity	Obesity
	weight	Class 1	Class 2	Class 3
<25	25-30	30-35	35-40	> 40

- 49% of subjects on 2.4 mg realized a 1-class reduction in BMI
- 29% of subjects on 2.4 mg realized a 2-class reduction in BMI
- 48% of subjects on 2.4 mg with baseline obesity no longer had obesity at the end of treatment

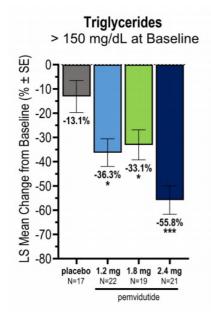


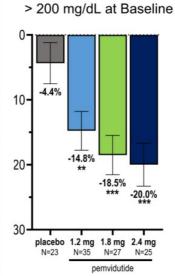
# Robust Reductions in Serum Lipids at Week 48

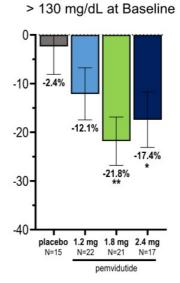


# Greater Reductions in Triglycerides, Total and LDL Cholesterol in Subjects with Elevated Baseline Levels

**Total Cholesterol** 







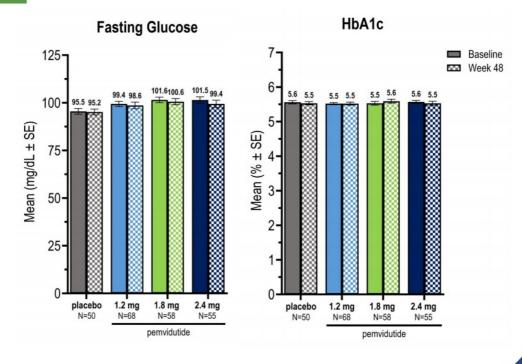
LDL

\* p < 0.05 \*\* p < 0.005 \*\*\* p < 0.001 vs. placebo (ANCOVA)



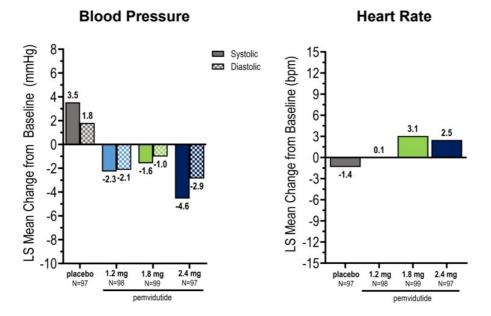
ANCOVA, analysis of covariance

# **Glucose Homeostasis Maintained**





# Improvements in Blood Pressure without Clinically Meaningful Increases in Heart Rate at Week 48





# **Overview of Adverse Events (AEs)**

		Treatment			
Characteristic		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
SAEs related to study drug	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)
AEs leading to study drug discontinuation					
All AEs leading to discontinuation	N (%)	6 (6.2%)	5 (5.1%)	19 (19.2%)	19 (19.6%)
Drug-related AEs leading to discontinuation	N (%)	2 (2.1%)	4 (4.1%)	16 (16.2%)	15 (15.5%)
Gastrointestinal (GI) AEs—mainly mild to moderate					
Nausea	N (%)	11 (11.3%)	25 (25.5%)	59 (59.6%)	50 (51.5%)
Vomiting	N (%)	3 (3.1%)	6 (6.1%)	27 (27.3%)	27 (27.8%)
Diarrhea	N (%)	5 (5.2%)	8 (8.2%)	10 (10.1%)	18 (18.6%)
Constipation	N (%)	8 (8.2%)	17 (17.3%)	13 (13.1%)	22 (22.7%)
AEs of Special Interest (AESI)	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Major Adverse Cardiac Events (MACE)	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiac AEs, including arrhythmias	N (%)	4 (4.1%)	3 (3.1%)	4 (4.0%)	3 (3.1%)

- Only 1 drug-related SAE of vomiting
- · No AESI or MACE events
- No imbalances in cardiac AEs across treatment groups

# **MOMENTUM Trial—Week 48 Summary**

# **Efficacy**

- · Robust mean weight loss of 15.6% on pemvidutide 2.4 mg at Week 48
- Mean and maximal weight losses of 32.2 lbs and 87.1 lbs, respectively, on 2.4 mg at Week 48
- Over 30% of subjects lost 20% or more body weight on 2.4 mg at Week 48
- Continued weight loss on 2.4 mg at Week 48—greater weight loss could potentially be achieved with longer duration of treatment
- · Substantial and clinically meaningful reductions in total cholesterol, LDL, triglycerides and blood pressu

# Safety and Tolerability

- Gastrointestinal AEs, common to incretin-based agents, mainly mild to moderate in severity
- No imbalance of cardiac AEs, including arrhythmias
- · No clinically meaningful increases in heart rate
- · Glucose homeostasis maintained



Rich Eisenstadt, CFO reisenstadt@altimmune.com



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NASDAQ: ALT