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): September 14, 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 September 14, 2022, Altimmune, Inc. (the "Company") issued a press release announcing results from its Phase 1b study of ALT-801 (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 September 14, 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 September 14, 2022, the Company announced results from a 12-week, Phase 1b study of pemvidutide (proposed INN, formerly known as ALT-801), an investigational glucagon-like peptide-1 (GLP-1)/glucagon dual receptor agonist.

The trial was a randomized, double-blind, placebo-controlled study, with Dr. Stephen A. Harrison, Medical Director, Pinnacle Research, serving as the Principal Investigator. Ninety-four (94) subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. No dose titration was used with 1.2 mg or 1.8 mg dose, while a short 4-week dose titration was employed at the 2.4 mg dose. The primary efficacy endpoint was the percent reduction in liver fat content from baseline, and the key secondary efficacy endpoint was the percent weight loss from baseline. The trial was conducted as a NAFLD clinical trial, and the dietary and exercise interventions that are standard for obesity trials were not employed.

Subjects were randomized and treated at 13 sites across the U.S. Mean BMI at baseline was 36 kg/m2 and mean liver fat content, as measured by MRI-PDFF, was approximately 22%. Twenty-seven (29%) subjects had type 2 diabetes at baseline, and approximately 75% of trial subjects were of Hispanic ethnicity.

The trial met its primary endpoint in all pemvidutide treatment groups. At the 1.8 mg dose (with and without diabetes), pemvidutide achieved a mean relative reduction of liver fat content of 68.5%, with 94.4% of subjects achieving a 30% reduction in liver fat, 72.2% achieving a 50% reduction in liver fat, and 55.6% of subjects achieving normalization of liver fat, defined as liver fat fraction of 5% or less. In addition, mean serum alanine aminotransferase (ALT) levels declined in all subjects, and in subjects with baseline serum ALT above 30 IU/L, levels declined more than 17 IU/L at all dose levels and 27.0 IU/L in the 2.4 mg dose cohort.

The trial also met its key secondary endpoint in all pemvidutide treatment groups. Employing an efficacy estimand, mean weight losses of 4.9% (placebo-adjusted 4.7%) in subjects without diabetes and 4.4% in subjects with diabetes (placebo-adjusted 3.9%) were achieved at the 1.8 and 2.4 mg doses, respectively.

Pemvidutide was reported to be generally well tolerated. Gastrointestinal events comprised the majority of the adverse events (AEs). Even without dose titration, the symptoms experienced by subjects were predominantly mild and transient in nature and consistent with known GLP-1 class effects. No serious or severe AEs were reported. Two subjects treated with pemvidutide discontinued treatment due to AEs [1 (4.3%) at 1.8 mg and 1 (4.2%) at 2.4 mg], both secondary to gastrointestinal intolerability. No clinically significant ALT elevations (defined as an increase to 3-fold or greater the upper limit of normal) were observed. Glycemic control was unaffected, with no clinically meaningful changes in HbA1c or fasting glucose. Clinically meaningful reductions in systolic blood pressure were observed, along with the 2-3 beat per minute increase in heart rate typical for GLP-1 class of drugs.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

No.	Description
99.1	Press Release of Altimmune, Inc. dated September 14, 2022
99.2	Slide Presentation of Altimmune, Inc. dated September 14, 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: September 14, 2022

Exhibit 99.1

Altimmune Announces Significant Reductions in Liver Fat Content and Body Weight in 12-Week Phase 1b Clinical Trial of Pemvidutide in Subjects with NAFLD

- *All 3 pemvidutide dosing groups (1.2 mg, 1.8 mg, 2.4 mg) achieved the primary endpoint of relative and absolute reductions in liver fat, with a 68.5% relative reduction in liver fat content in subjects receiving 1.8 mg dose at 12 weeks of treatment*
- *Mean weight loss of 4.9% (placebo-adjusted 4.7%) in subjects without diabetes receiving 1.8 mg dose at 12 weeks of treatment*
- *Altimmune to host conference call today at 8:30 am ET*

GAITHERSBURG, MD, -- September 14, 2022 -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced positive topline results from its 12-week Phase 1b study of pemvidutide[1] in subjects with non-alcoholic fatty liver disease (NAFLD).

The trial was a randomized, double-blind, placebo-controlled study, with Dr. Stephen A. Harrison, Medical Director, Pinnacle Research, serving as the Principal Investigator. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. No dose titration was used with 1.2 mg or 1.8 mg dose, while a short 4-week dose titration was employed at the 2.4 mg dose. The primary efficacy endpoint was the percent (%) reduction in liver fat content from baseline, and the key secondary efficacy endpoint was the % weight loss from baseline, both at 12 weeks of treatment. The trial was conducted without adjunctive diet and exercise interventions that are the standard for obesity trials.

Ninety-four (94) subjects were randomized and treated at 13 sites across the U.S. Mean BMI at baseline was approximately 36 kg/m^2 and mean liver fat content (LFC), as measured by MRI-PDFF, was approximately 22%. Twenty-seven (29%) subjects had type 2 diabetes at baseline, and approximately 75% of study subjects were of Hispanic ethnicity.

The trial met its primary endpoint in all pemvidutide treatment groups. At the 1.8 mg dose (with and without diabetes), pemvidutide achieved a mean reduction of liver fat content of 68.5%, with 94.4% of subjects achieving a 30% reduction in liver fat, 72.2% achieving a 50% reduction in liver fat, and 55.6% of subjects achieving normalization of liver fat, defined as liver fat fraction of 5% or less. In addition, mean serum alanine aminotransferase (ALT) levels declined in all subjects, and in subjects with baseline serum ALT above 30 IU/L, levels declined more than 17 IU/L at all dose levels and 27.0 IU/L in the 2.4 mg dose cohort.

The trial also met its key secondary endpoint in all pemvidutide treatment groups. Employing an efficacy estimand, mean weight losses of 4.9% (placebo-adjusted 4.7%) in subjects without diabetes and 4.4% in subjects with diabetes (placebo-adjusted 3.9%) were achieved at the 1.8 and 2.4 mg doses, respectively.

[1] *proposed INN*

Pemvidutide was reported to be generally well tolerated. Gastrointestinal events comprised the majority of the adverse events (AEs). Even without dose titration, the symptoms experienced by subjects were predominantly mild and transient in nature, consistent with known GLP-1 class effects. No serious or severe AEs were reported. Two subjects treated with pemvidutide discontinued treatment due to AEs [1 (4.3%) at 1.8 mg and 1 (4.2%) at 2.4 mg], both secondary to gastrointestinal intolerability. No clinically significant ALT elevations (defined as an increase to 3-fold or greater the upper limit of normal) were observed. Glycemic control was unaffected, with no clinically meaningful changes in HbA1c or fasting glucose. Clinically meaningful reductions in systolic blood pressure were observed, along with the 2-3 beat per minute increase in heart rate typical for GLP-1 class of drugs.

"We are pleased with the results of this trial, including the extent of liver fat and serum ALT reductions. Weight loss was within our target range, and good tolerability was observed without the need for dose titration. In addition, no clinically significant ALT elevations were observed," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "With these positive results in hand, we look forward to reporting data from the 24-week NAFLD trial, as well as 24-week interim data from our MOMENTUM obesity trial."

Dr. Stephen Harrison, Principal Investigator, remarked, "Significant reductions in the liver fat fraction and serum ALT have been shown to correlate with improvement of non-alcoholic steatohepatitis (NASH) in clinical trials. The marked decreases in both liver fat and serum ALT, together with approximately 5% weight loss in just 12 weeks in this NAFLD patient population, highlight pemvidutide as potentially a promising therapeutic for both NASH and obesity." Dr. Harrison also noted, "It is important to recognize that the baseline liver fat content and demographics in this study diverged substantially from a typical obesity study population."

Baseline Study Demographics

Characteristic		**Treatment**			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
Age, years	mean (SD)	47.9 (14)	48.6 (11)	50.3 (9)	48.8 (8)
Sex	female, n (%)	14 (58.3%)	9 (39.1%)	12 (52.2%)	15 (62.5%)
Race	white, n (%)	21 (87.5%)	21 (91.3%)	20 (87.0%)	24 (100%)
	other, n (%)	3 (12.5%)	2 (8.7%)	3 (13.0%)	0 (0.0%)
Ethnicity	Hispanic, n (%)	14 (58.3%)	20 (87.0%)	19 (82.6%)	18 (75.0%)
	Non-Hispanic, n (%)	10 (41.7%)	3 (13.0%)	4 (17.4%)	6 (25.0%)
BMI, kg/m2	mean (SD)	36.9 (4.7)	36.3 (5.6)	35.4 (3.9)	35.3 (5.0)
Body weight, kg	mean (SD)	105.1 (20.8)	102.4 (14.6)	98.9 (19.7)	98.2 (18.9)
Diabetes status	T2D, n (%)	6 (25.0%)	7 (30.4%)	7 (30.4%)	7 (33.3%)
LFC, %	mean (SD)	23.8 (9.2)	21.6 (7.3)	21.8 (8.0)	20.2 (7.0)

Reduction of Liver Fat Content (MRI-PDFF)—All Subjects

Endpoint		Treatment			
		Placebo (n = 24)	**1.2 mg (n=20)**	**1.8 mg (n=18)**	**2.4 mg (n=20)**
Absolute reduction, %	mean (SE)	0.2 (1.7)	8.9 (1.8)**	14.7 (1.7)**	11.3 (2.0)**
Relative reduction, %	mean (SE)	4.4 (8.7)	46.6 (8.1)**	68.5 (9.7)**	57.1 (8.0)**
30% reduction	n (%)	1 (4.2%)	13 (65.0%)**	17 (94.4%)**	17 (85.0%)**
50% reduction	n (%)	0 (0.0%)	8 (40.0%)**	13 (72.2%)**	14 (70.0%)**
Normalization (≤ 5% LFC)	n (%)	0 (0.0%)	4 (20.0%)*	10 (55.6%)**	10 (50.0%)**

**p < .05, **p<.001 compared to placebo*

Reductions in Body Weight—Efficacy Estimand

Population		Treatment			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
No diabetes, (% change)	LSM (SE)	-0.2 (0.7)	-3.4** (0.8)	-4.9** (0.8)	-3.5** (0.8)
Diabetes, (% change)	LSM (SE)	-0.5 (1.3)	-3.3* (1.1)	-3.8* (1.2)	-4.4* (1.3)
All subjects (% change)	LSM (SE)	-0.2 (0.7)	-3.4** (0.7)	-4.3** (0.7)	-3.7** (0.7)

*LSM, least square mean; *p < .05, **p<.001 compared to placebo*

Summary of Safety Findings

Characteristic		Treatment			
		Placebo (n = 24)	1.2 mg (n=23)	1.8 mg (n=23)	2.4 mg (n=24)
Severe AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SAEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs leading to treatment discontinuation	n (%)	0 (0.0%)	0 (0.0%)	1 (4.3%)	1 (4.2%)
Nausea	mild, n (%)	3 (12.5%)	3 (13.0%)	6 (26.1%)	6 (25.0%)
	mod, n (%)	0 (0.0%)	1 (4.3%)	6 (26.1%)	3 (12.5%)
Vomiting	mild, n (%)	0 (0.0%)	3 (13.0%)	2 (8.7%)	2 (8.3%)
	mod, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea	mild, n (%)	4 (16.7%)	3 (13.0%)	5 (21.7%)	1 (4.2%)
	mod, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation	Mild, n (%)	0 (0.0%)	3 (13.0%)	4 (17.4%)	1 (4.2%)
	mod, n (%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)

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 likely slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability. In a 12-week Phase 1 clinical trial, pemvidutide-treated subjects demonstrated substantial reductions in body weight, liver fat and serum lipids commonly associated with cardiovascular disease.

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:	Wednesday, September 14
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.

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 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:

Rich Eisenstadt
Chief Financial Officer
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12-Week, Phase 1b Study of Pemvidutide in Overweight and Obese Subjects with Non-Alcoholic Fatty Liver Disease (NAFLD)—Topline Results
Stephen Harrison, MD, Lead Investigator
14 September 2022
altimmune | NASDAQ: ALT

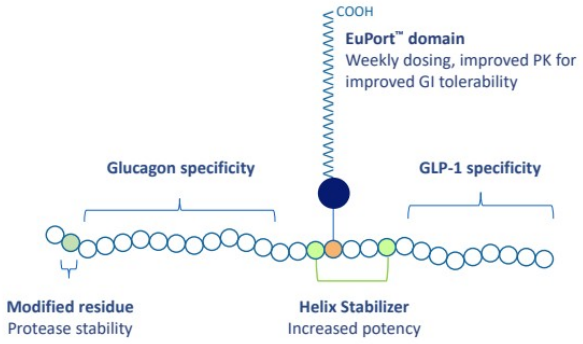
Forward-looking statements

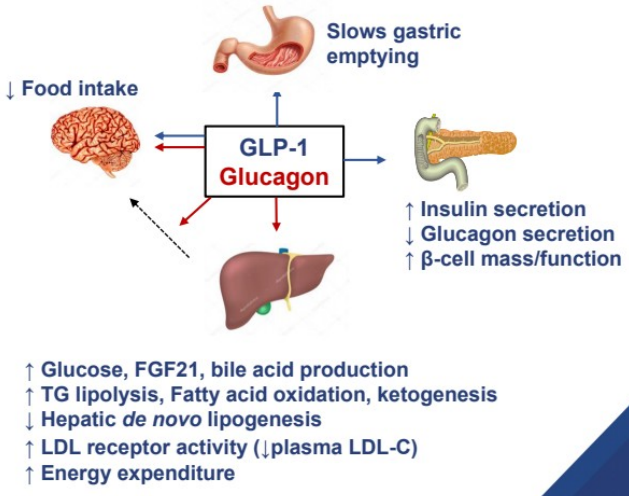
Safe-Harbor Statement

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 regarding the timing of clinical development and funding milestones for our clinical assets as well as statements relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, and the prospects for commercializing or selling any product or drug candidates. In addition, when or if used in this presentation, 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 due to the COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, the ongoing conflict in Ukraine, adverse effects on healthcare systems and disruption of the global economy, the timing and reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; and, interpretation of the results of our clinical trials of the behavior of the Company's product candidates as to how those product candidates may perform in future studies. 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 reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, which are available at www.sec.gov. The statements made herein speak only as of the date stated herein, and any forward-looking statements contained herein are based on assumptions that the Company believes to be reasonable as of this date. The Company undertakes no obligation to update these statements as result of new information or future events.

Pemvidutide[1]

Balanced (1:1) GLP-1:glucagon dual receptor agonist





[1]proposed INN

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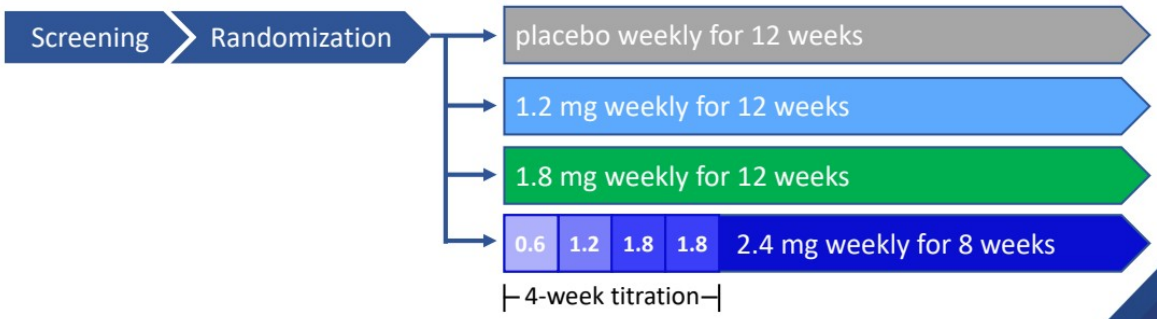
Pemvidutide Phase 1b NAFLD Trial Design

- **12-week, randomized, placebo-controlled study of pemvidutide in subjects with overweight/obesity and non-alcoholic fatty liver disease (NAFLD)**
- **94 subjects randomized 1:1:1:1 and dosed across 13 US sites to 1 of 4 treatment arms, stratified by the presence or absence of type 2 diabetes (T2D)**



- **No caloric restriction or lifestyle intervention**

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Study Population—Key Eligibility Criteria

- **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/mL**

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Study Endpoints

Efficacy

- **Primary Endpoint: Reduction in liver fat content by MRI-PDFF**
- **Key Secondary Endpoint: Percent (%) weight loss**

Safety

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

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Characteristics of Study Participants

Characteristic		Treatment			
		Placebo (n = 24)	1.2 mg (n=23)	1.8 mg (n=23)	2.4 mg (n=24)
Age, years	mean (SD)	47.9 (14)	48.6 (11)	50.3 (9)	48.8 (8)
Gender	female, n (%)	14 (58.3%)	9 (39.1%)	12 (52.2%)	15 (62.5%)
Race	white, n (%)	21 (87.5%)	21 (91.3%)	20 (87.0%)	24 (100%)
	other, n (%)	3 (12.5%)	2 (8.7%)	3 (13.0%)	0 (0.0%)
Ethnicity	Hispanic, n (%)	14 (58.3%)	20 (87.0%)	19 (82.6%)	18 (75.0%)
	not Hispanic, n (%)	10 (41.7%)	3 (13.0%)	4 (17.4%)	6 (25.0%)
BMI, kg/m^2	mean (SD)	36.9 (4.7)	36.3 (5.6)	35.4 (3.9)	35.3 (5.0)
Body weight, kg	mean (SD)	105.1 (20.8)	102.4 (14.6)	98.9 (19.7)	98.2 (18.9)
Diabetes status	T2D, n (%)	6 (25.0%)	7 (30.4%)	7 (30.4%)	7 (33.3%)
Liver fat content (LFC), %	mean (SD)	23.8 (9.2)	21.6 (7.3)	21.8 (8.0)	20.2 (7.0)
ALT, IU/L	mean (SD)	39.5 (21.4)	32.4 (13.8)	36.4 (15.6)	37.8 (24.4)
Blood pressure, mm Hg	systolic, mean (SD)	122.8 (11.4)	129.0 (14.1)	123.2 (15.9)	125.9 (12.3)
	diastolic, mean (SD)	79.6 (6.0)	79.3 (9.1)	77.8 (9.7)	80.1 (8.6)
Total cholesterol, mg/dL	mean (SD)	181.4 (39.0)	186.9 (44.8)	200.0 (35.2)	182.2 (39.7)
LDL cholesterol, mg/dL	mean (SD)	100.0 (38.2)	100.2 (34.3)	116.6 (33.6)	101.3 (33.0)
Triglycerides, mg/dL	mean (SD)	169.3 (90.1)	224.9 (119.1)	192.2 (114.9)	220.0 (169.3)
HDL cholesterol, mg/dL	mean (SD)	47.5 (6.8)	42.6 (9.1)	47.0 (9.9)	45.3 (7.3)

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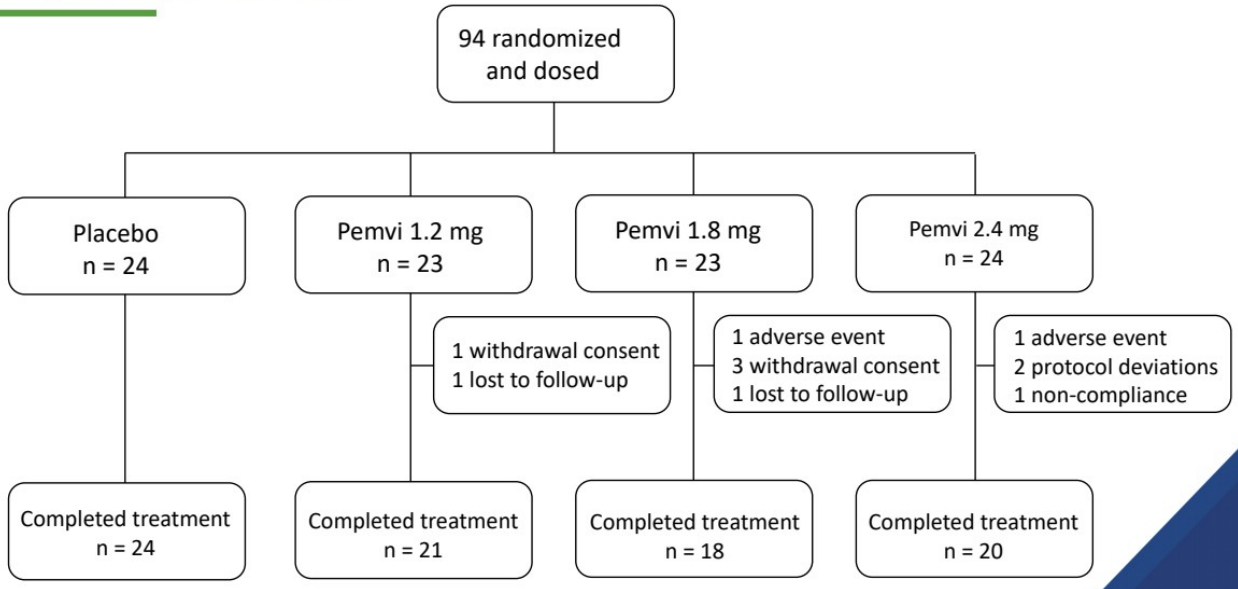
Study Disposition



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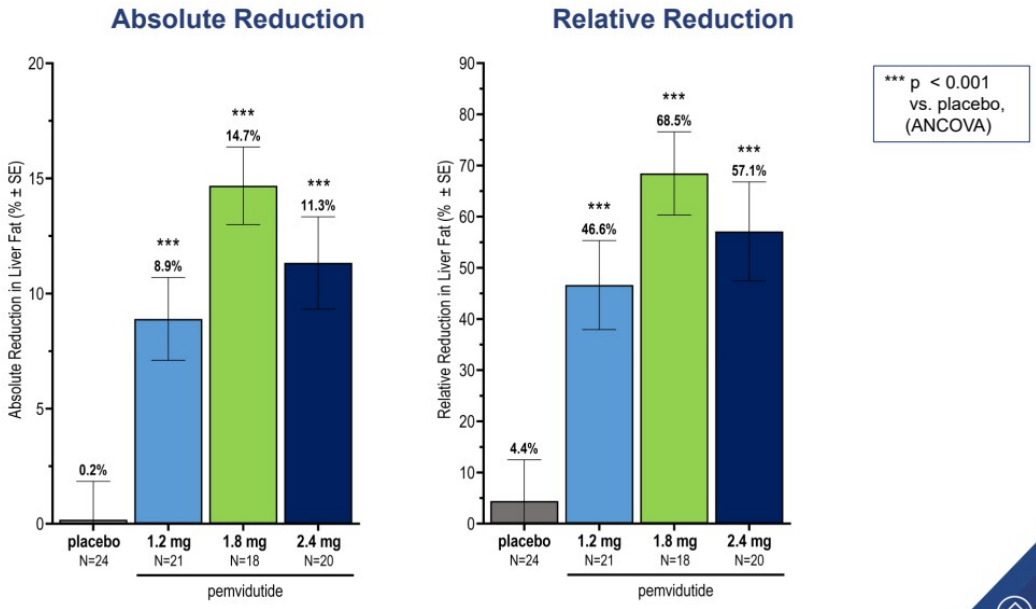
Reduction in Liver Fat Content by MRI-PDFF at Week 12



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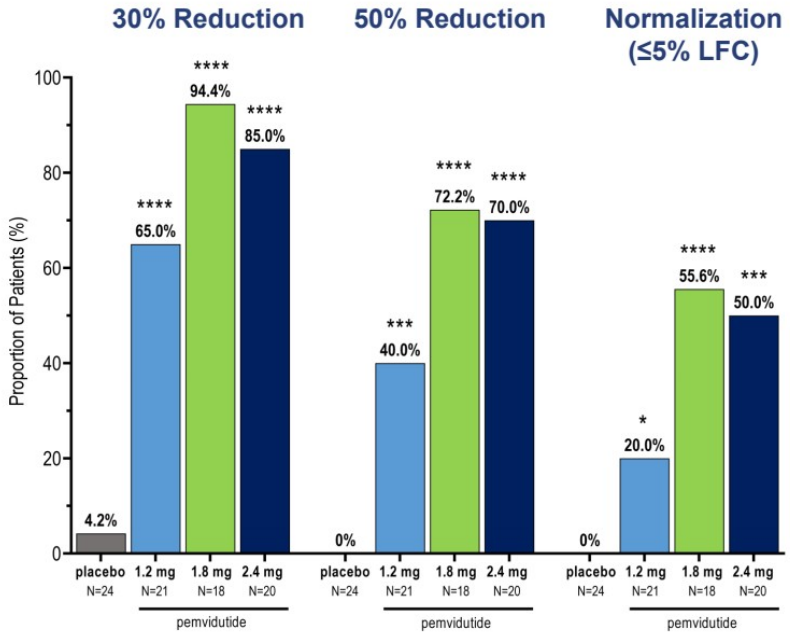
Reduction in Liver Fat Content by MRI-PDFF at Week 12—Responder Analyses



* p < 0.05
*** p < 0.001
**** p < 0.0001
vs. placebo, (ANCOVA)

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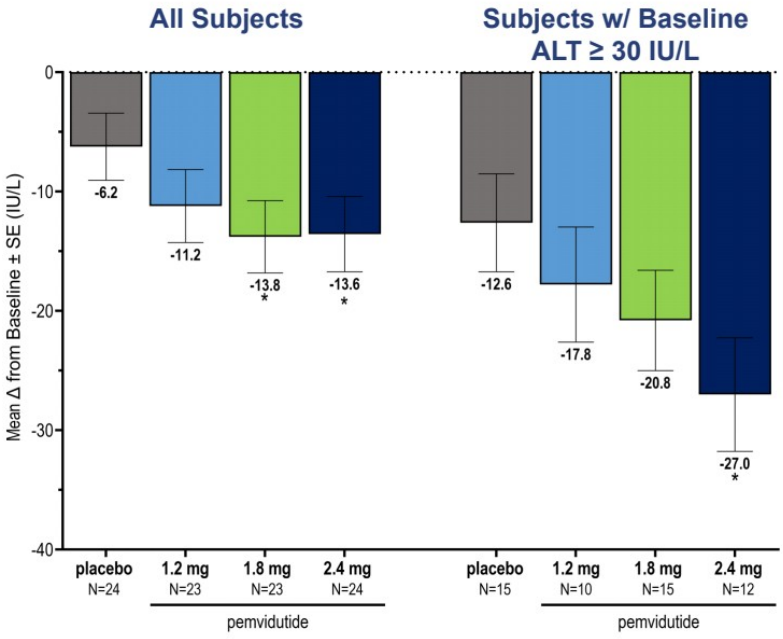
ALT Reduction at Week 12



* p < 0.05 vs. placebo, (MMRM1)

[1]Mixed Model Repeated Measures

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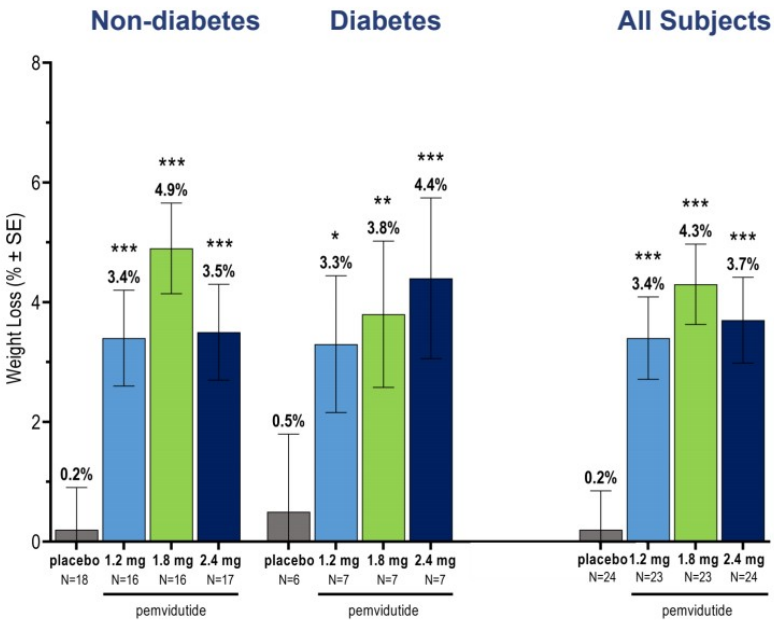
Weight Loss at Week 12—Efficacy Estimand



* p < 0.05
** p < 0.005
*** p < 0.001
vs. placebo,
(MMRM)

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Changes in Serum Lipids at Week 12

Characteristic		Treatment			
		Placebo (n = 24)	1.2 mg (n=21)	1.8 mg (n=18)	2.4 mg (n=20)
% Change from baseline to Week 12					
Total cholesterol, mean (SE)	%	-5.9 (4.4)	-10.1 (4.7)	-9.0 (4.5)	-12.2 (5.1)
LDL, mean (SE)	%	4.2 (8.1)	1.2 (8.6)	2.7 (8.1)	0.5 (9.6)
HDL, mean (SE)	%	-5.3 (3.3)	-1.1 (3.5)	-9.7 (3.3)	-6.9 (3.8)
Triglycerides, mean (SE)	%	-18.7 (14.7)	-42.8 (15.6)	-33.7 (14.7)	-44.6 (16.8)

ANCOVA model

Safety Overview

Characteristic		Treatment			
		Placebo (n = 24)	1.2 mg (n=23)	1.8 mg (n=23)	2.4 mg (n=24)
Severe AEs	**n (%)**	**0 (%)**	**0 (%)**	**0 (%)**	**0 (%)**
SAEs	**n (%)**	**0 (%)**	**0 (%)**	**0 (%)**	**0 (%)**
AEs leading to treatment discontinuation	**n (%)**	**0 (%)**	**0 (%)**	**1 (4.3%)**	**1 (4.2%)**
Nausea					
Mild	n (%)	3 (12.5%)	3 (13.0%)	6 (26.1%)	6 (25.0%)
Moderate	n (%)	0 (0.0%)	1 (4.3%)	6 (26.1%)	3 (12.5%)
Vomiting					
Mild	n (%)	0 (0.0%)	3 (13.0%)	2 (8.7%)	2 (8.3%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea					
Mild	n (%)	4 (16.7%)	3 (13.0%)	5 (21.7%)	1 (4.2%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation					
Mild	n (%)	0 (0.0%)	3 (13.0%)	4 (17.4%)	1 (4.2%)
Moderate	n (%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)

No clinically significant increases in ALT (defined as > 3x above ULN)

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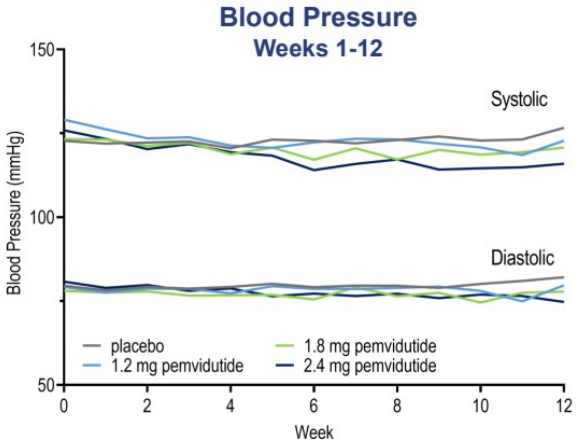
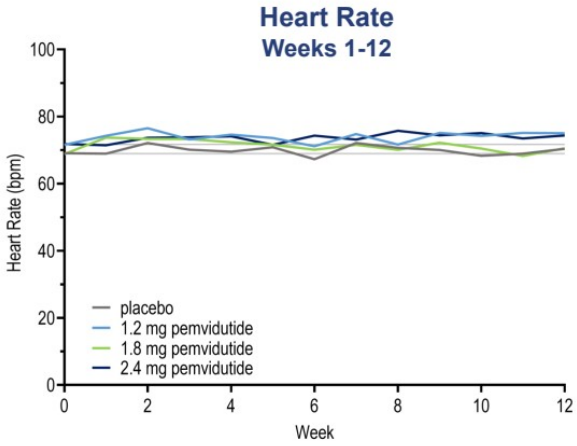
Blood Pressure and Heart Rate



Mean systolic BP decreases of 6-10 mmHg compared to placebo
Mean diastolic BP decreases of 3-7 mmHg compared to placebo



Mean HR increases of 1-3 bpm compared to placebo

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Glycemic Variables — Non-diabetes and Diabetes

Characteristic		Treatment			
		Placebo	1.2 mg	1.8 mg	2.4 mg
NON-DIABETES		N=18	N=16	N=16	N=17
Fasting glucose					
Baseline, mg/dL	mean (SD)	99.9 (13.6)	99.4 (12.4)	95.1 (10.3)	97.9 (13.6)
Week 12, mg/dL	mean (SD)	101.6 (16.7)	99.5 (12.5)	96.0 (10.8)	100.1 (11.0)
HbA1c					
Baseline, %	mean (SD)	5.8 (0.2)	5.7 (0.3)	5.7 (0.3)	5.6 (0.4)
Week 12, %	mean (SD)	5.8 (0.2)	5.9 (0.4)	5.6 (0.4)	5.8 (0.3)
DIABETES		N=6	N=7	N=7	N=7
Fasting glucose					
Baseline, mg/dL	mean (SD)	114.0 (18.1)	124.4 (26.1)	117.3 (34.7)	166.1 (49.6)
Week 12, mg/dL	mean (SD)	128.5 (33.9)	118.4 (36.8)	135.9 (65.5)	129.9 (52.6)
HbA1c					
Baseline, %	mean (SD)	6.2 (0.6)	6.6 (1.4)	6.4 (0.5)	7.5 (1.3)
Week 12, %	mean (SD)	6.3 (0.8)	6.4 (1.6)	6.9 (1.5)	7.7 (1.2)

Summary and Conclusions

Liver fat reduction

- Robust (>68%) relative liver fat reductions at 12 weeks, better than or equal to the effects of other leading NASH candidates
- Significant reductions in serum ALT point to potent effects in NASH clinical trials

Weight loss

- Non-diabetes—placebo-adjusted weight loss (4.7%) at Week 12
- Diabetes—placebo-adjusted weight loss (3.9%) at Week 12

Safety and tolerability

- No severe or serious AEs and low rates of AEs leading to treatment discontinuations
- Well-tolerated without the need for dose titration, consistent with prior experience
- No clinically significant ALT elevations
- Glycemic control maintained


Questions pertaining to this presentation:
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