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): December 20, 2022

ALTIMMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-32587**	**20-2726770**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

910 Clopper Road, Suite 201S **Gaithersburg, Maryland** **(Address of principal executive offices)**	**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 ☐

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. ☐

Item 7.01 Regulation FD Disclosure

On December 20, 2022, Altimmune, Inc. (the "Company") issued a press release announcing results from its trial of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD). The Company intends to host a conference call and live webcast to discuss the results on December 20, 2022 at 8:30 a.m. E.T. 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 December 20, 2022, the Company announced results from a 24-week (12 week extension) trial of pemvidutide (formerly known as ALT-801), an investigational glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist.

Of the 83 subjects who completed the initial 12-week Phase 1b NAFLD trial, 66 subjects consented to participate in this 12-week extension trial to receive a total of 24 weeks of treatment, and 64 subjects were enrolled. The trial was conducted without adjunctive diet and exercise interventions and the double-blinding of the trial was maintained during the extension study. The same endpoints as the parent, 12-week Phase 1b NAFLD trial were employed, with a primary efficacy endpoint of percent (%) reduction in liver fat content; key secondary endpoints were reduction in liver inflammation, as measured by serum ALT levels and cT1, and percent weight loss.

At baseline, across all treatment groups, mean BMI was 36.7 kg/m2 and mean liver fat content, as measured by MRI-PDFF, was 22.2%. Type 2 diabetes was present in 26.6% of subjects and 73.4% of study subjects were of Hispanic ethnicity.

The trial met its primary endpoint in all pemvidutide treatment groups. At the 1.8 mg and 2.4 mg doses, subjects receiving pemvidutide achieved mean relative reductions of liver fat content of 75.2% and 76.4%, respectively; 92.3% and 100% of subjects, respectively, achieved a 30% reduction in liver fat, 84.6% and 72.7% of subjects, respectively, achieved a 50% reduction in liver fat, and 53.8% and 45.5% of subjects, respectively, achieved normalization of liver fat, defined as liver fat fraction of 5% or less.

Statistically significant declines in mean serum ALT levels were observed in all pemvidutide-treated subjects, and in subjects with baseline serum ALT ≥30 IU/L, ALT levels declined at least 17 IU/L at all pemvidutide dose levels. In a subset of subjects evaluated for cT1 response, 75.0% and 100% of subjects receiving 1.8 mg or 2.4 mg pemvidutide, respectively, achieved an 80 millisecond (ms) decrease in cT1. Elevated cT1 levels have been associated with increased risk of major adverse cardiac events and major adverse liver outcomes, and an 80 ms reduction has been associated with a 2-point reduction of NAFLD Activity Score.

The trial also met its key secondary weight loss endpoint in all pemvidutide treatment groups. Employing an efficacy estimand, mean weight losses of 7.2% (placebo-adjusted 6.0%) in subjects without diabetes and 6.2% (placebo-adjusted 4.8%) in all subjects were achieved at the 1.8 mg dose.

Pemvidutide was generally well tolerated. A total of 3 serious or severe adverse events (AEs) were reported, each unrelated to study drug administration (chest pain post-elective cardiac stent placement; Salmonella infection; and hypertension greater than 3 weeks after the completion of treatment). Three AEs led to treatment discontinuation, 1 being the Salmonella infection, and 2 gastrointestinal AEs, 1 (6.3%) at the 1.2 mg dose and 1 (6.7%) at the 1.8 mg dose. As expected, gastrointestinal events comprised the majority of AEs and were predominantly mild in nature. No clinically significant ALT elevations were observed. Glycemic control was maintained, with pemvidutide groups demonstrating trends toward improvements in fasting glucose and HbA1c over the 24 weeks of treatment. Meaningful reductions in systolic blood pressure were observed, and increases in heart rate, typical of the incretin class of agents, were minimal at 0 to 4 beats per minute and independent of dose.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

No.	Description
99.1	Press Release of Altimmune, Inc. dated December 20, 2022
99.2	Slide Presentation of Altimmune, Inc. dated December 20, 2022
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: December 20, 2022

Exhibit 99.1

Altimmune Announces Positive Topline Results from 24-Week (12-Week Extension) Trial of Pemvidutide in Subjects with Non-Alcoholic Fatty Liver Disease (NAFLD)

- *Greater than 75% relative reduction in liver fat content achieved at the 1.8 mg and 2.4 mg doses at 24 weeks*
- *Significant reductions in serum alanine aminotransferase (ALT) and corrected T1 (cT1) observed, both established markers of liver inflammation*
- *Mean weight loss of 7.2% (placebo adjusted 6.0%) in subjects without diabetes at the 1.8 mg dose*
- *Glycemic control maintained with trends toward improvements in fasting glucose and HbA1c in subjects with diabetes*
- *Meaningful reductions in blood pressure with minimal increases in heart rate*
- *Altimmune to host conference call today at 8:30 am ET*

GAITHERSBURG, MD, -- December 20, 2022 -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced topline results from its 24-week (12-week extension) trial of pemvidutide in subjects with NAFLD.

Sixty-six (66) of the 83 subjects who completed the initial 12-week Phase 1b NAFLD trial consented to participate in this 12-week extension trial to receive a total of 24 weeks of treatment, and 64 subjects were enrolled. The trial was conducted without adjunctive diet and exercise interventions and the double-blinding of the trial was maintained during the extension study. The same endpoints as the 12-week parent NAFLD trial were employed, with a primary efficacy endpoint of percent (%) reduction in liver fat content; key secondary endpoints were reduction in liver inflammation, as measured by serum ALT levels and cT1, and percent weight loss.

The population of the 12-week extension trial had similar baseline characteristics as the population of the parent, 12-week Phase 1b NAFLD trial. At baseline, across all treatment groups, mean BMI was 36.7 kg/m^2 and mean liver fat content (LFC), as measured by MRI-PDFF, was 22.2%. Type 2 diabetes was present in 26.6% of subjects and 73.4% of study subjects were of Hispanic ethnicity.

The trial met its primary endpoint in all pemvidutide treatment groups. At the 1.8 mg and 2.4 mg doses, subjects receiving pemvidutide achieved mean relative reductions of liver fat content of 75.2% and 76.4%, respectively; 92.3% and 100% of subjects, respectively, achieved a 30% reduction in liver fat, 84.6% and 72.7% of subjects, respectively, achieved a 50% reduction in liver fat, and 53.8% and 45.5% of subjects, respectively, achieved normalization of liver fat, defined as liver fat fraction of 5% or less. Statistically significant declines in mean serum ALT levels were observed in all pemvidutide-treated subjects, and in subjects with baseline serum ALT ≥30 IU/L, ALT levels declined at least 17 IU/L at all pemvidutide dose

levels. In a subset of subjects evaluated for cT1 response, 75.0% and 100% of subjects receiving 1.8 mg or 2.4 mg pemvidutide, respectively, achieved an 80 millisecond (ms) decrease in cT1. Elevated cT1 levels have been associated with increased risk of major adverse cardiac events (MACE) and major adverse liver outcomes (MALO), and an 80 ms reduction has been associated with a 2-point reduction of NAFLD Activity Score (NAS).

The trial also met its key secondary weight loss endpoint in all pemvidutide treatment groups. Employing an efficacy estimand, mean weight losses of 7.2% (placebo-adjusted 6.0%) in subjects without diabetes and 6.2% (placebo-adjusted 4.8%) in all subjects were achieved at the 1.8 mg dose.

Pemvidutide was generally well tolerated. A total of 3 serious or severe adverse events (AEs) were reported, each unrelated to study drug administration (chest pain post-elective cardiac stent placement; Salmonella infection; and hypertension greater than 3 weeks after the completion of treatment). Three AEs led to treatment discontinuation, 1 being the Salmonella infection, and 2 gastrointestinal AEs, 1 (6.3%) at the 1.2 mg dose and 1 (6.7%) at the 1.8 mg dose. As expected, gastrointestinal events comprised the majority of AEs and were predominantly mild in nature. No clinically significant ALT elevations were observed. Glycemic control was maintained, with pemvidutide groups demonstrating trends toward improvements in fasting glucose and HbA1c over the 24 weeks of treatment. Meaningful reductions in systolic blood pressure were observed, and increases in heart rate, typical of the incretin class of agents, were minimal at 0 to 4 beats per minute and independent of dose.

“We have seen in recent study announcements that the magnitudes of change in non-invasive markers like liver fat reduction and ALT are associated with improvement in non-alcoholic steatohepatitis (NASH) histopathology. The impressive results announced today suggest a high likelihood of success on histopathological assessment in Phase 2b,” said Stephen Harrison, M.D., Chairman and Co-Founder of Pinnacle Clinical Research and Summit Clinical Research. “Effective weight loss is also extremely important for these patients, as many suffer from metabolic co-morbidities such as obesity, hyperlipidemia and diabetes putting them at greater risk for cardiovascular disease. I believe pemvidutide is one of the few candidate drugs for NASH with the potential to deliver in a meaningful way on both NASH activity and weight loss and that the magnitude and consistency of these results place pemvidutide among the most promising agents in development for NASH.”

“These results, which include some of the most compelling reductions in liver fat content observed to date, together with robust reductions in ALT and cT1, highlight the potential for pemvidutide to achieve significant rates of NASH resolution and fibrosis improvement in biopsy-driven NASH trials,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. “We believe that both NASH and obesity are important value drivers of our pemvidutide program. We look forward to the weight loss data from the interim analysis of our MOMENTUM obesity trial in Q1 2023 and commencing a Phase 2b NASH trial in 2023.”

Summary of Efficacy Findings

Endpoint	Treatment			
	Placebo	**1.2 mg**	**1.8 mg**	**2.4 mg**
Primary Endpoint—Liver Fat Content	**n = 18**	**n = 14**	**n = 13**	**n = 11**
Liver fat reduction, absolute, % change, LSM (SE)	1.6 (0.8)	11.2 (2.3) ***	17.0 (2.4) ***	15.6 (2.1) ***
Liver fat reduction, relative, % change, LSM (SE)	14.0 (3.8)	56.3 (11.6) ***	75.2 (8.1) ***	76.4 (5.9) ***
Proportion of subjects with 30% reduction, (%)	5.6	76.9 ****	92.3 ****	100.0 ****
Proportion of subjects with 50% reduction, (%)	0.0	61.5 ***	84.6 ****	72.7 ****
Proportion of subjects with normalization, (%)	0.0	30.8 *	53.8 ***	45.5 **
Secondary Endpoint—Markers of Inflammation				
ALT, change from baseline, IU/L, LSM (SE)	**n = 19**	**n = 16**	**n = 15**	**n = 14**
	-2.2 (2.5)	-13.3 (3.7) **	-13.7 (5.1) **	-15.2 (5.8) **
ALT, change from baseline, IU/L, LSM (SE), baseline ≥ 30 IU/	**n = 13**	**n = 7**	**n = 10**	**n = 9**
	-3.1 (3.5)	-17.0 (7.6) *	-17.7 (7.2) *	-20.6 (9.8) *
Proportion of subjects with cT1 response, (%)	**n = 6**	**n = 7**	**n = 4**	**n = 2**
	0.0	85.7 **	75.0 *	100.0 *
Secondary Endpoint—Weight Loss				
Weight loss, no diabetes, (% change), LSM (SE)	**n = 14**	**n = 13**	**n = 9**	**n = 11**
	1.2 (0.7)	5.2 (1.7) **	7.2 (1.1) ***	5.8 (1.6) **
Weight loss, diabetes, (% change), LSM (SE) †	**n = 5**	**n = 3**	**n = 6**	**n = 3**
	3.4 (2.1)	4.3 (1.9)	5.3 (2.7)	3.5 (2.5)
Weight loss, all subjects, (% change), LSM (SE	**n = 19**	**n = 16**	**n = 15**	**n = 14**
	1.4 (0.7)	5.1 (1.4) **	6.2 (1.3) ***	5.2 (1.4) **

Normalization of liver fat defined as ≤ 5%; cT1 response define as an 80 ms change from baseline; LSM, least square mean
† High variability due to the small numbers of diabetic subjects (n = 5, 3, 6, 3 in respective treatment groups)

*p < . 05; ** p < 0.01, *** p < 0.001, ****p < 0.0001 compared with placebo.

Glycemic Control

Characteristic	Treatment			
	Placebo	1.2 mg	1.8 mg	2.4 mg
Non-diabetes	**n = 14**	**n = 13**	**n = 9**	**n = 11**
Fasting glucose				
Baseline, mg/dL, mean (SD)	96.2 (12.4)	99.4 (11.9)	96.0 (12.4)	99.3 (13.6)
Week 24, mg/dL, mean (SD)	93.3 (12.1)	99.1 (13.1)	96.9 (12.5)	98.4 (24.5)
HbA1c				
Baseline, %, mean (SD)	5.8 (0.2)	5.7 (0.3)	5.7 (0.2)	5.5 (0.4)
Week 24, %, mean (SD)	5.7 (0.3)	5.8 (0.3)	5.8 (0.3)	5.6 (0.3)
Diabetes	**n = 5**	**n = 3**	**n = 6**	**n = 3**
Fasting glucose				
Baseline, mg/dL, mean (SD)	111.5 (19.2)	132.1 (28.2)	120.2 (37.1)	147.4 (40.4)
Week 24, mg/dL, mean (SD)	109.4 (14.8)	123.4 (50.8)	109.0 (13.1)	75.5 (29.0)
HbA1c				
Baseline, %, mean (SD)	6.1 (0.6)	7.8 (1.4	6.4 (0.5)	6.8 (1.3)
Week 24, %, mean (SD)	6.4 (1.1)	7.4 (2.3	6.4 (0.3)	6.3 (1.3)

Summary of Safety Findings

Characteristic		Treatment			
		Placebo (n = 19)	1.2 mg (n=16)	1.8 mg (n=15)	2.4 mg (n=14)
Serious or severe AEs	n (%)	1 (5.3%)	1 (6.3%)	1 (6.7%)	0 (0.0 %)
AEs leading to treatment discontinuation	n (%)	0 (0.0%)	2 (12.5%)	1 (6.7%)	0 (0.0 %)
Nausea	Mild, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	3 (20.0%)	0 (0.0%)
Vomiting	Mild, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea	Mild, n (%)	1 (5.3%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
	Moderate, n (%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
Constipation	Mild, n (%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
	Moderate, n (%)	1 (5.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
Systolic Blood Pressure, mm Hg, LSM (SE)		-2.3 (2.8)	-10.1 (4.2) *	-5.5 (3.7)	-12.0 (3.5) *
Diastolic Blood Pressure, mm Hg, LSM (SE)		-2.5 (1.5)	-2.9 (2.6)	-4.0 (3.7)	-3.8 (2.8)
Heart Rate, mmHg, LSM (SE)		-1.0 (1.7)	3.7 (1.8)	0.5 (2.8)	-0.1 (1.8)

A total of 3 serious or severe adverse events (AEs) were reported, each unrelated to study drug administration (chest pain post-elective cardiac stent placement; Salmonella infection; and hypertension greater than 3 weeks after the completion of treatment), with only the Salmonella infection leading to treatment discontinuation. The other AEs leading to treatment discontinuation were mild (Grade 1) abdominal pain in 2 subjects. No significant ALT elevations were reported. *p < .05 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 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. At both 12 and 24 weeks of Phase 1b clinical trials, NAFLD subjects treated with pemvidutide demonstrated promising reductions in liver fat content, serum ALT levels and body weight.

Conference Call Information
Altimmune management will host a conference call and webcast with a slide presentation presented by Dr. Stephen A. Harrison beginning at 8:30 am E.T. 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 Information:

Date:	Tuesday, December 20
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 the development of novel peptide-based therapeutics for the treatment of obesity and liver diseases. The Company's lead product candidate, pemvidutide (ALT-801), 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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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 timing of key milestones for our clinical assets, the timing of the data readouts of the NAFLD trials, the Phase 2 obesity clinical trial of pemvidutide, and the prospects for 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. (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 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 impact of liver fat content and demographics in the Phase 1b NAFLD study 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 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.

Investor & Media Contacts:

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Chief Financial Officer
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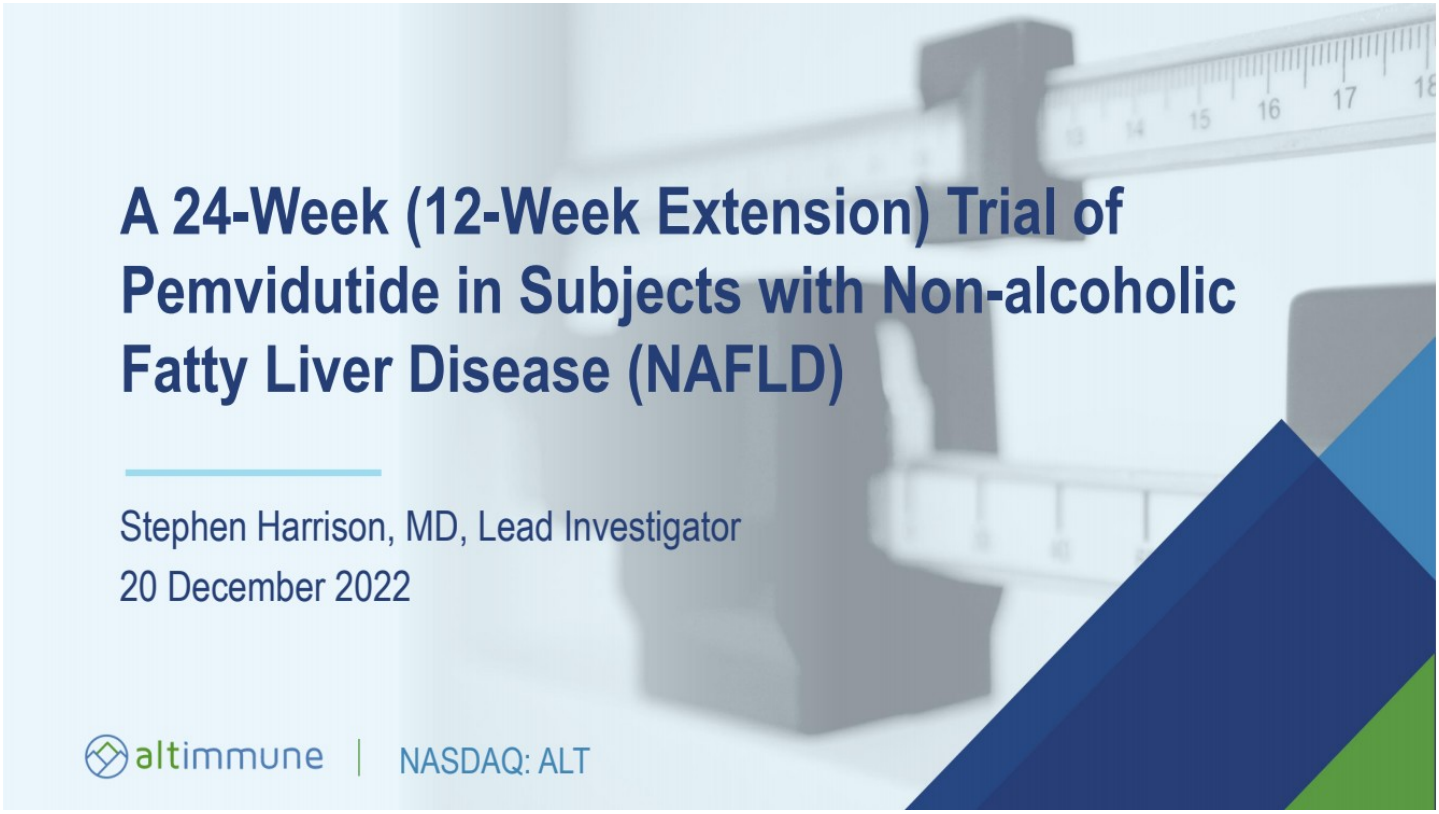
A 24-Week (12-Week Extension) Trial of Pemvidutide in Subjects with Non-alcoholic Fatty Liver Disease (NAFLD)
Stephen Harrison, MD, Lead Investigator
20 December 2022
altimmune | NASDAQ: ALT

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 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 timing of the data readouts of the NAFLD trials, the Phase 2 obesity clinical trial of pemvidutide, 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 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 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 impact of liver fat content and demographics in the Phase 1b NAFLD study 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 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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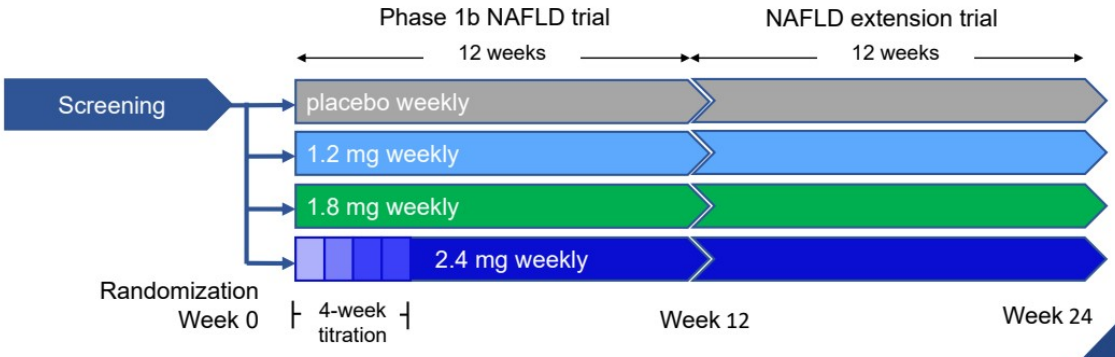
Pemvidutide NAFLD Extension Trial Design

- **12-week extension trial of pemvidutide in subjects with non-alcoholic fatty liver disease (NAFLD)**
- **83 subjects who completed the 12-week Phase 1b NAFLD trial were invited to participate, to receive a total of 24 weeks of treatment**
- **66 subjects consented to rollover, of whom 64 were eligible to participate**



Study Population—Key Eligibility Criteria

Subjects needed to have completed dosing in the 12-week Phase 1b NAFLD trial and met the following criteria at parent trial entry:

- **Men and women, ages 18-65 years**
- **BMI ≥ 28 kg/m^2**
- **NAFLD, defined as liver fat content (LFC) by MRI-PDFF ≥ 10%**
- **Absence of significant fibrosis, defined as FibroScan® LSM < 10kPa**
- **Non-diabetes OR diabetes if:**
  - Stable dose (≥ 3 months) metformin or SLGT-2 therapy AND
  - No use of insulin, sulfonylureas, DPP-4, GLP-1 treatment
- **HbA1c < 9.5%**
- **Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) laboratory values ≤ 75 IU/L**

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Study Endpoints

Efficacy

- **Primary Endpoint:**
  - Reduction in liver fat content (LFC) by MRI-PDFF at Week 24 compared to Week 0
- **Key Secondary Endpoints:**
  - Liver inflammation by serum alanine aminotransferase (ALT) levels and corrected T1 (cT1) imaging at Week 24 compared to Week 0
  - Percent (%) weight loss at Week 24 compared to Week 0

Safety

- **Adverse events (AEs)**
  - Serious and severe AEs
  - AEs leading to discontinuation
  - GI tolerability
- **Vital signs**
- **Glycemic control (fasting glucose, HbA1c)**

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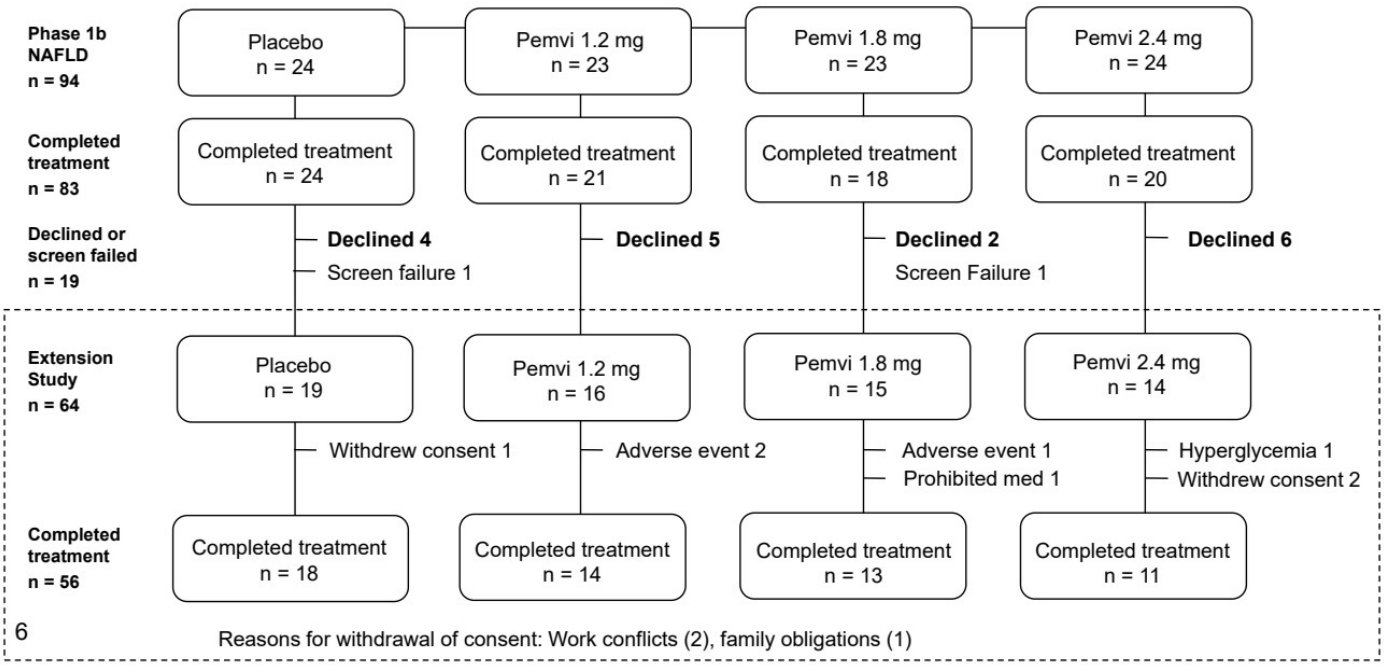
Study Disposition



Baseline Characteristics of Extension Study Participants

Characteristic		Treatment			
		Placebo (n = 19)	1.2 mg (n=16)	1.8 mg (n=15)	2.4 mg (n=14)
Age, years	mean (SD)	49.0 (15)	48.6 (11)	49.9 (10)	48.4 (8)
Gender	female, n (%)	11 (57.9%)	7 (43.8%)	8 (53.3%)	8 (57.1%)
Race	white, n (%)	17 (89.5%)	14 (87.5%)	13 (86.7%)	14 (100%)
	other, n (%)	2 (10.5%)	2 (12.5%)	2 (13.3%)	0 (0.0%)
Ethnicity	Hispanic, n (%)	11 (57.9%)	15 (93.8%)	12 (80.0%)	9 (64.3%)
	not Hispanic, n (%)	8 (42.1%)	1 (6.3%)	3 (20.0%)	5 (35.7%)
BMI, kg/m^2	mean (SD)	37.1 (4.9)	36.7 (6.1)	36.0 (3.8)	37.0 (5.3)
Body weight, kg	mean (SD)	104.4 (21.2)	101.4 (16.3)	100.9 (13.2)	107.4 (17.2)
Diabetes status	T2D, n (%)	5 (26.3%)	3 (18.8%)	6 (40.0%)	3 (21.4%)
Liver fat content (LFC), %	mean (SD)	24.0 (9.6)	20.1 (7.7)	23.9 (7.4)	20.5 (6.5)
ALT, IU/L	mean (SD)	41.0 (21.3)	32.4 (14.2)	35.3 (13.0)	39.6 (26.6)
Blood pressure, mm Hg	systolic, mean (SD)	122.7 (10.3)	128.6 (16.0)	123.8 (17.4)	127.6 (9.9)
	diastolic, mean (SD)	79.4 (6.0)	79.4 (9.5)	77.0 (10.9)	82.4 (8.7)

Baseline is defined as Week 0 of the Phase 1b NAFLD trial

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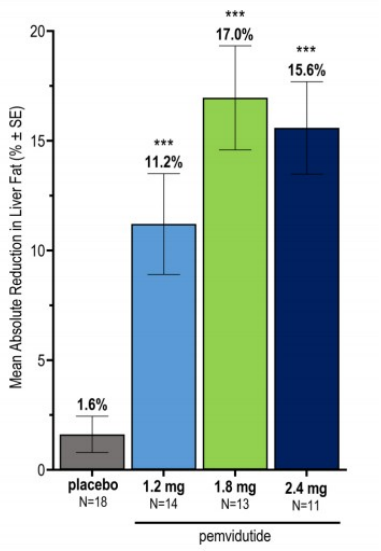
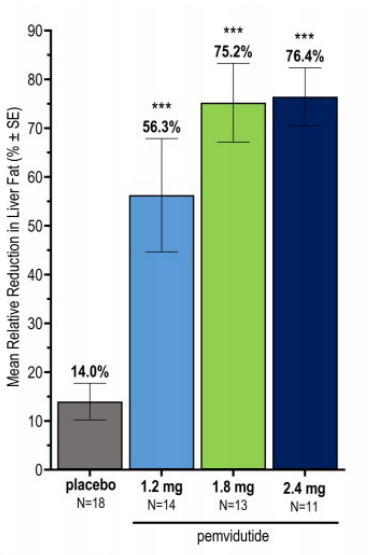
Robust Reduction in Liver Fat Content by MRI-PDFF at Week 24

Absolute Reduction



Relative Reduction



*** p < 0.001 vs. placebo, (ANCOVA)

Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial, LS mean ± SE

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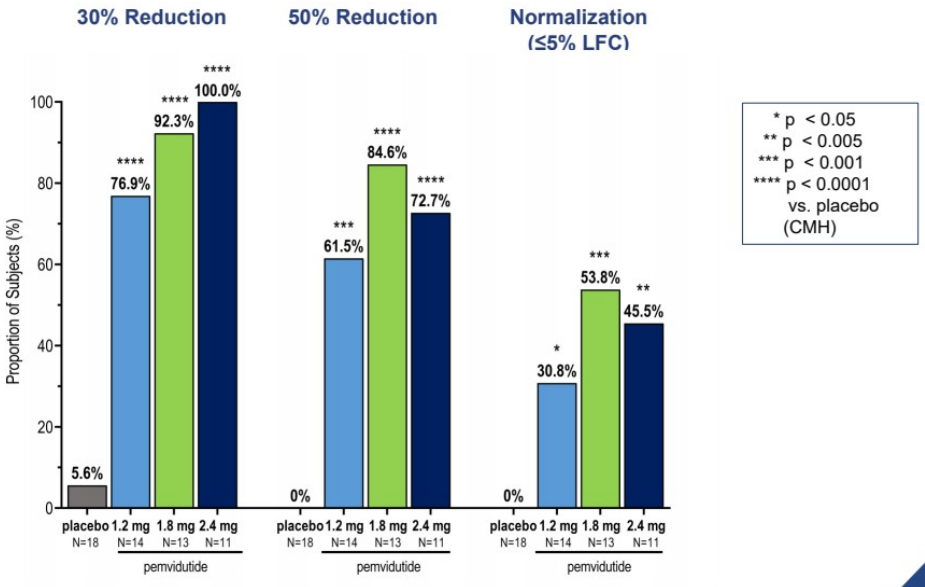
Robust Reduction in Liver Fat Content by MRI-PDFF—Responder Analyses at Week 24



Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial; CMH, Cochran-Mantel-Haenszel

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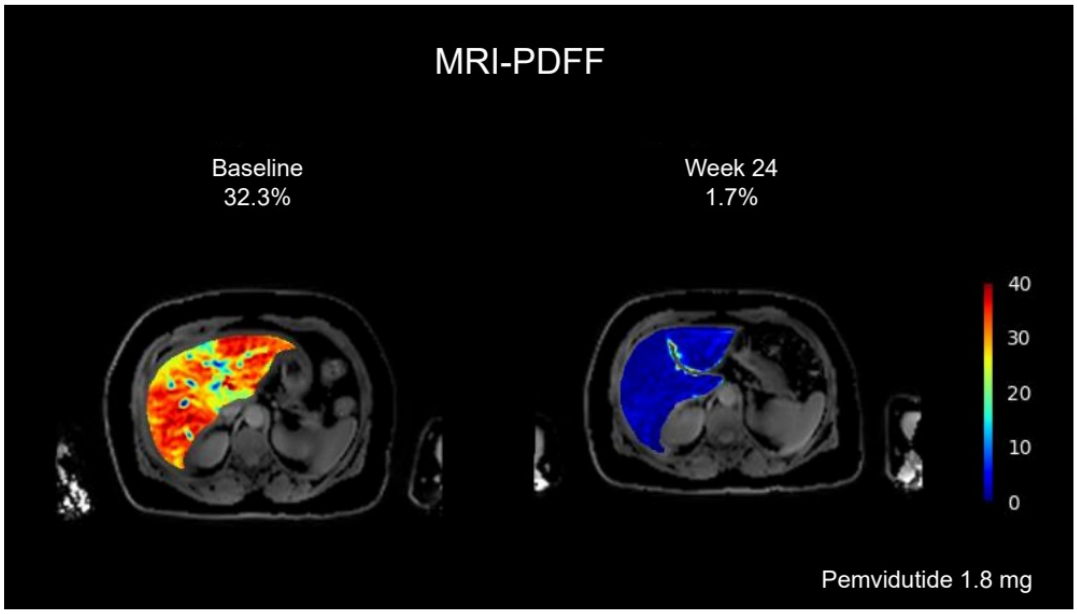
Marked Reduction of Liver Fat Content by MRI-PDFF at Week 24



This reduction was accompanied by a 38.1% decrease in liver volume

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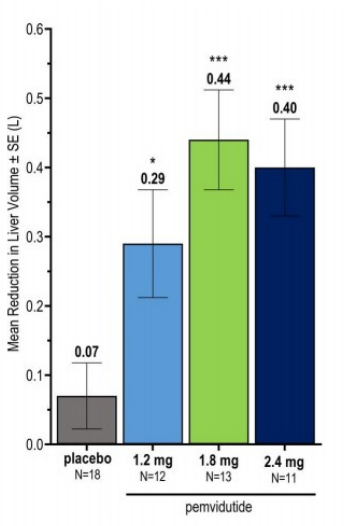
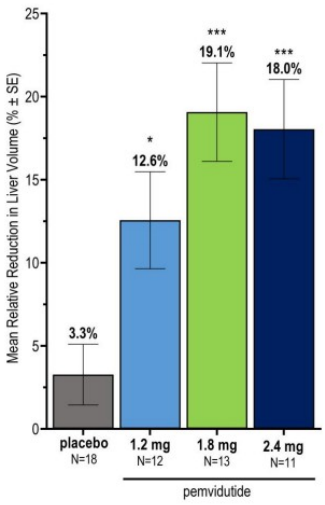
Robust Reduction in Liver Volume by MRI-PDFF at Week 24

Absolute Reduction



Relative Reduction



* p < 0.05
*** p < 0.001
vs. placebo,
(ANCOVA)

Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial, LS mean ± SE

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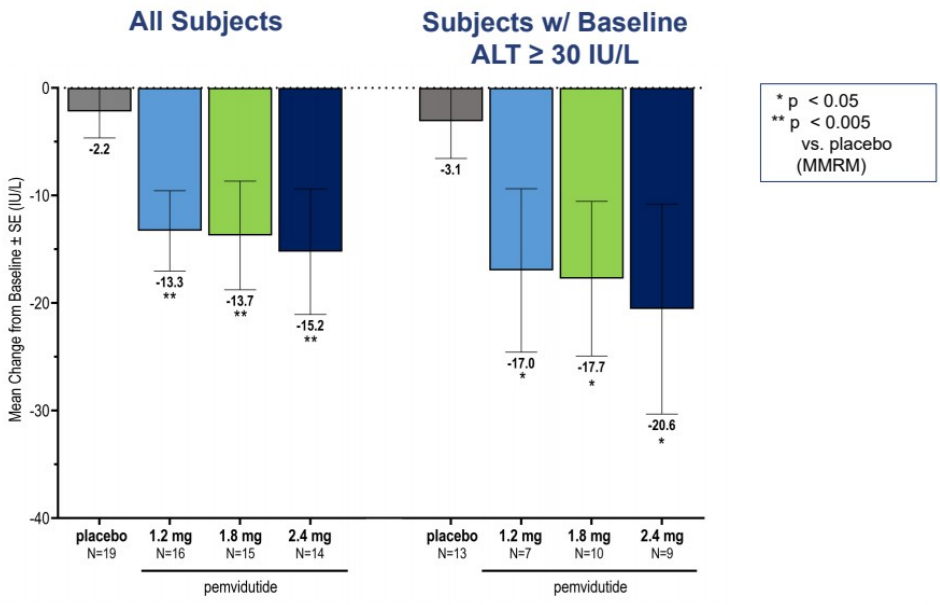
Robust Reduction of Serum ALT at Week 24

BIOMARKER OF LIVER INFLAMMATION



Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial; MMRM, mixed model with repeated measures, LS mean ± SE

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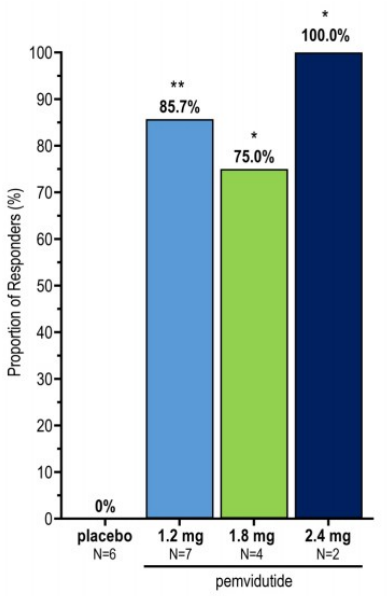
High Rates of cT1 Response at Week 24

RESPONSE DEFINED AS AN 80ms REDUCTION IN cT1 FROM BASELINE



* p < 0.05
** p < 0.005
vs. placebo
(Fisher's Exact Test)

- 80ms reduction in cT1 has been associated with a 2-point reduction of NASH Activity Score (NAS)[1]
- Elevated cT1 levels have been associated with increased risk of major adverse cardiac events (MACE) and major adverse liver outcomes (MALO)[2,3]

Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial; [1]Dennis A, Front Endocrinol 2021; [2]Jayaswal, A. Liver Int 2020; [3]Roca-Fernandez A, MedRxiv 2022;

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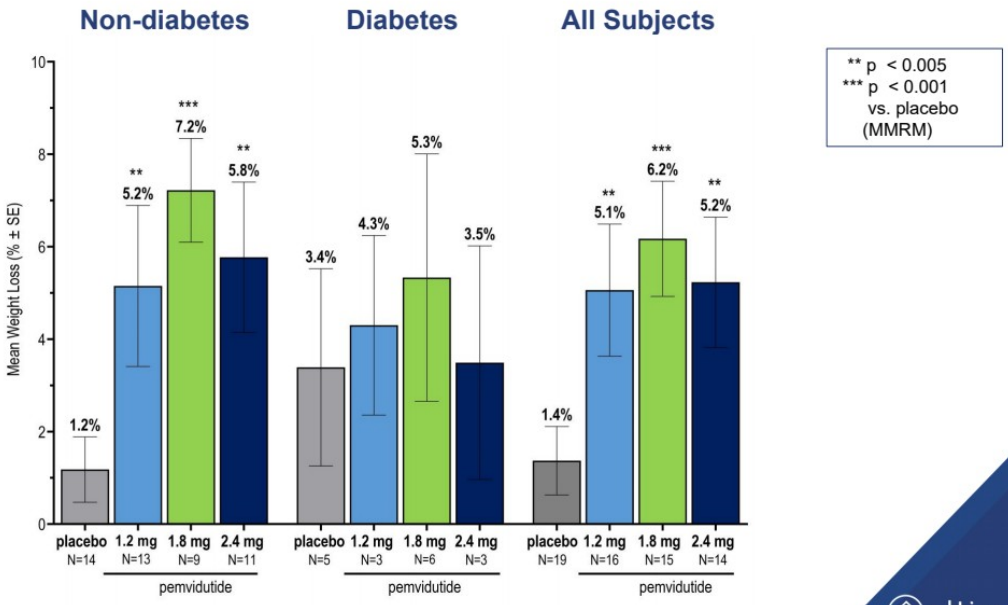
Continued Weight Loss at Week 24—Efficacy Estimand

DIFFERENTIATES PEMVIDUTIDE FROM NASH DRUGS WITH COMPARABLE LEVELS OF LIVER FAT REDUCTION



Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial; MMRM, mixed model with repeated measures, LS mean ± SE

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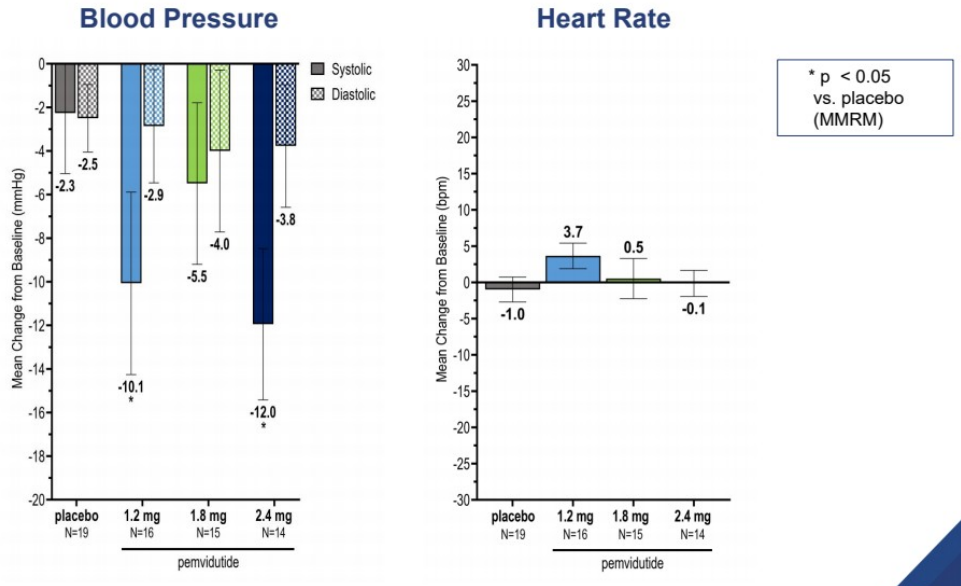
Changes in Serum Lipids at Week 24

Characteristic		Treatment			
		Placebo (n = 19)	1.2 mg (n=16)	1.8 mg (n=15)	2.4 mg (n=14)
Total cholesterol, mean (SD)					
Baseline	mg/dL	181.4 (35.7)	184.1 (46.8)	196.8 (38.6)	187.2 (36.0)
Week 24	mg/dL	169.4 (44.1)	170.9 (40.1)	173.2 (23.7)	162.0 (33.1)
LDL cholesterol, mean (SD)					
Baseline	mg/dL	97.8 (37.1)	95.5 (38.9)	110.6 (36.4)	104.8 (29.6)
Week 24	mg/dL	94.7 (43.7)	95.9 (31.8)	98.6 (26.1)	95.5 (30.9)
HDL cholesterol, mean (SD)					
Baseline	mg/dL	47.2 (7.3)	43.3 (10.2)	45.6 (8.4)	47.2 (6.7)
Week 24	mg/dL	44.9 (7.7)	42.2 (8.9)	41.4 (4.1)	43.3 (6.7)
Triglycerides, mean (SD)					
Baseline	mg/dL	182.5 (96.3)	232.1 (127.2)	217.0 (102.0)	209.9 (146.1)
Week 24	mg/dL	148.8 (78.9)	190.4 (177.0)	167.4 (94.5)	115.1 (37.6)

Baseline refers to Week 0 of the Phase 1b NAFLD trial

Improvements in Blood Pressure without Clinically Meaningful Increases in Heart Rate at Week 24



Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial; MMRM, mixed model with repeated measures, LS mean ± SE

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Safety Overview—AEs During 12-Week Extension Study

Characteristic		Treatment			
		Placebo (n = 19)	1.2 mg (n=16)	1.8 mg (n=15)	2.4 mg (n=14)
Serious or severe AEs	**n (%)**	1 (5.3%)	1 (6.3%)	1 (6.7%)	0 (0.0%)
AEs leading to treatment discontinuation	**n (%)**	0 (0.0%)	2 (12.5%)	1 (6.7%)	0 (0.0%)
Nausea					
Mild	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	3 (20.0%)	0 (0.0%)
Vomiting					
Mild	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea					
Mild	n (%)	1 (5.3%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
Moderate	n (%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
Constipation					
Mild	n (%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
Moderate	n (%)	1 (5.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)

The serious and severe AEs were the same events: 1) chest pain post elective coronary stent placement (placebo), 2) Salmonella infection (pemvi 1.2 mg), and 3) hypertension >3 weeks post last dose of study medication (pemvi 1.8 mg), all unrelated to study medication, with only the Salmonella infection leading to treatment discontinuation. The other AEs leading to treatment discontinuation were mild (Grade 1) abdominal pain in 2 subjects. No significant ALT elevations were reported.

Glycemic Control at Week 24

Characteristic		Treatment			
		Placebo	1.2 mg	1.8 mg	2.4 mg
NON-DIABETES		N=14	N=13	N=9	N=11
Fasting glucose					
Baseline, mg/dL	mean (SD)	96.2 (12.4)	99.4 (11.9)	96.0 (12.4)	99.3 (13.6)
Week 24, mg/dL	mean (SD)	93.3 (12.1)	99.1 (13.1)	96.9 (12.5)	98.4 (24.5)
HbA1c					
Baseline, %	mean (SD)	5.8 (0.2)	5.7 (0.3)	5.7 (0.2)	5.5 (0.4)
Week 24, %	mean (SD)	5.7 (0.3)	5.8 (0.3)	5.8 (0.3)	5.6 (0.3)
DIABETES		N=5	N=3	N=6	N=3
Fasting glucose					
Baseline, mg/dL	mean (SD)	111.5 (19.2)	132.1 (28.2)	120.2 (37.1)	147.4 (40.4)
Week 24, mg/dL	mean (SD)	109.4 (14.8)	123.4 (50.8)	109.0 (13.1)	75.5 (29.0)
HbA1c					
Baseline, %	mean (SD)	6.1 (0.6)	7.8 (1.4)	6.4 (0.5)	6.8 (1.3)
Week 24, %	mean (SD)	6.4 (1.1)	7.4 (2.3)	6.4 (0.3)	6.3 (1.3)

Baseline refers to Week 0 of the Phase 1b NAFLD trial

Summary and Conclusions

Liver fat reduction

- Greater than 75% relative liver fat reduction at 24 weeks, better than or equal to the effects of other leading NASH candidates
- Significant reductions and normalization in serum ALT and improvement in cT1 point to potent effects in NASH clinical trials

Weight loss

- Non-diabetes—continued weight loss, achieving 7.2% at pemvidutide 1.8 mg at Week 24
- Diabetes—achieved 5.3% weight loss at pemvidutide 1.8 mg at Week 24

Safety and tolerability

- Low rates of AEs leading to treatment discontinuation, no serious/severe AEs related to pemvidutide
- Cardioprotective reductions in blood pressure without increases in heart rate
- Glycemic control maintained with trends toward improvements in fasting glucose and HbA1c in subjects with diabetes
- No clinically significant ALT elevations

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Questions pertaining to this presentation:
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