Pemvidutide Significantly Reduces Liver Fat, Non-invasive Markers of Fibro-inflammation, and Body Weight in Patients with NAFLD: Results of a Randomized, Placebo-controlled Trial

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PEMVI: GLP-1/GLUCAGON RECEPTOR DUAL AGONIST

Optimized for weight loss and NASH

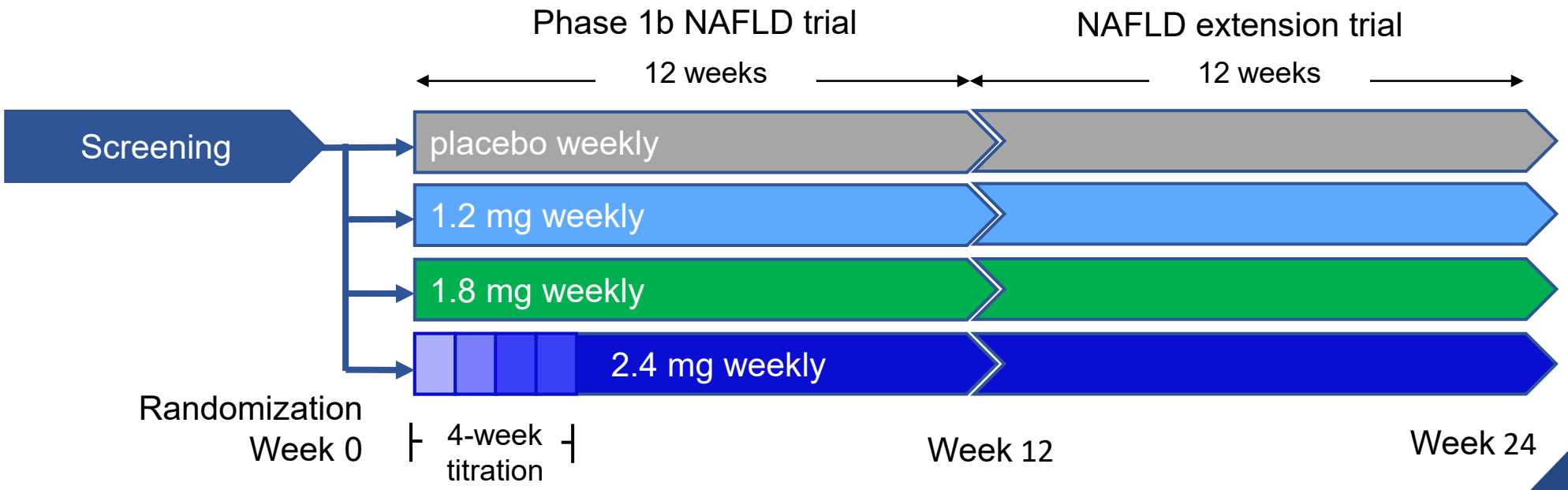
Designed for significant reductions in:

BODY WEIGHT

LIVER FAT, INFLAMMATION, & RESULTING FIBROSIS

Pemvidutide NAFLD Trial Design

- 12-week, randomized, placebo-controlled study
- Completers were invited to participate in a 12-week extension to receive a total of 24 weeks of treatment
- Primary endpoint: Reduction in liver fat content by MRI-PDFF at Week 12
  Secondary endpoints: Hepatic inflammation (serum ALT, cT1) and body weight
- No caloric restriction or lifestyle intervention



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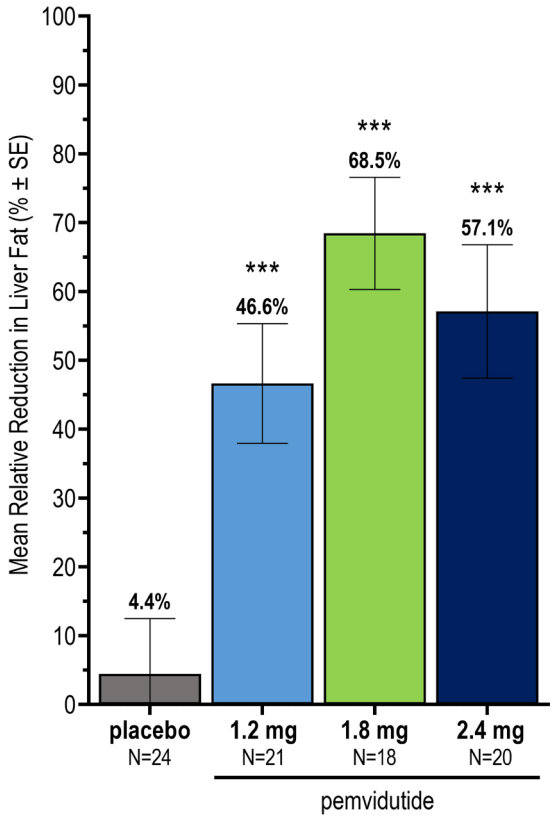
Study Population

Key Eligibility Criteria	• MRI-PDFF ≥ 10% • FibroScan® LSM < 10kPa • Non-diabetes or non-insulin dependent diabetes with HbA1c< 9.5% • Serum ALT ≤ 75 IU/L

Baseline Characteristics		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%)
Ethnicity	Hispanic, n (%)	14 (58.3%)	20 (87.0%)	19 (82.6%)	18 (75.0%)
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, %	mean (SD)	23.8 (9.2)	21.6 (7.3)	21.8 (8.0)	20.2 (7.0)
Serum ALT, IU/L	mean (SD)	39.5 (21.4)	32.4 (13.8)	36.4 (15.6)	37.8 (24.4)

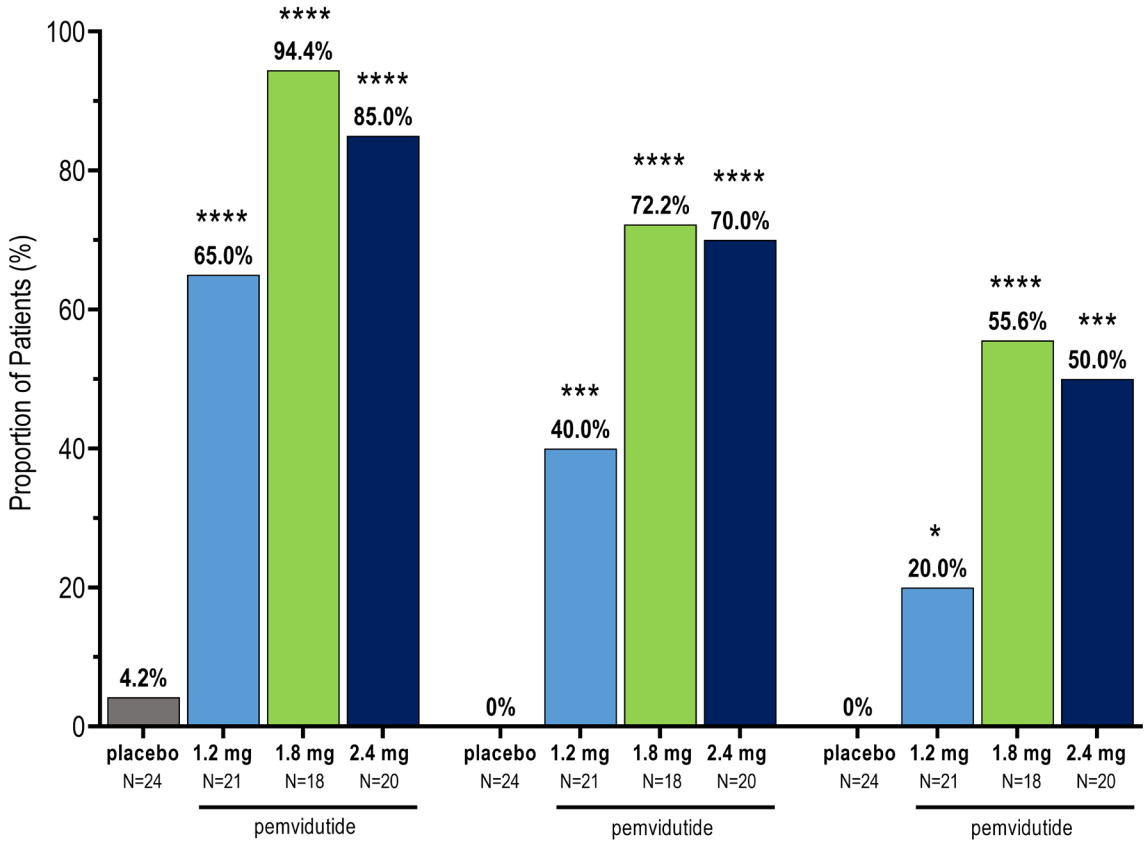
Reduction in Liver Fat Content at Week 12

Relative Reduction



*** p < 0.001 vs placebo, ANCOVA , LS mean ± SE

30% Reduction | 50% Reduction | Normalization (≤5% LFC)



* p < 0.05, *** p < 0.001, ****, p < 0.0001 vs placebo, Cochran-Mantel-Haenszel

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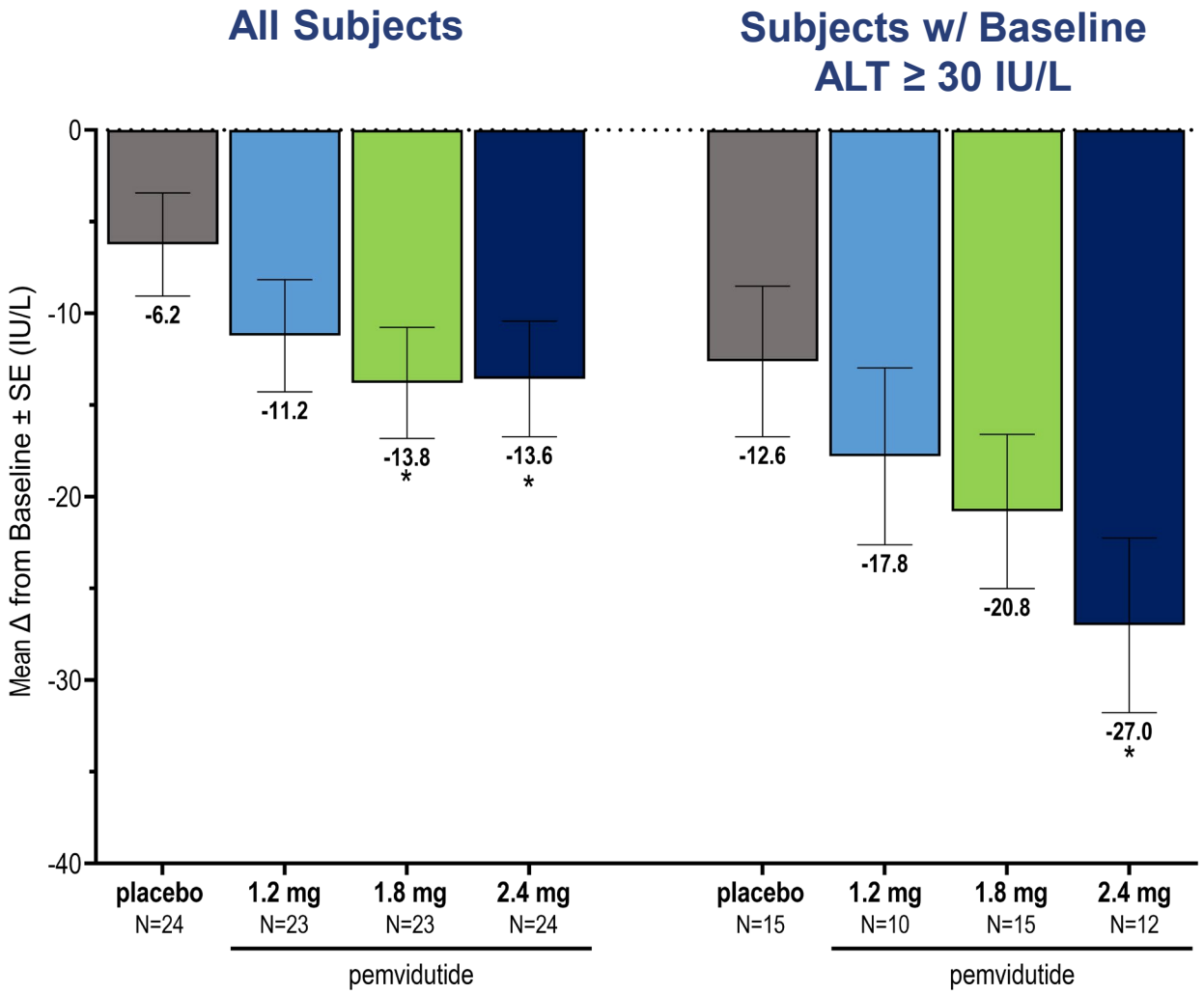
Reduction of Serum ALT at Week 12



* p < 0.05 vs placebo, mixed model repeated measures, LS mean ± SE

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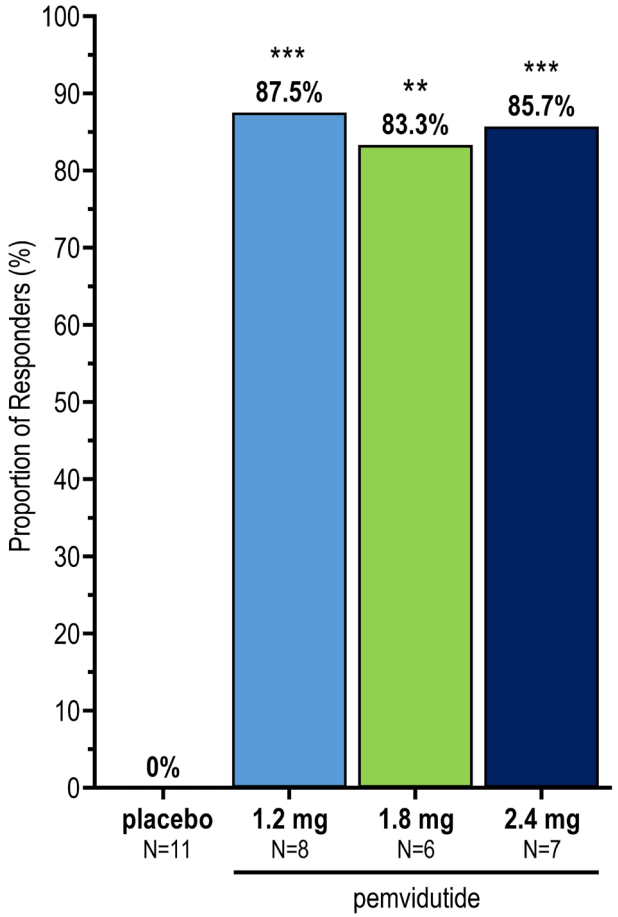
cT1 Responder Rates at Week 12

RESPONDER DEFINED AS A SUBJECT WITH AN 80ms REDUCTION IN cT1 FROM BASELINE



** p < 0.001, *** p < 0.0001 vs placebo, Cochran-Mantzel-Haenszel

- 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]

[1]Dennis A, Front Endocrinol 2021; [2]Jayaswal, A. Liver Int 2020; [3]Roca-Fernandez A, MedRxiv 2022;

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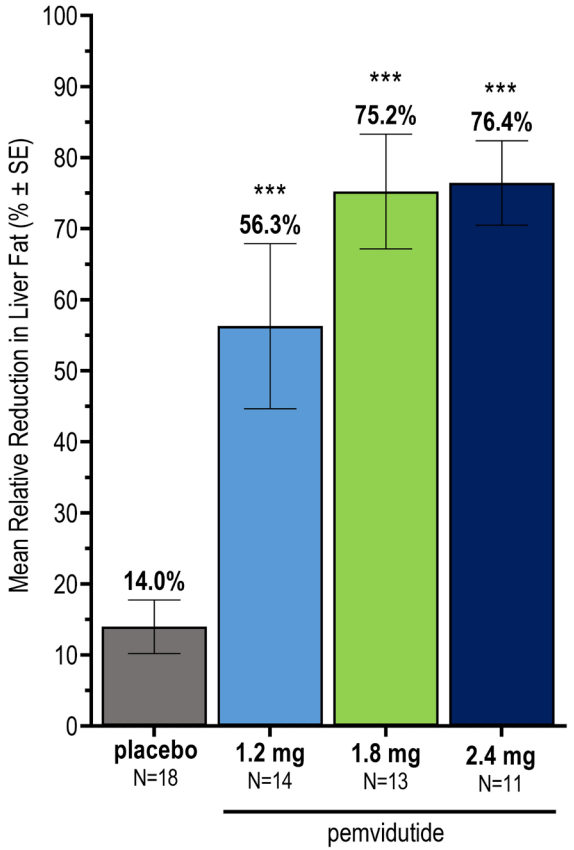
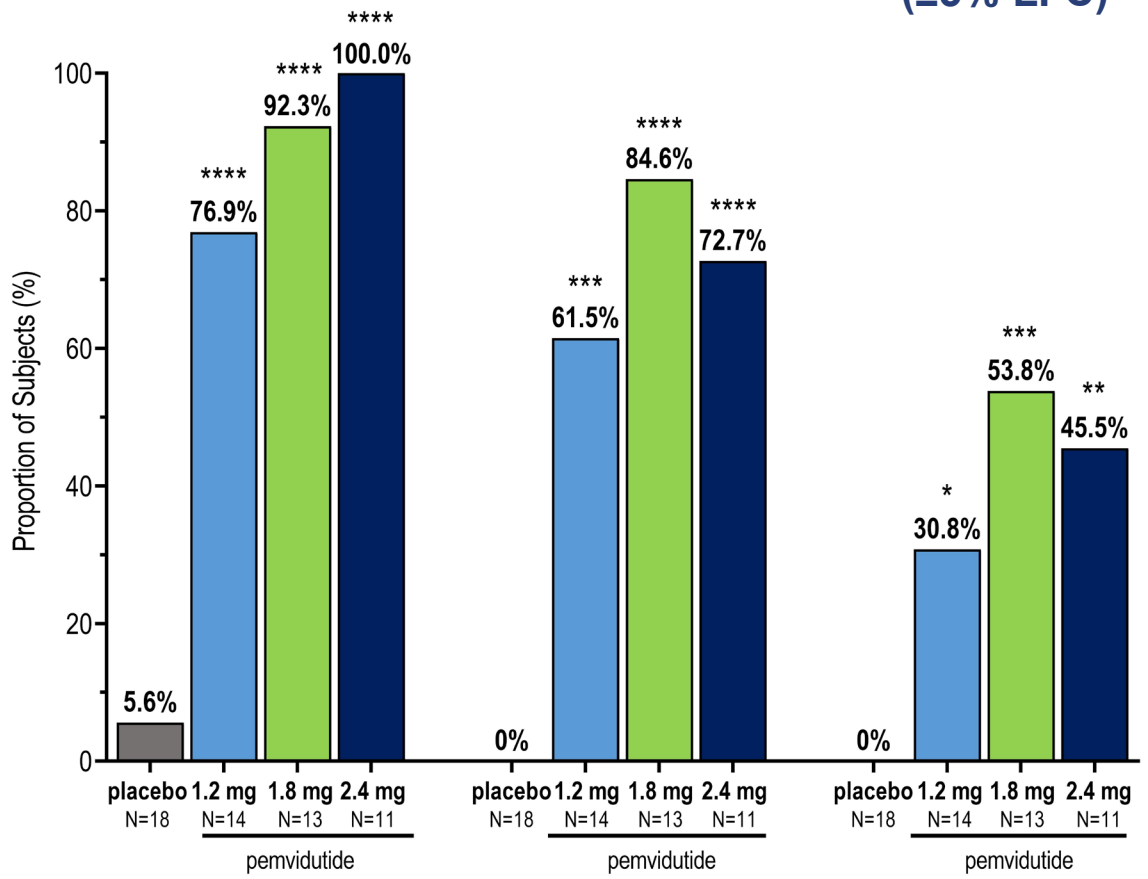
Additional Reduction in Liver Fat Content at Week 24

Relative Reduction



*** p < 0.001 vs placebo ANCOVA, LS mean ± SE

30% Reduction | 50% Reduction | Normalization (≤5% LFC)



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Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial

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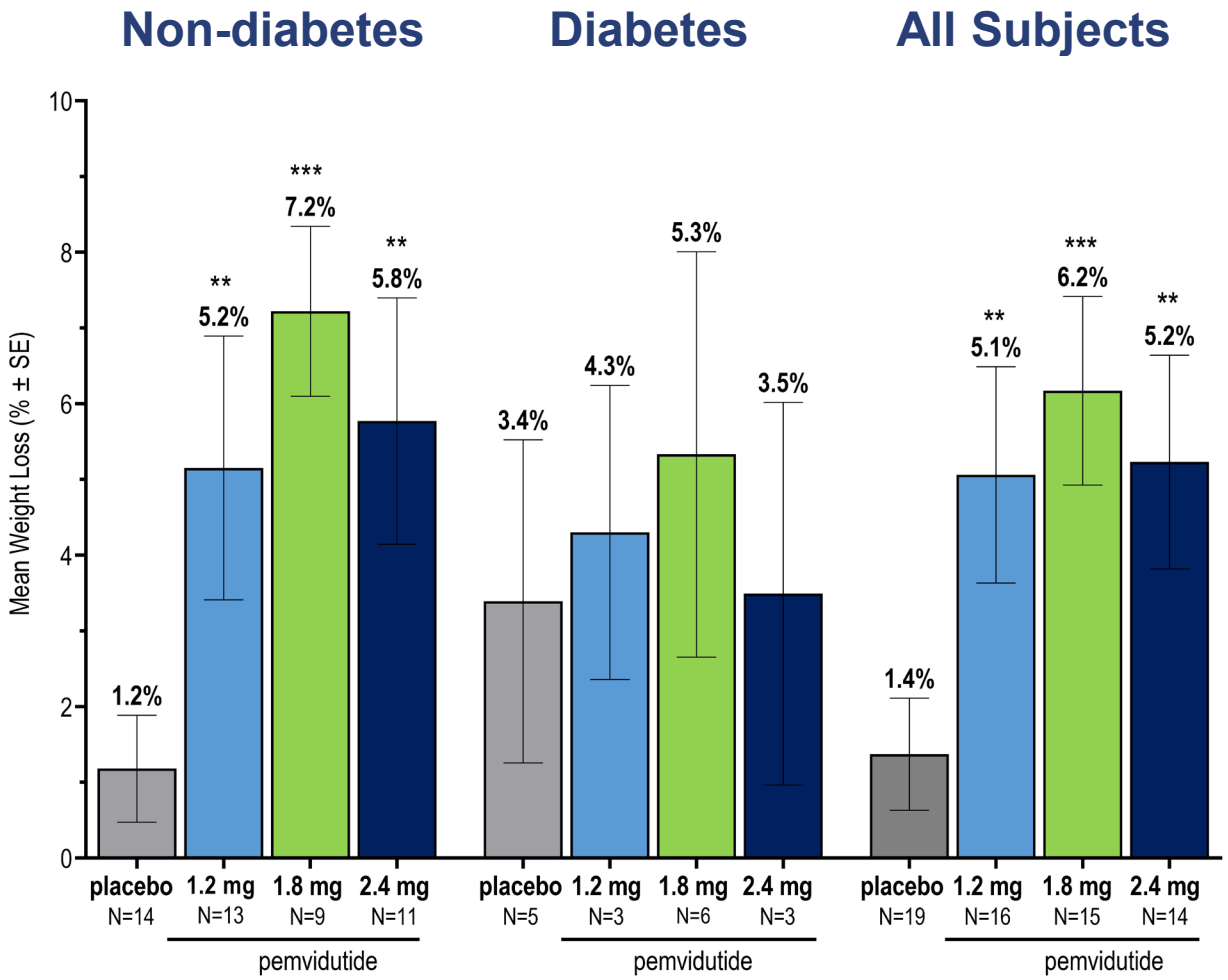
Weight Loss at Week 24

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



** p < 0.005, ** p < 0.001 vs placebo, mixed model with repeated measures, LS mean ± SE

Comparison to Week 0 (Baseline) of the Phase 1b NAFLD trial

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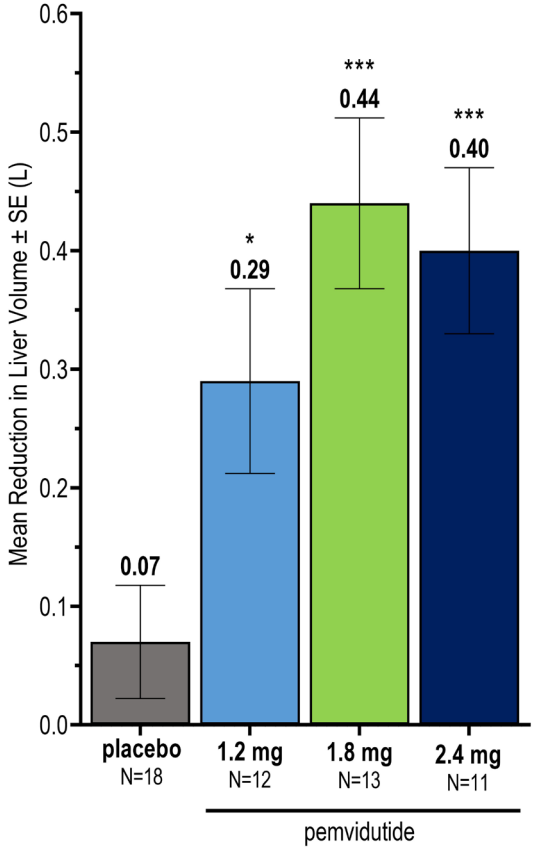
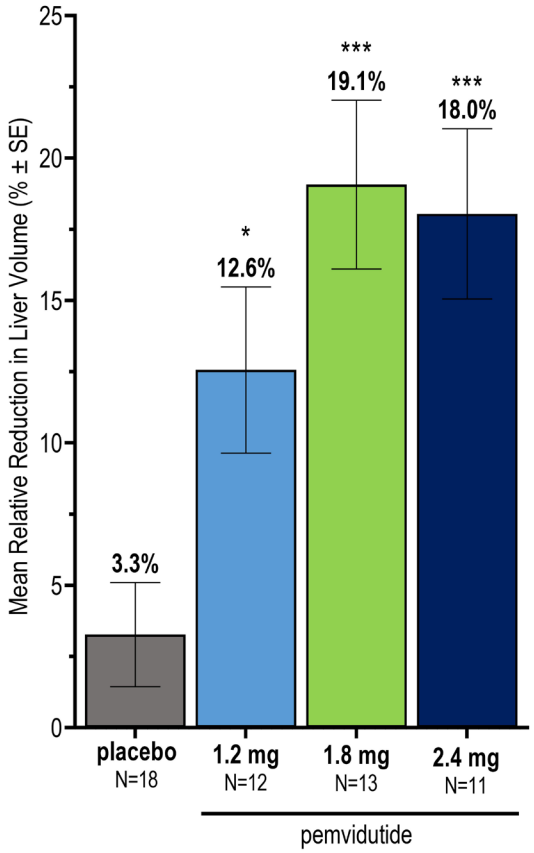
Reduction in Liver Volumes at Week 24

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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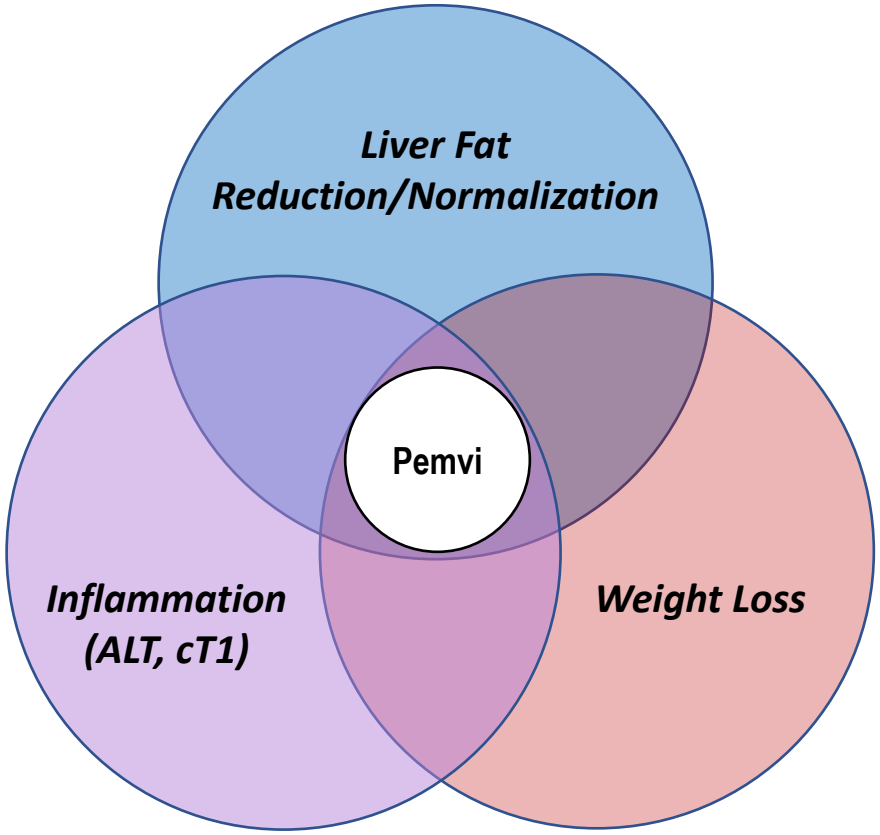
Safety Summary

- GI intolerability comparable to other drugs in the GLP-1 class of agents
- 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 significant ALT elevations

PEMVIDUTIDE REDUCES LIVER FAT, INFLAMMATION AND BODY WEIGHT

RAPID EFFECTS ON ALL THREE THERAPEUTIC OBJECTIVES

- Potent reduction in liver fat content, with >50% achieving normalization
- Potent reduction in serum ALT/ cT1 (inflammation)
- Significant reduction in body weight



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Thank you

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