NASH Renaissance 2023

Pemvidutide—Potent GLP-1/Glucagon Dual Receptor Agonist for the Treatment of NASH and Obesity

Evercore ISI Research Event
30 March 2023

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Forward-looking statements

Safe-Harbor Statement

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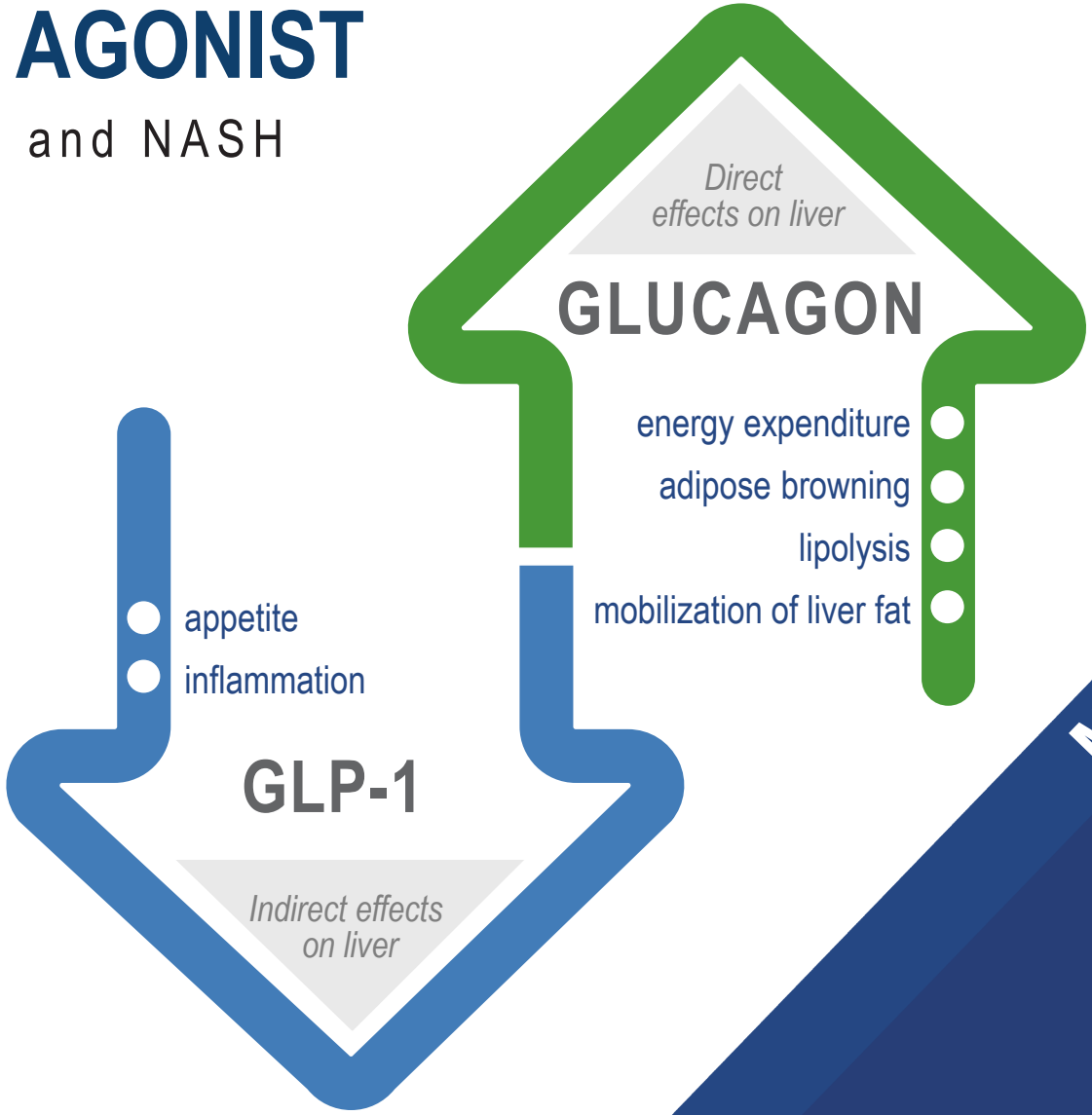
PEMVIDUTIDE:GLP-1/GLUCAGON DUAL RECEPTOR AGONIST

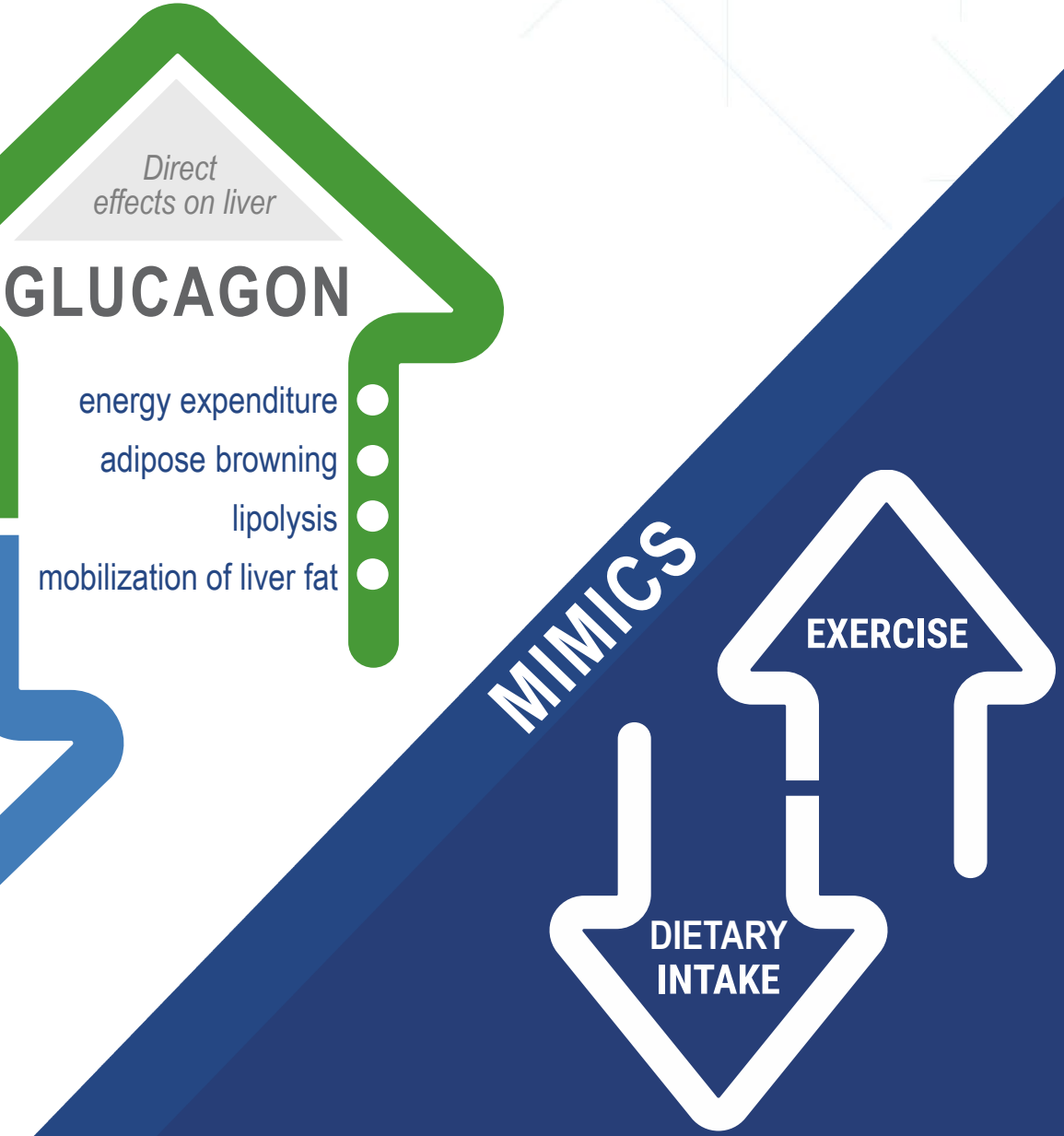
Optimized for weight loss and NASH

Designed for significant reductions in:

BODY WEIGHT

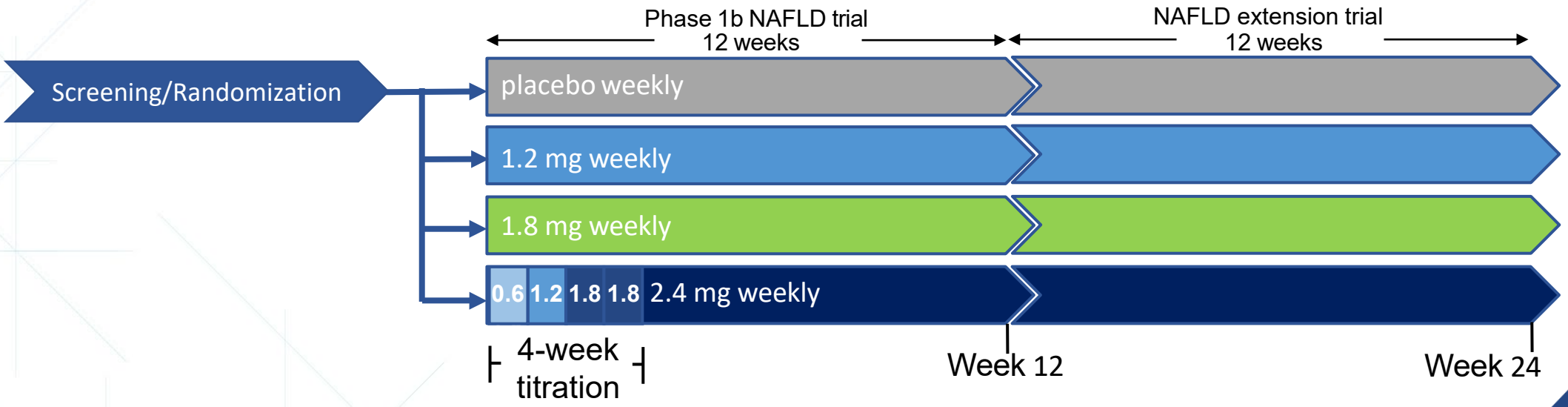
LIVER FAT, INFLAMMATION, & RESULTING FIBROSIS





PEMVIDUTIDE PHASE 1b NAFLD TRIAL WITH 12-WEEK EXTENSION

- 12-week, randomized, placebo-controlled study of 94 subjects with obesity or overweight and non-alcoholic fatty liver disease (NAFLD)
- 64 completers participated in a 12-week extension trial to receive a total of 24 weeks of treatment
- 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=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%)
Ethnicity	Hispanic, n (%)	11 (57.9%)	15 (93.8%)	12 (80.0%)	9 (64.3%)
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, %	mean (SD)	24.0 (9.6)	20.1 (7.7)	23.9 (7.4)	20.5 (6.5)
Serum ALT, IU/L	mean (SD)	41.0 (21.3)	32.4 (14.2)	35.3 (13.0)	39.6 (26.6)

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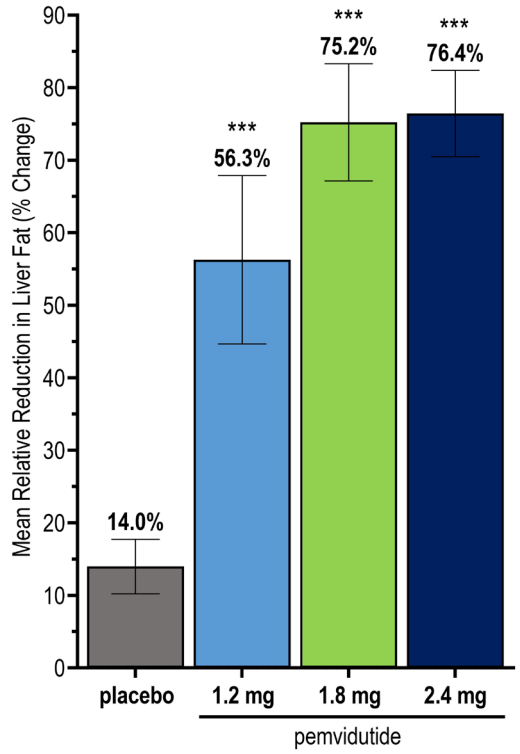
ROBUST REDUCTIONS IN LIVER FAT CONTENT (LFC) AT WEEK 24

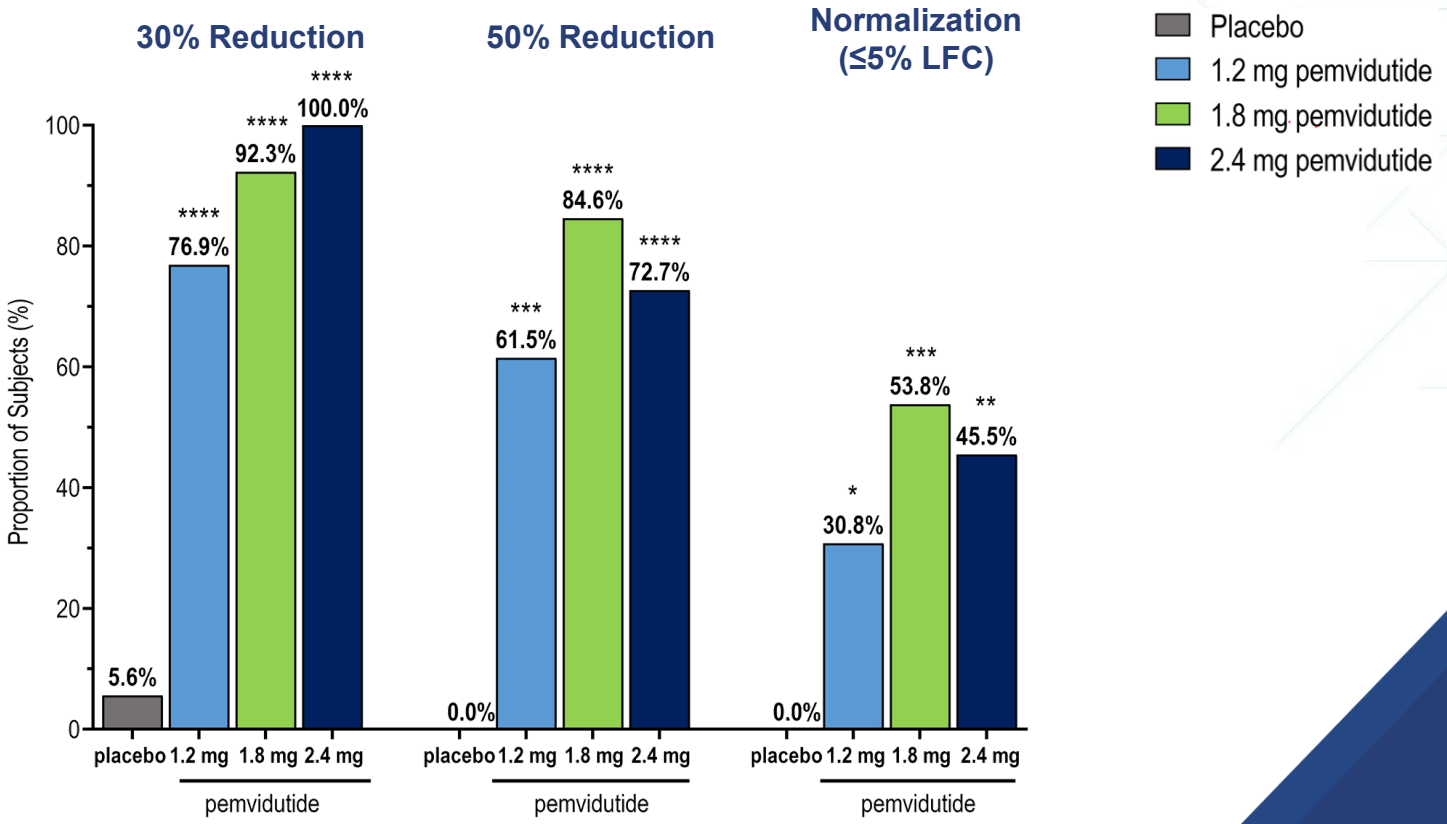
SIGNIFICANT EFFECTS OBSERVED AS EARLY AS WEEK 6

Relative Reduction at Week 24



*** p < 0.001 vs. placebo (ANCOVA[1])

Responder Analyses at Week 24



* p < 0.05, ** p < 0.005, *** p < 0.001, **** p < 0.0001 vs. placebo (CMH[3])

[1] Analysis of covariance; [2] Cochran Mantel Haenszel

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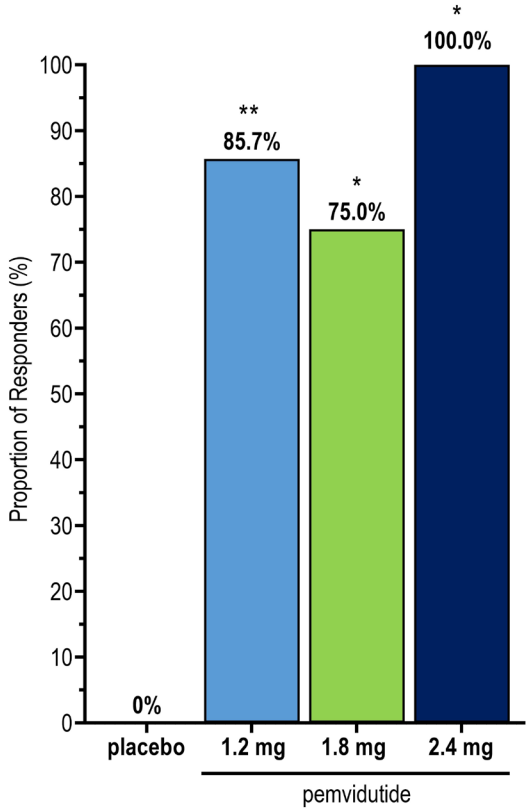
SIGNIFICANT cT1 RESPONSE RATES AND ALT REDUCTION AT WEEK 24

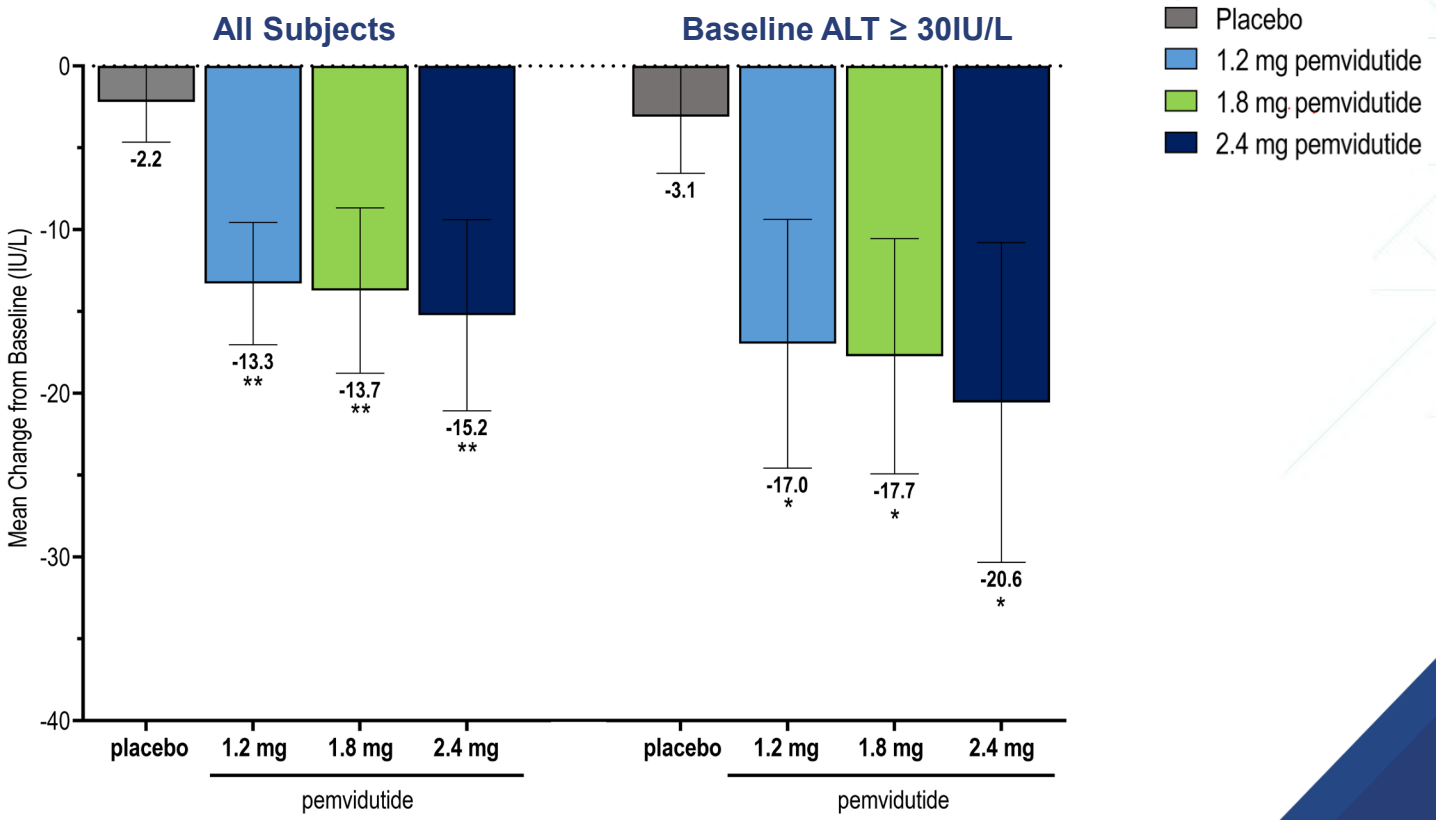
INDEPENDENT INDICATORS OF REDUCED LIVER INFLAMMATION

cT1 Responder Rates[1]



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

ALT Reduction



* p < 0.05, ** p < 0.005 vs. placebo (MMRM[3])

80ms reduction in cT1 has been associated with a 2-point reduction of NASH Activity Score (NAS)[2]

[1]80ms reduction from baseline; [2]Dennis A, Front Endocrinol 2021; [3]mixed model for repeated measures

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FIBROSIS IMPROVEMENT DRIVEN BY DEGREE OF LFC REDUCTION

EFFECTS ARE INDEPENDENT OF MECHANISM

Agents with Direct Effects on Liver - Fibrosis Improvement Achieved

Compound	Dose	Mechanism	Duration of Treatment	LFC Reduction	Fibrosis Improvement		
					Treatment	Placebo	Δ
Resmetirom	100 mg QD	THR-β	52 weeks	48%	26%*	14%	12%
Pegozafermin	44 mg Q2W	FGF21	24 weeks	54%	27%*	7%	20%
Efruxifermin	50 mg QW	FGF21	24 weeks	64%	41%*	20%	21%
Pemvidutide	1.8 mg QW	GLP-1/GCG	24 weeks	75%	TBD	TBD	TBD

Agents with Indirect Effects on Liver - Fibrosis Improvement Not Achieved

Compound	Dose	Mechanism	Duration of Treatment	LFC Reduction	Fibrosis Improvement		
					Treatment	Placebo	Δ
Semaglutide	0.4 mg QD	GLP-1	72 weeks	35%[1]	43%	33%	10%

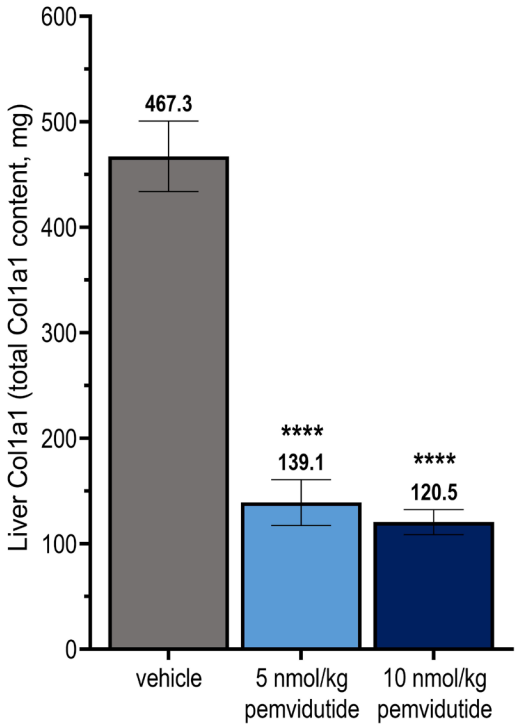
Data derived from different clinical trials with differences in trial design, patient populations and timepoints. Direct trial comparisons cannot be made.

[1] estimated at Week 24; * $p < 0.05$

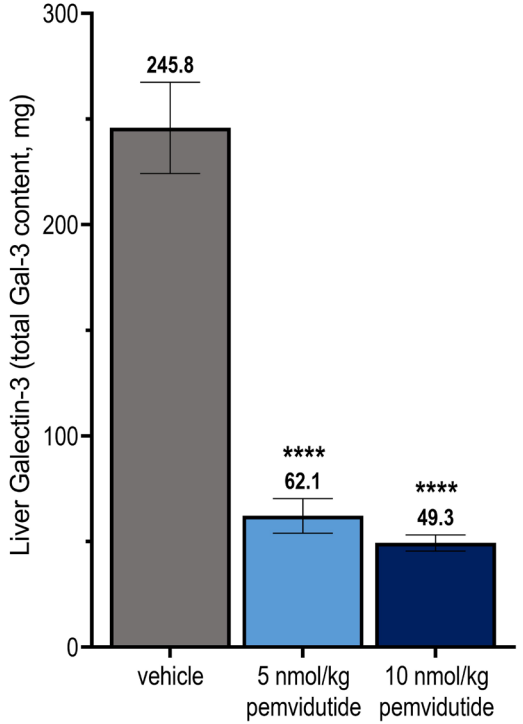
PEMVIDUTIDE DEMONSTRATED POTENT ANTI-FIBROTIC EFFECTS AND SUPPRESSION OF PROFIBROTIC GENES IN PRECLINICAL STUDIES

Gubra Mouse NASH Model

Col1A1



Galectin-3



**** p < .0001 vs. vehicle (ANOVA[1])

Changes accompanied by suppression of stellate cell pathways and profibrotic genes

- A-SMA (ACTA2)
- Platelet-derived growth factor subunit B (PDGFB)
- Transforming growth factor-beta (TGF-β)

Nestor, Scientific Reports 2022; [1] analysis of variance

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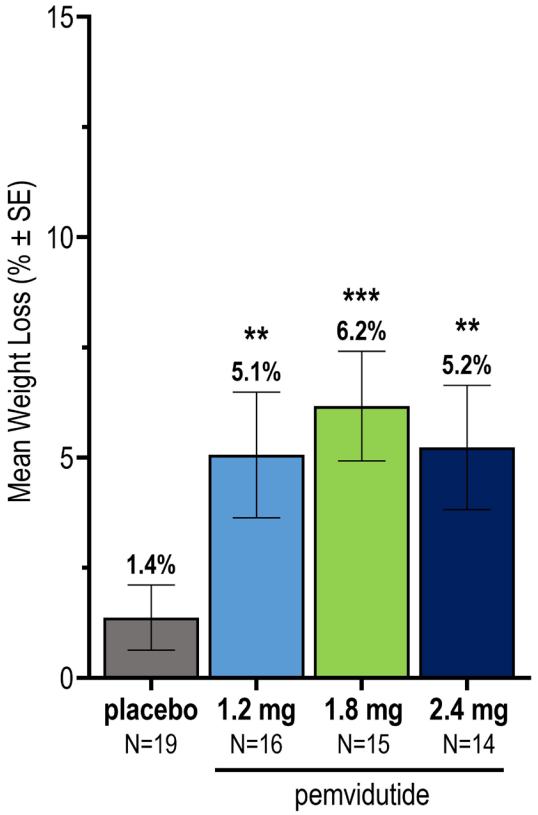
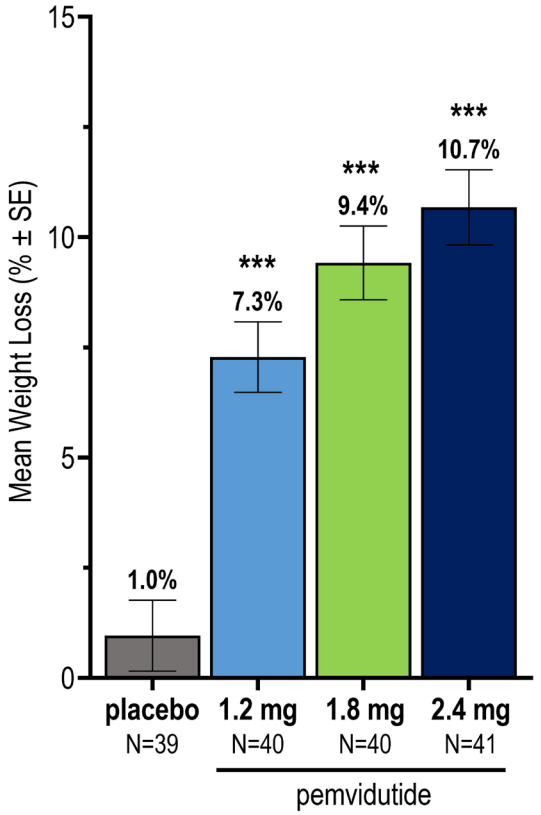
SIGNIFICANT REDUCTIONS IN BODY WEIGHT AT WEEK 24

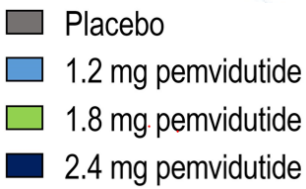
POTENT EFFECTS IN BOTH NAFLD AND OBESITY POPULATIONS

Phase 1b NAFLD Trial[1]



Phase 2 MOMENTUM Obesity Trial





[1] all subjects (diabetes and non-diabetes); ** p < 0.005. *** p < 0.001 vs. placebo (MMRM)

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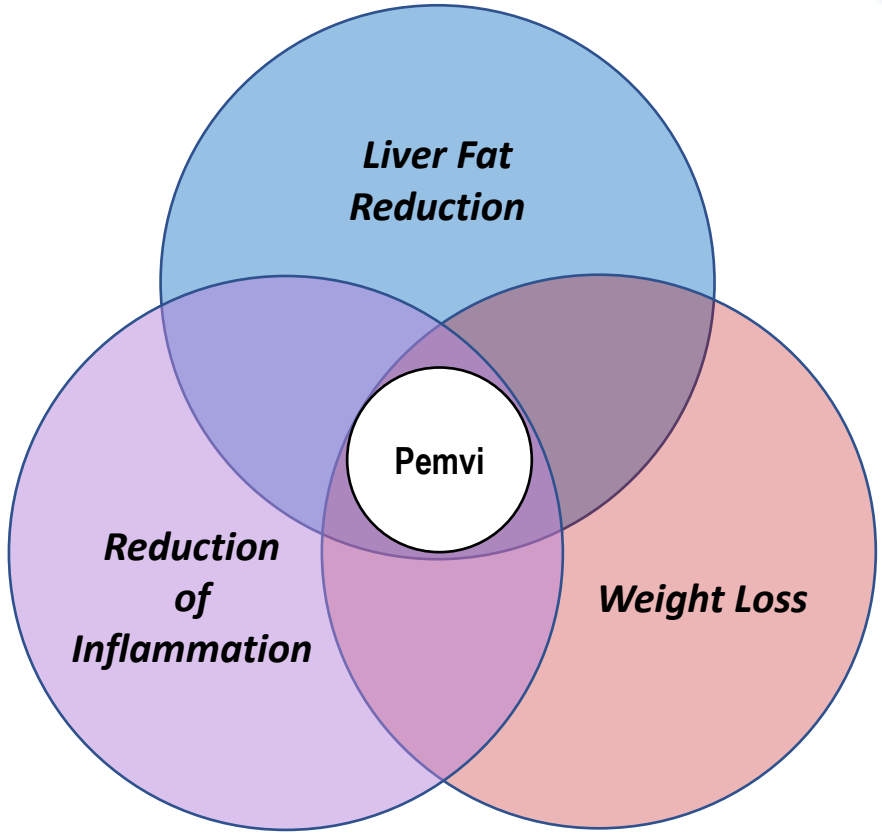
GLUCOSE HOMEOSTASIS MAINTAINED THROUGH WEEK 24

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

PEMVIDUTIDE—SUMMARY AND CONCLUSIONS

- Robust liver fat reduction accompanied by significant weight loss
- Potent anti-inflammatory effects (cT1 responses and ALT reductions)
- Potent anti-fibrotic effects with suppression of profibrotic genes in preclinical studies
- Initiation of Phase 2b biopsy-driven NASH trial expected mid-year 2023



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