A placebo-controlled, double-blind, first-in-human study of pemvidutide (ALT-801), a novel GLP-1/glucagon dual receptor agonist for the treatment of NASH and obesity

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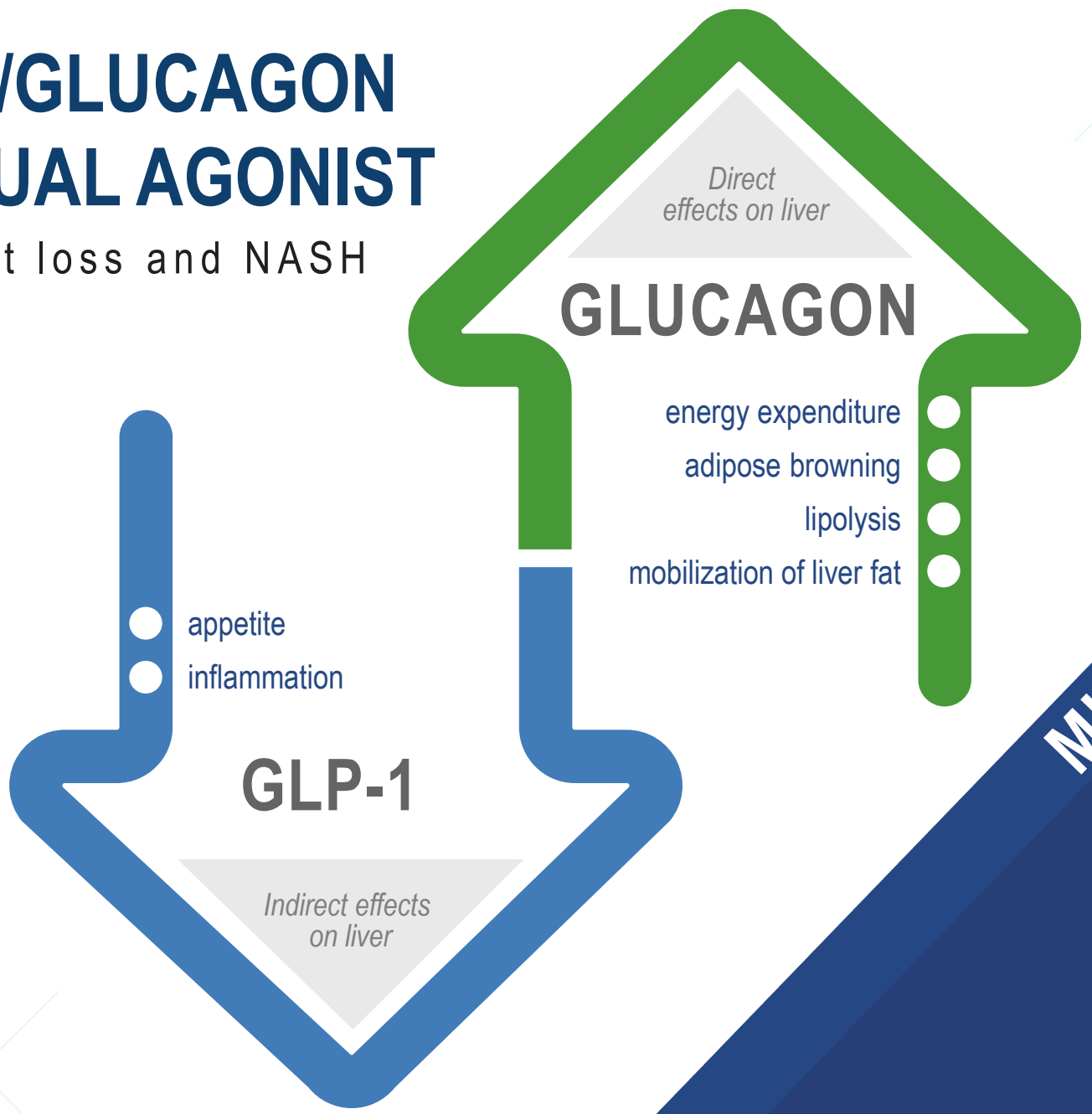
PEMVI: GLP-1/GLUCAGON RECEPTOR DUAL AGONIST

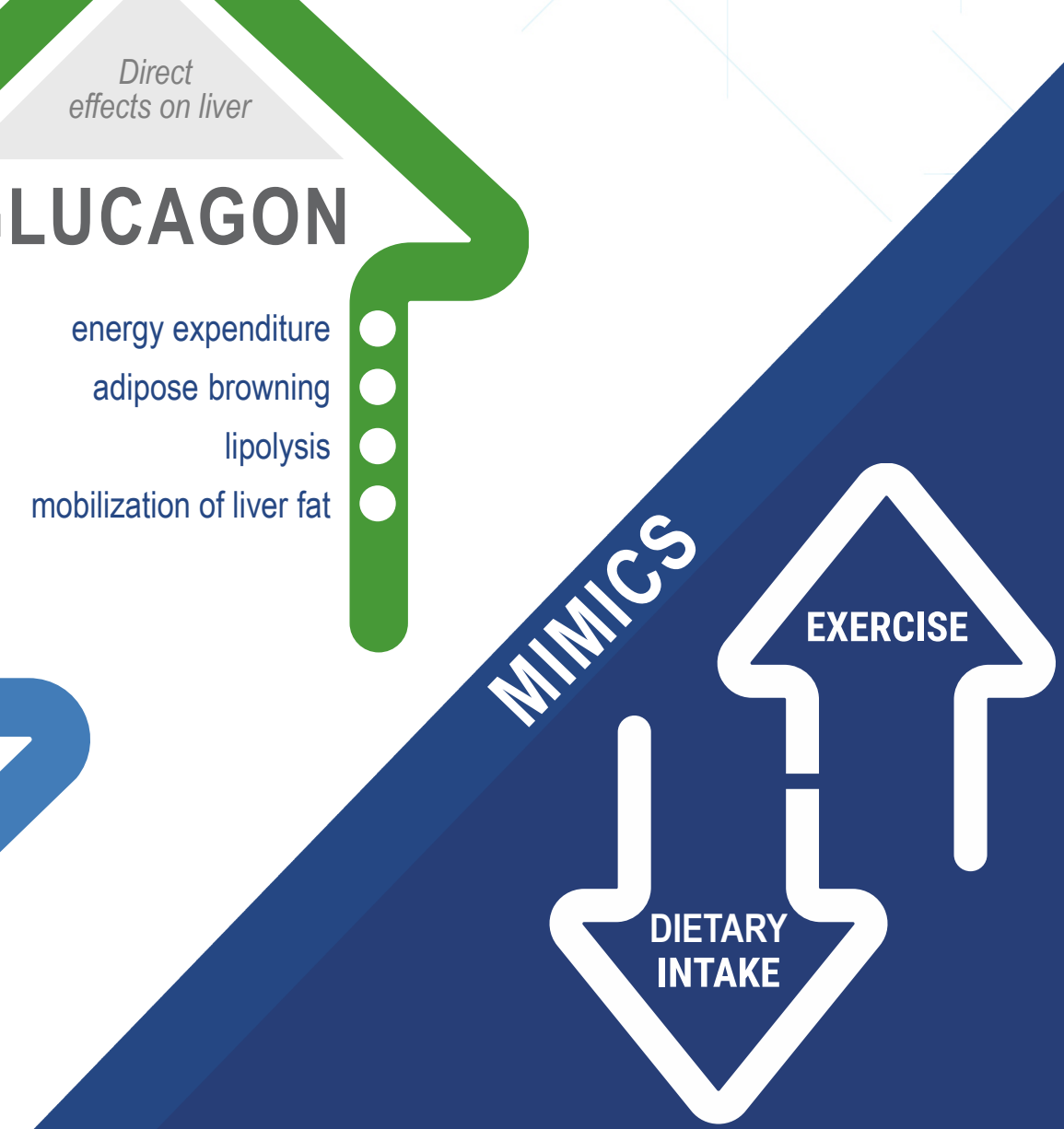
Optimized for weight loss and NASH

Designed for significant reductions in:

BODY WEIGHT

LIVER FAT, INFLAMMATION, & RESULTING FIBROSIS

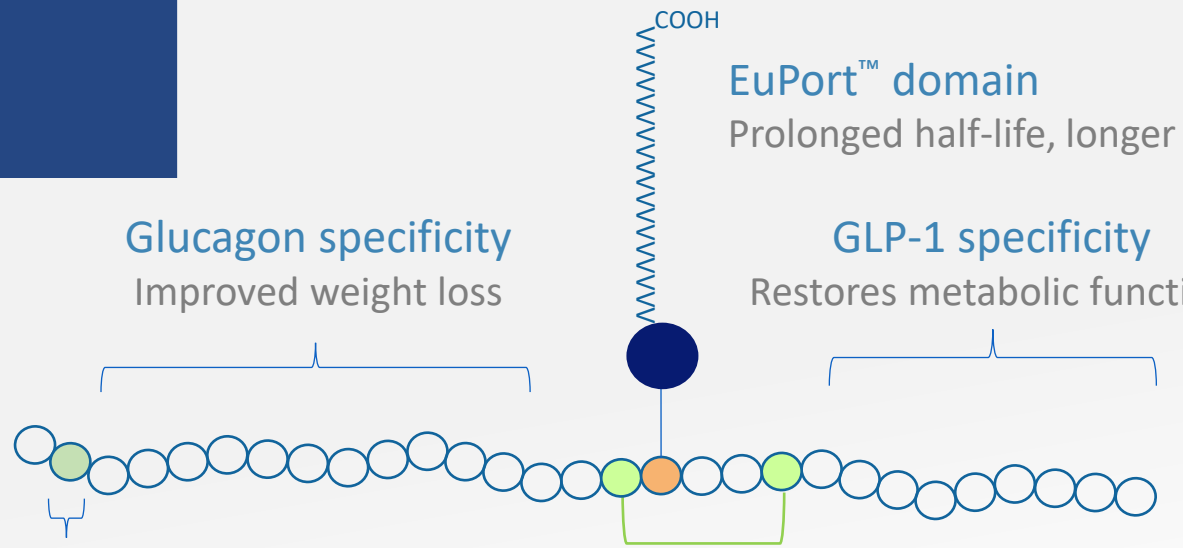




PEMVI: RATIONALLY DESIGNED AND HIGHLY DIFFERENTIATED

DESIGNED WITH THE GOAL OF ENHANCED EFFICACY AND TOLERABILITY WITHOUT USE OF DOSE TITRATION

Balanced GLP-1: Glucagon Agonism



[1]Guarracino DA et al., Chem Rev. 2019 Sep 11;119(17):9915-9949

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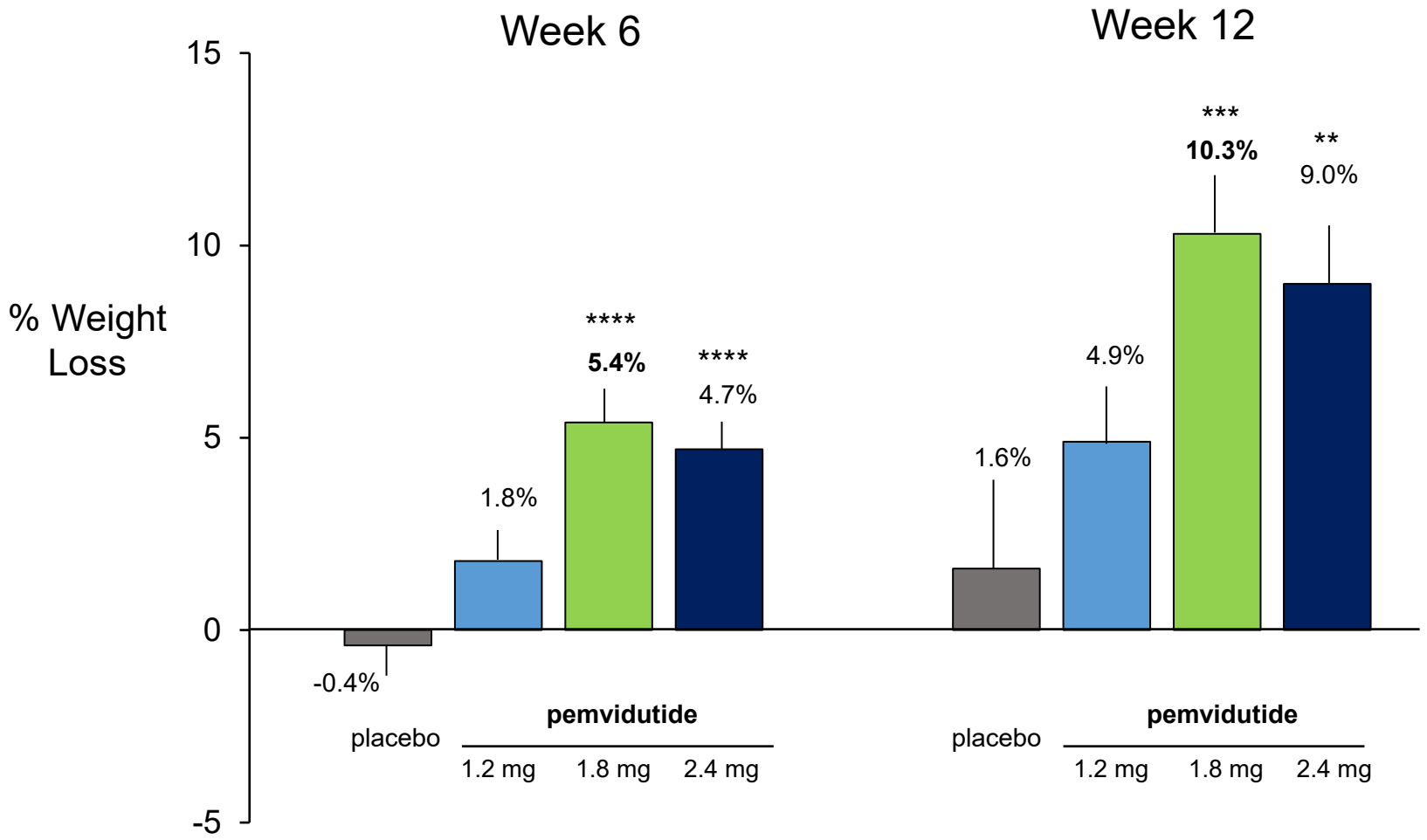
SUBSTANTIAL WEIGHT LOSS AT WEEK 12

10.3% MEAN WEIGHT LOSS ACHIEVED AT 1.8 MG DOSE



*** p < .01, ***p < .005, ****p < .001; compared to placebo*

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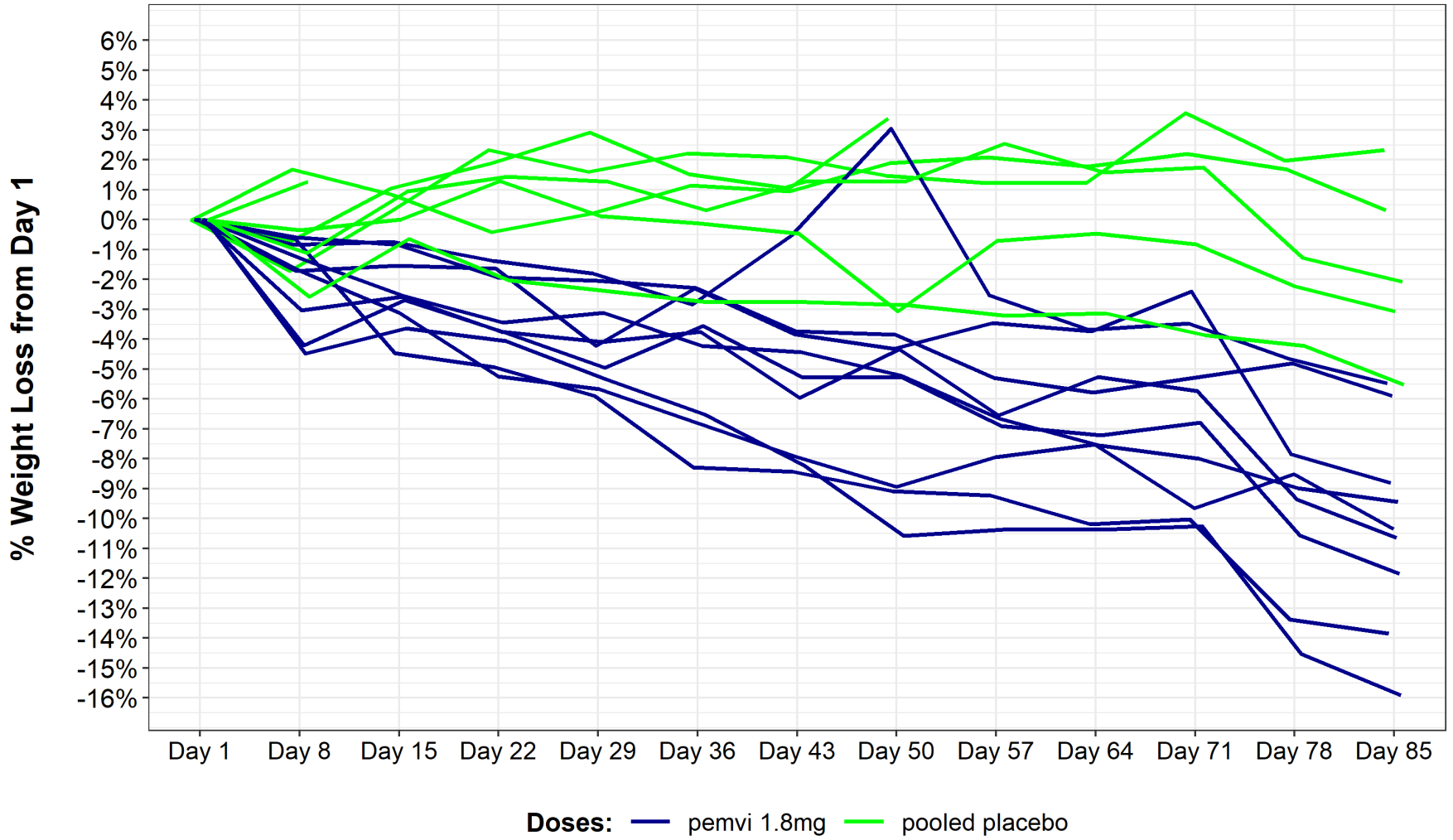
MAJORITY OF SUBJECTS AT 1.8 MG DOSE ACHIEVED 10% OR MORE WEIGHT LOSS AT WEEK 12



- 55% of subjects achieved 10% or more weight loss by Week 12
- 100% of subjects achieved 5% or more weight loss by Week 12

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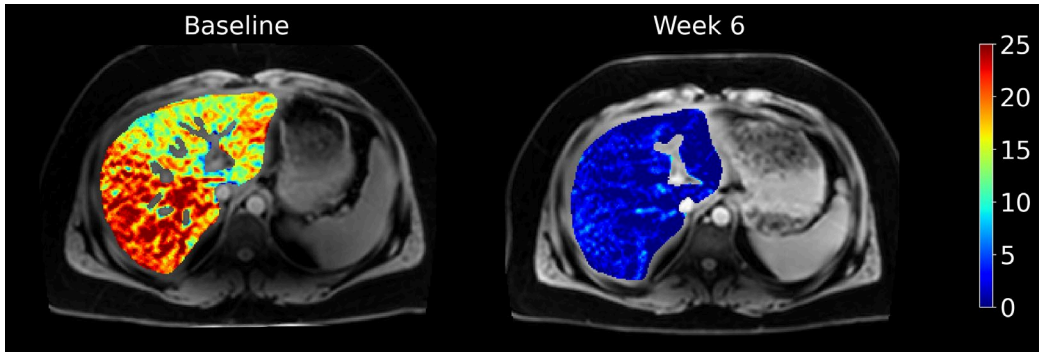
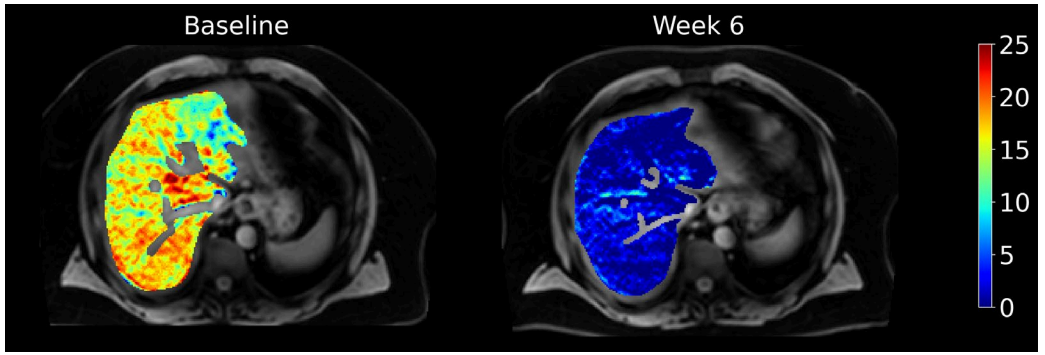
GREATER THAN 90% REDUCTION IN LIVER FAT BY MRI-PDFF IN 6 WEEKS

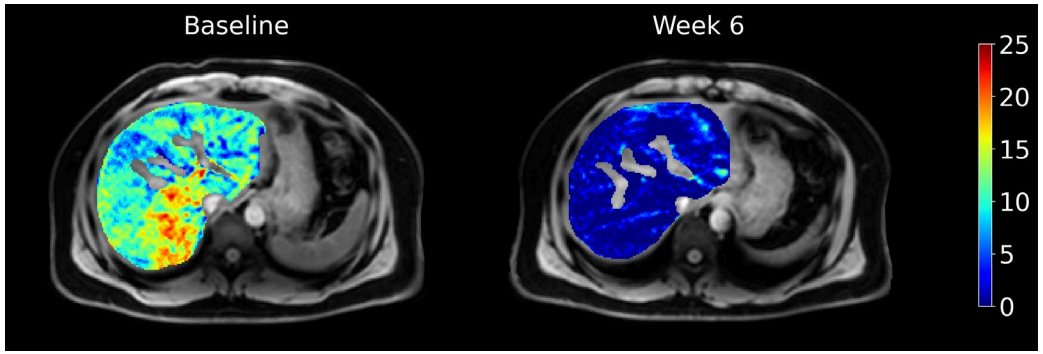
PEMVIDUTIDE DECREASED LFC TO UNDETECTABLE LEVELS AT THE 1.8 MG AND 2.4 MG DOSES



19.5% **Below LOD**



17.0% **Below LOD**



12.5% **Below LOD**

Exploratory analysis of subjects with baseline LFC ≥ 5%

All subjects receiving pemvidutide 1.8 or 2.4 mg achieved undetectable levels of liver fat by MRI-PDFF – a greater than 90% reduction – at Week 6

LFC, liver fat content; LOD, limit of detection = 1.5%; for absolute and relative Δ, values < LOD are set at 0.75%

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SAFETY OVERVIEW

NO STUDY DISCONTINUATIONS DUE TO ADVERSE EVENTS

Characteristic		Treatment			
		1.2 mg	1.8 mg	2.4 mg	Pooled placebo
AEs leading to discontinuation	**n (%)**	**0 (%)**	**0 (%)**	**0 (%)**	**0 (%)**
Serious or severe AEs	**n (%)**	**0 (%)**	**0 (%)**	**0 (%)**	**0 (%)**
Nausea					
Mild	n (%)	1 (14.3%)	5 (55.6%)	5 (45.5%)	1 (14.3%)
Moderate	n (%)	1 (14.3%)	1 (11.1%)	5 (45.5%)	0 (0.0%)
Vomiting					
Mild	n (%)	1 (14.3%)	1 (11.1%)	5 (45.5%)	1 (14.3%)
Moderate	n (%)	0 (0.0%)	1 (11.1%)	3 (27.3%)	0 (0.0%)
Diarrhea					
Mild	n (%)	0 (0.0%)	0 (0.0%)	2 (18.2%)	0 (0.0%)
Moderate	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation					
Mild	n (%)	0 (0.0%)	1 (11.1%)	2 (18.2%)	0 (0.0%)
Moderate	n (%)	0 (0.0%)	1 (11.1%)	1 (9.1%)	0 (0.0%)
Hyperglycemia	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

One subject receiving pemvidutide 1.8 mg and 1 subject receiving placebo experienced 3-5x elevations of alanine aminotransferase (ALT) without other significant findings

Gastrointestinal Adverse Events

- Most frequently mild at 1.8 mg dose with on-drug resolution and not requiring treatment
- No study discontinuations due to AEs

No significant effects on

- Blood glucose control by fasting serum glucose and HbA1c
- Mean heart rate at Week 6 and Week 12

CONCLUSIONS

- *Double-digit weight loss* in 12 weeks and reduction of LFC to below detectable levels potentially sets new standards for weight loss and liver fat reduction for NASH therapeutics

- These effects were achieved without the use of dose titration

Thank you

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