Week 48 top-line results from the phase 2b, multicenter, randomized, placebo-controlled IMPACT trial of pemvidutide in metabolic dysfunction-associated steatohepatitis

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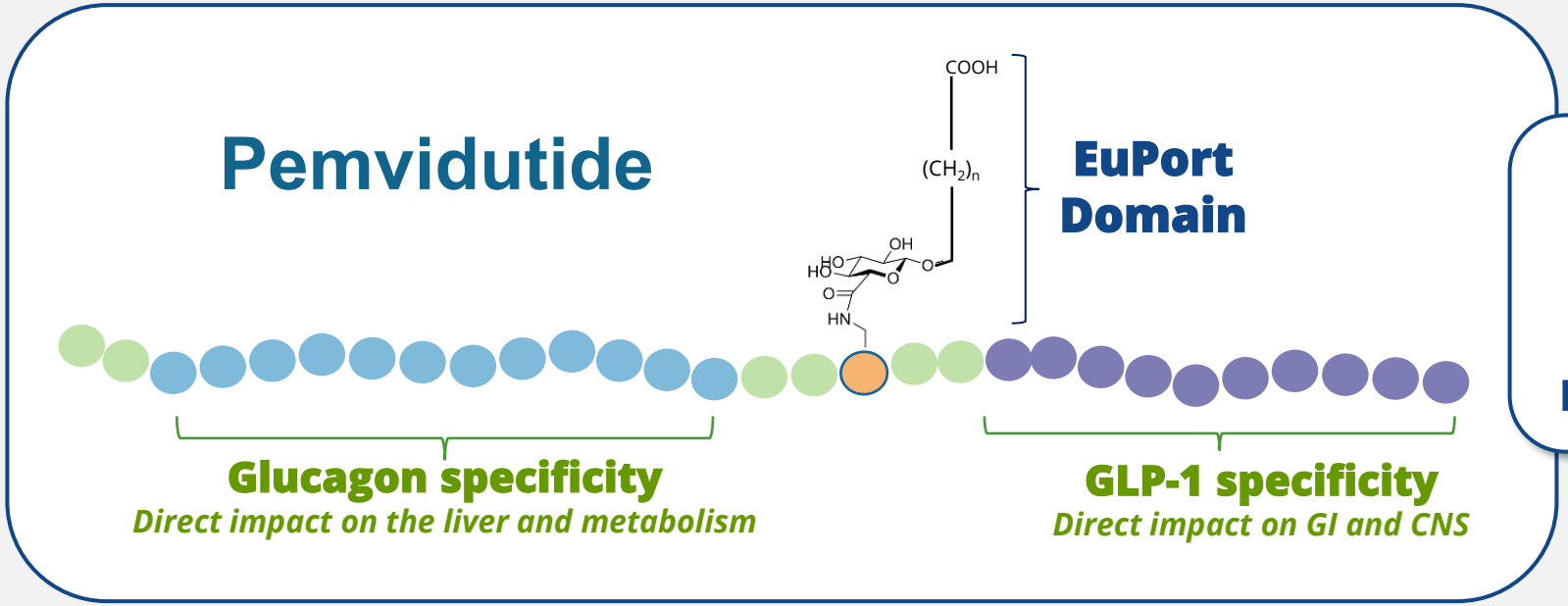
Disclosures

Dr Noureddin Disclosures:
Advisory Board/Consulting: D&D Pharmatech, Neuraly, Akero, Altimmune, Alligos, AstraZeneca, BI, Boston Pharma, Curve bioscience, Cytodyn, GSK, Histoindex, Kryia , Lilly, Madrigal, Merck, Novo Nordisk, OPKO, Rivus, Sagimet, Terns and Takeda. Principal Investigator for a Drug Study: Allergan, Altimmune, Akero, BI, BMS, Boston Pharma, Conatus, Corcept, Gilead, Galectin, Genfit, GSK, Kowa, Enanta, Madrigal, Lilly, Merck, Novartis, Novo Nordisk, Rivus, Shire, Takeda, Terns, Viking and Zydus. Stockholder: OPKO, Kryia and Akero. Speaking bureau: Madrigal and Novo Nordisk

Disclaimer:
This presentation discusses pemvidutide, an investigational product candidate that has not been approved by the FDA or any other regulatory authority. Its safety and efficacy have not been established.
The statements about pemvidutide are based on current expectations and are subject to risks and uncertainties that could cause actual results to differ materially. For additional information regarding these risks and uncertainties, please refer to the Company's filings with the U.S. Securities and Exchange Commission, including the most recent Form 10-K and Form 10-Q.
This study was sponsored by Altimmune, inc.

Pemvidutide 1:1 Glucagon/GLP-1 Dual Receptor Agonist



EuPort

↓

Delayed T_{max} with lower C_{max} †

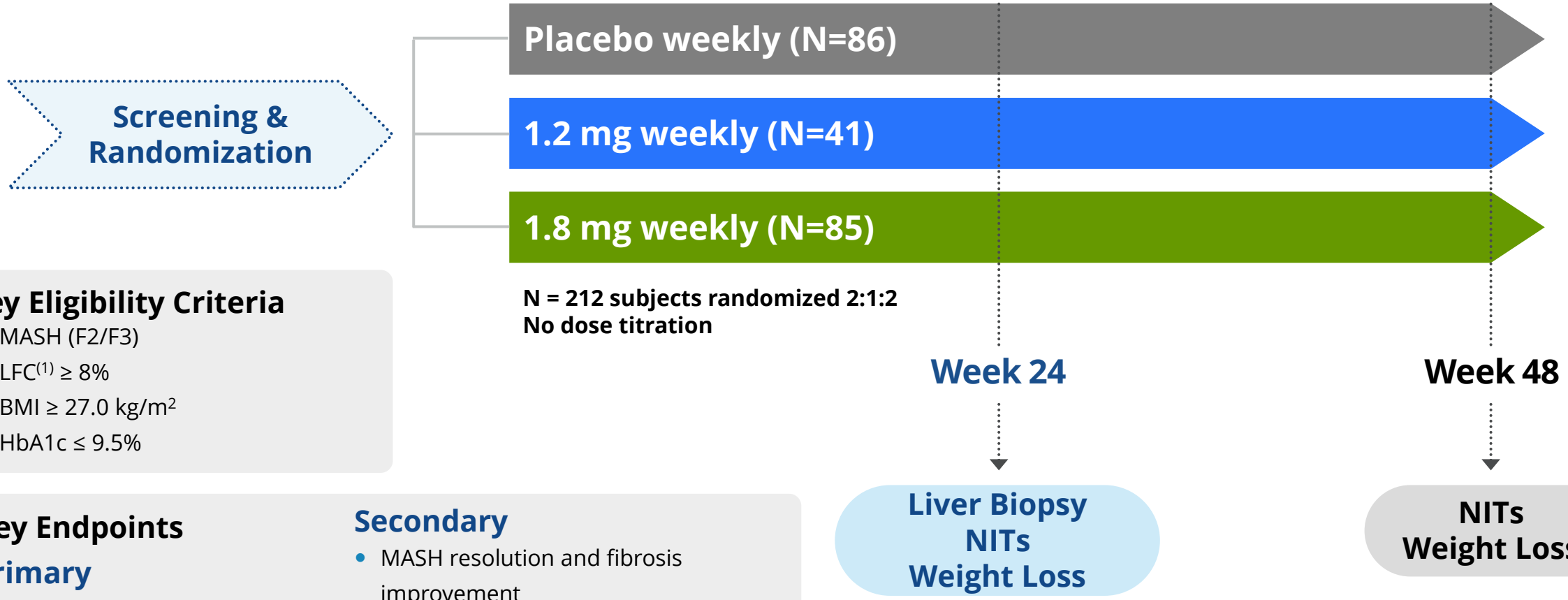
↓

Designed to Increase Tolerability

Pemvidutide is an investigational product candidate that has not been approved by the FDA or any other regulatory authority.

† *Nestor et al. Sci Rep. 2022 Apr 23;12(1):6666..*

IMPACT Phase 2b MASH Trial Design



Key Eligibility Criteria

- MASH (F2/F3)
- LFC[1] ≥ 8%
- BMI ≥ 27.0 kg/m^2
- HbA1c ≤ 9.5%

Key Endpoints

Primary

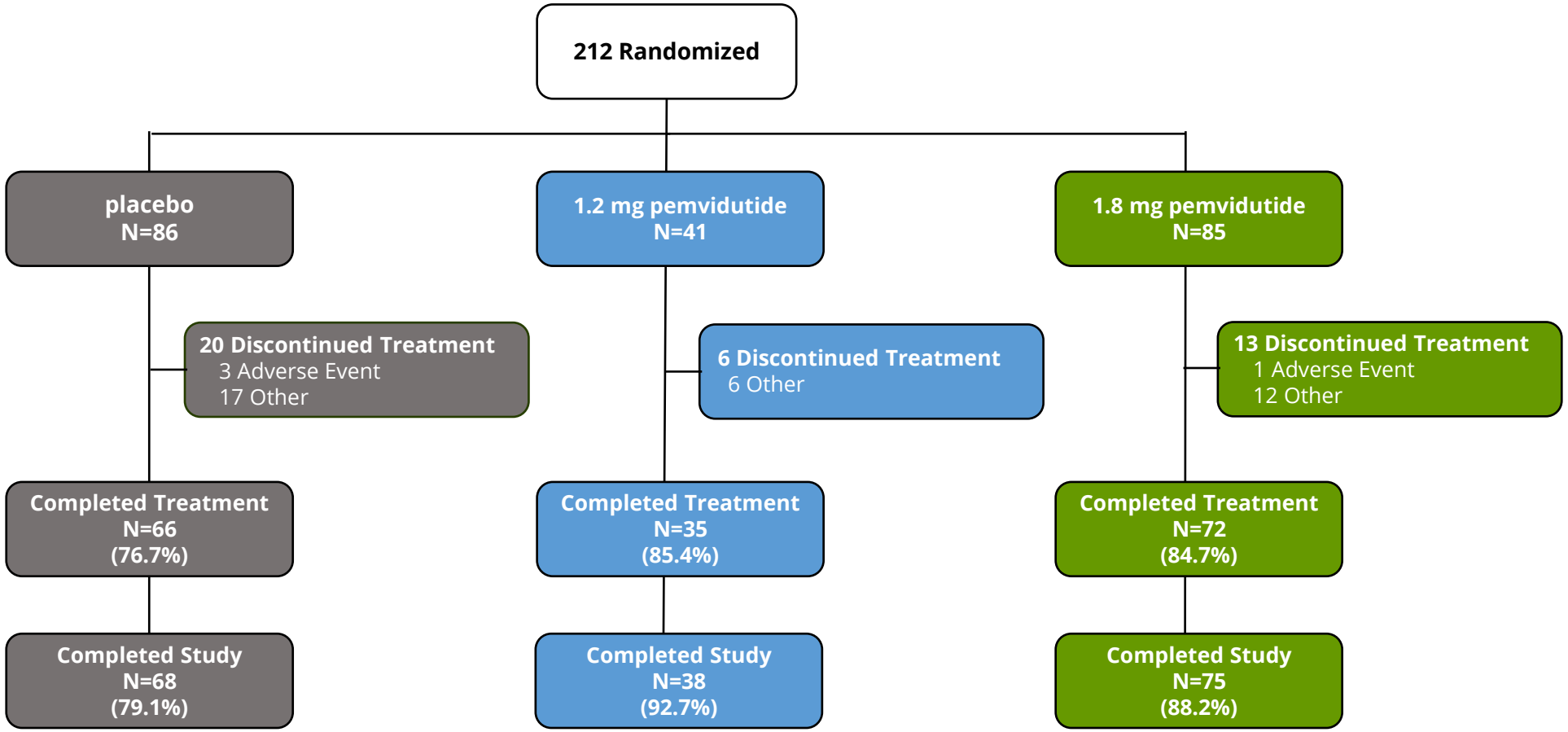
MASH resolution or fibrosis improvement[2] at Week 24

Secondary

- MASH resolution and fibrosis improvement
- Non-invasive tests (NITs)
- Weight Loss

1. Liver fat content. 2. MASH Resolution without worsening of fibrosis or Fibrosis Improvement without worsening of MASH.

IMPACT Phase 2b MASH Trial Patient Disposition



85% of patients receiving pemvidutide completed treatment
vs. 77% of patients receiving placebo

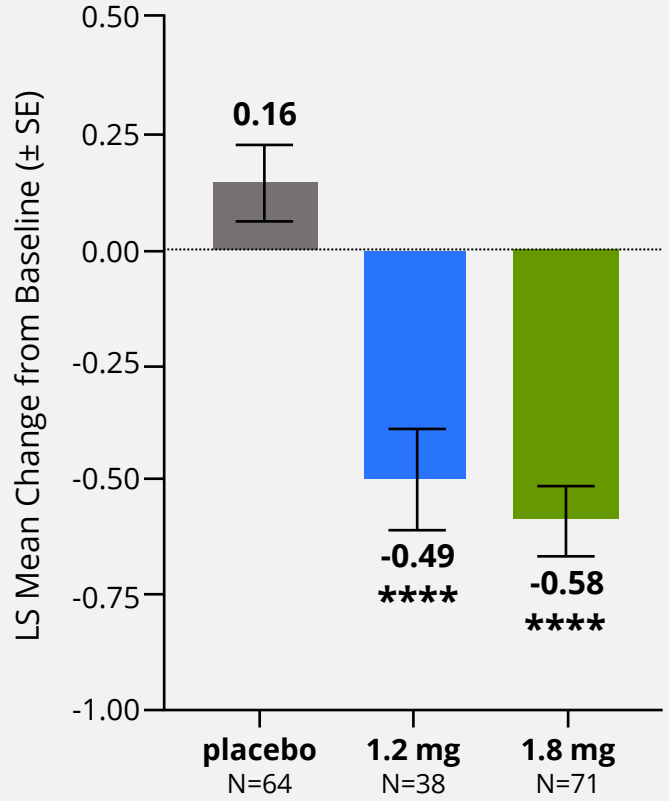
IMPACT Baseline Demographics and Disease Characteristics

Characteristic	Placebo (N=86)	1.2 mg (N=41)	1.8 mg (N=85)
Age, years	52.5 (12.2)	55.2 (13.0)	53.4 (12.4)
Female sex, n	48 (55.8%)	25 (61.0%)	50 (58.8%)
Body weight, kg	109.7 (28.0)	110.7 (26.3)	107.7 (21.3)
BMI, kg/m^2	38.3 (8.4)	39.2 (8.4)	38.7 (6.9)
Type 2 Diabetes, n	36 (41.9%)	18 (43.9%)	36 (42.4%)
F3 Fibrosis, n	40 (46.5%)	17 (41.5%)	39 (45.9%)
ELF	9.7 (0.8)	10.0 (0.8)	9.9 (1.0)
VCTE, kPa	12.5 (4.4)	12.3 (3.6)	12.8 (4.4)
Liver Fat Content , %	19.6 (6.4)	20.0 (7.1)	19.0 (6.8)
ALT, IU/L	56.6 (32.7)	67.6 (54.6)	67.6 (43.0)

Data are presented as mean (SD) or n (%)

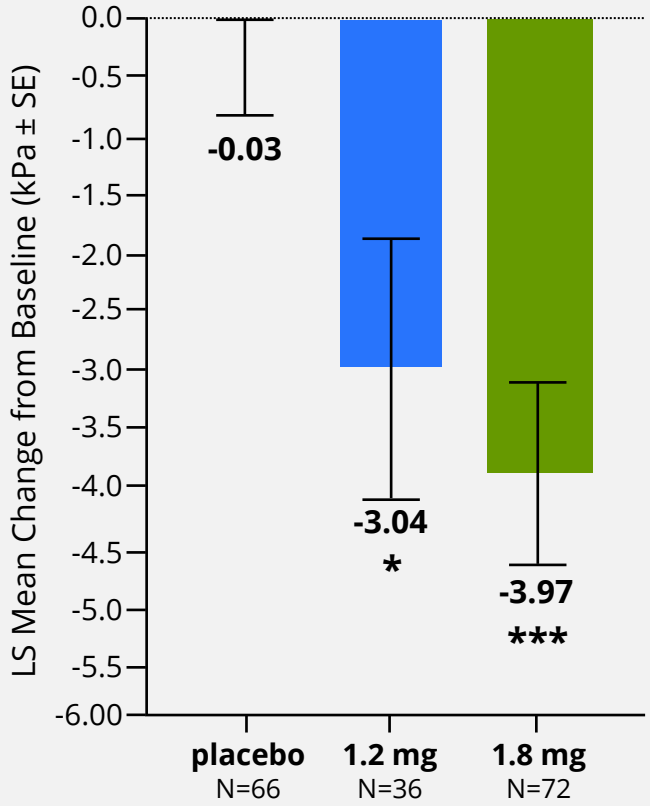
Significant Improvements in Non-invasive Tests of Fibrosis at 48 Weeks

Enhanced Liver Fibrosis (ELF)



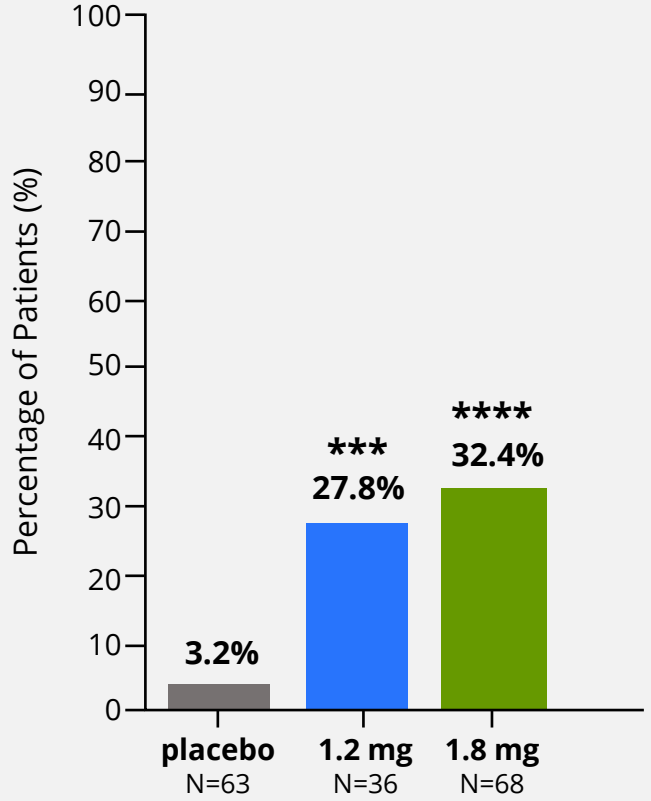
**** $p < 0.0001$ vs. placebo (ANCOVA)

Liver Stiffness Measurement (LSM)



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

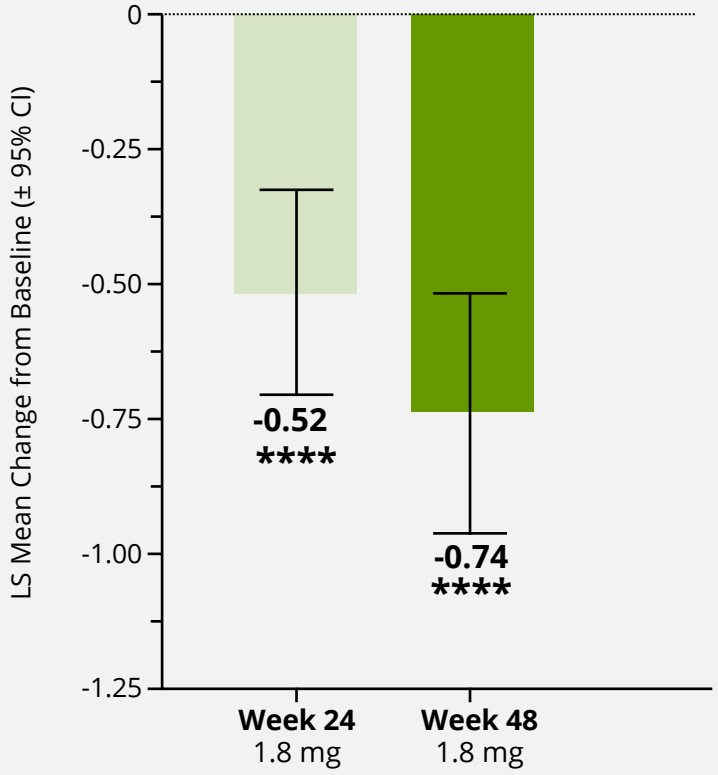
≥0.5 ELF Reduction + 30% LSM Reduction Threshold



*** $p < 0.001$ | **** $p < 0.0001$ vs. placebo (Cochran-Mantel-Haenszel)

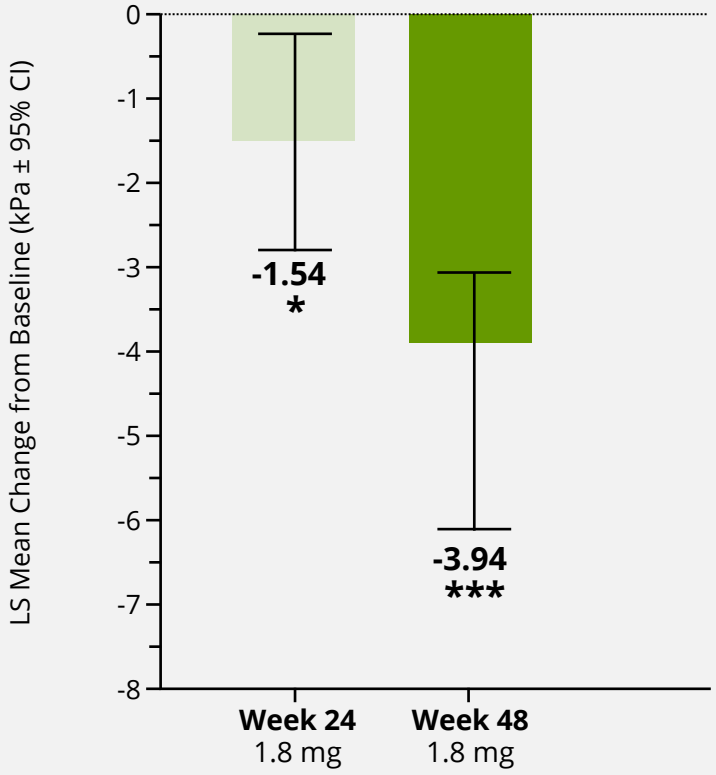
Improvements in Primary Non-invasive Markers of Fibrosis from 24 to 48 Weeks with 1.8 mg

Enhanced Liver Fibrosis (ELF)
Placebo-Adjusted



**** p < 0.0001 vs. placebo (ANCOVA)

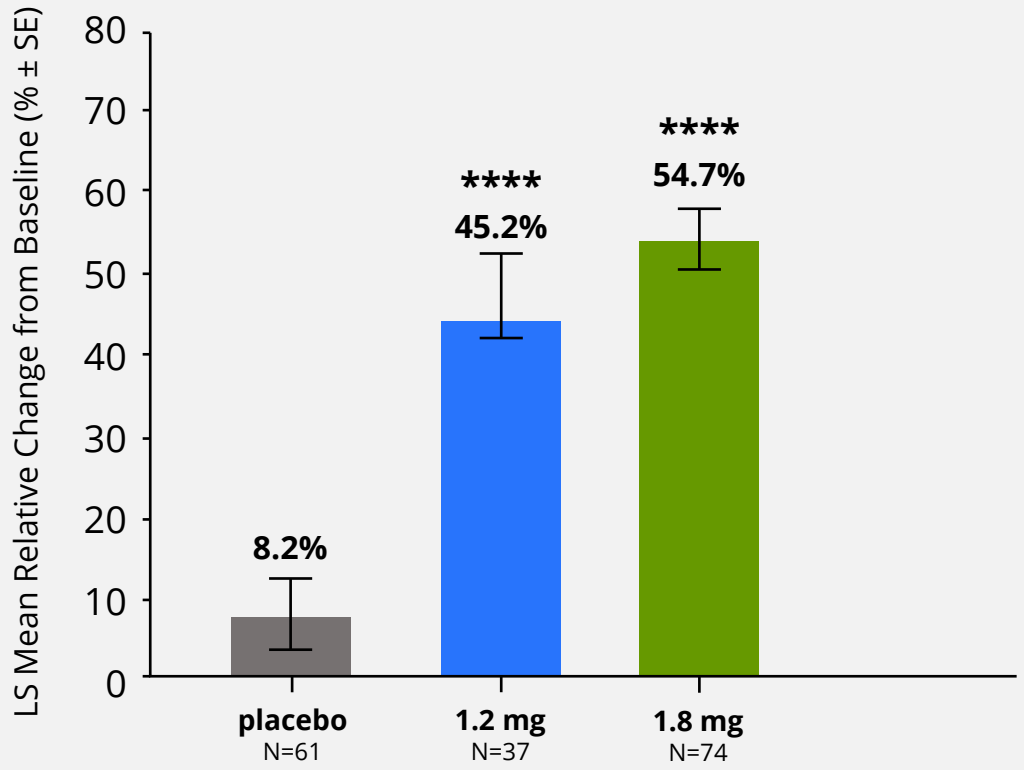
Liver Stiffness Measurement (LSM)
Placebo-Adjusted



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

1.8 mg Dose Maintained >50% Reduction in Liver Fat Over 48 Weeks

Liver Fat Content Reduction



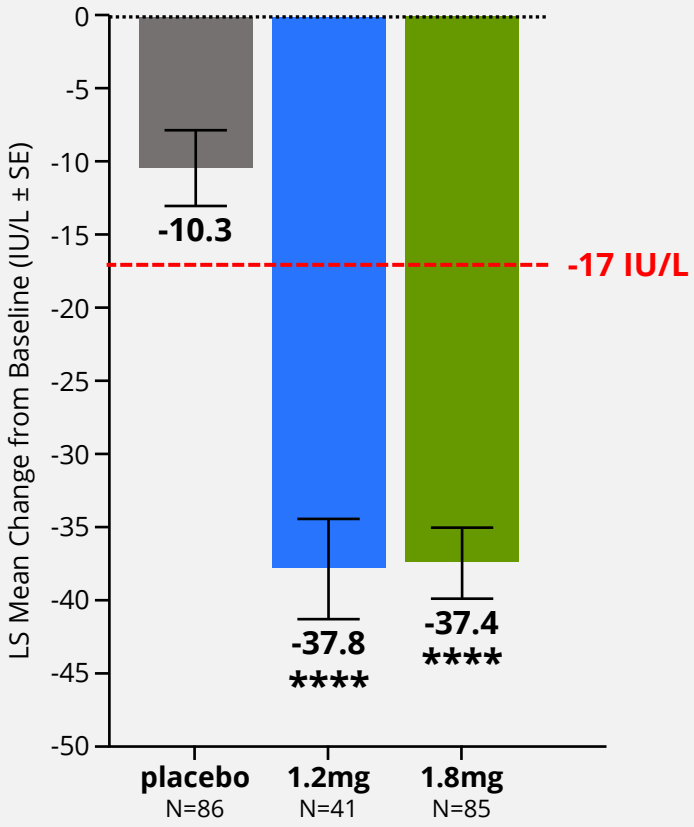
***** p < 0.0001 vs. placebo (ANCOVA)*

- Similar levels of liver fat reduction were observed as early as at 24 weeks[†]
- A ≥30% reduction in liver fat content is associated with MASH resolution[††]

[†] *Nourredin et al. Lancet; 2025; Dec 6;406 (10520):2644-2655.*
[††] *Alkhouri et al. J Hepatology 2024;82:438-445.*

Significant Reductions in Alanine Aminotransferase (ALT)

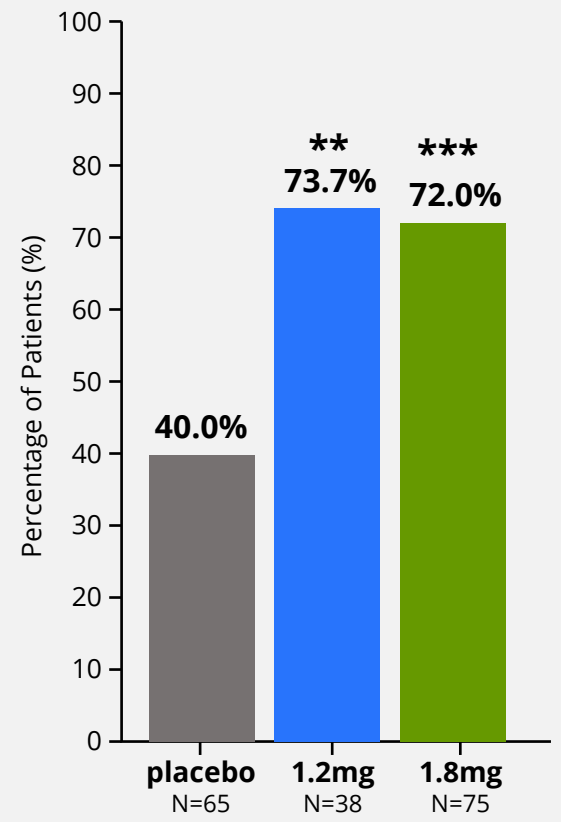
Alanine Aminotransferase (ALT)



**** $p < 0.0001$ vs. placebo (MMRM)

- ALT is a measure of hepatic inflammation and disease activity
- A -17 IU/L reduction of ALT is significantly associated with a high probability of histological response in patients with MASH[†]
- Pemvidutide demonstrated normalization of ALT (≤30 IU/L) in most patients

≤30 IU/L ALT Threshold

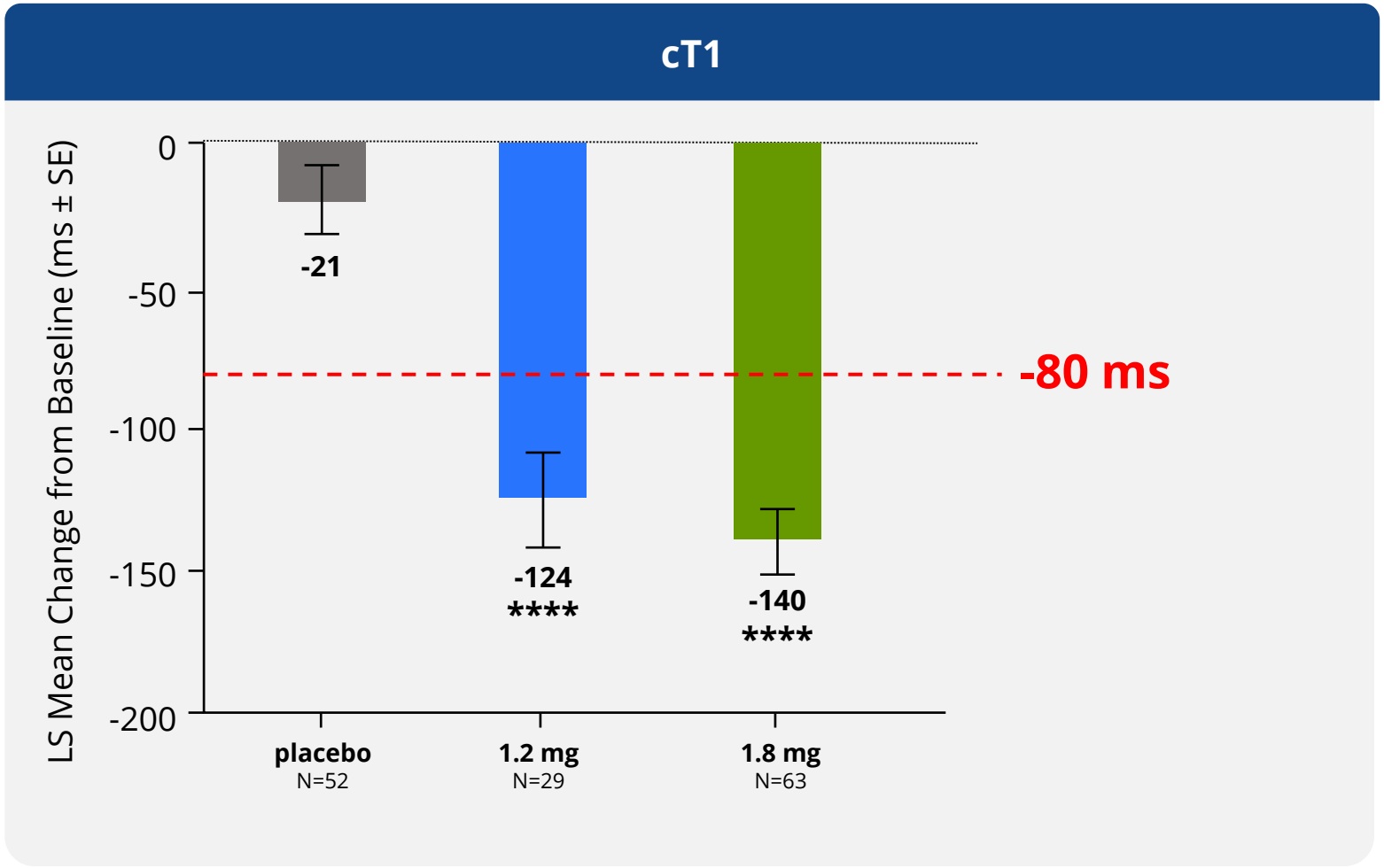


** $p < 0.005$ | *** $p < 0.001$ vs. placebo (CMH)

[†] Loomba et al. Gastroenterol 2019;156:88-95

Significant Reductions in Corrected T1 (cT1)

Reduction of ≥80 ms is associated with an improvement in histology in MASH†



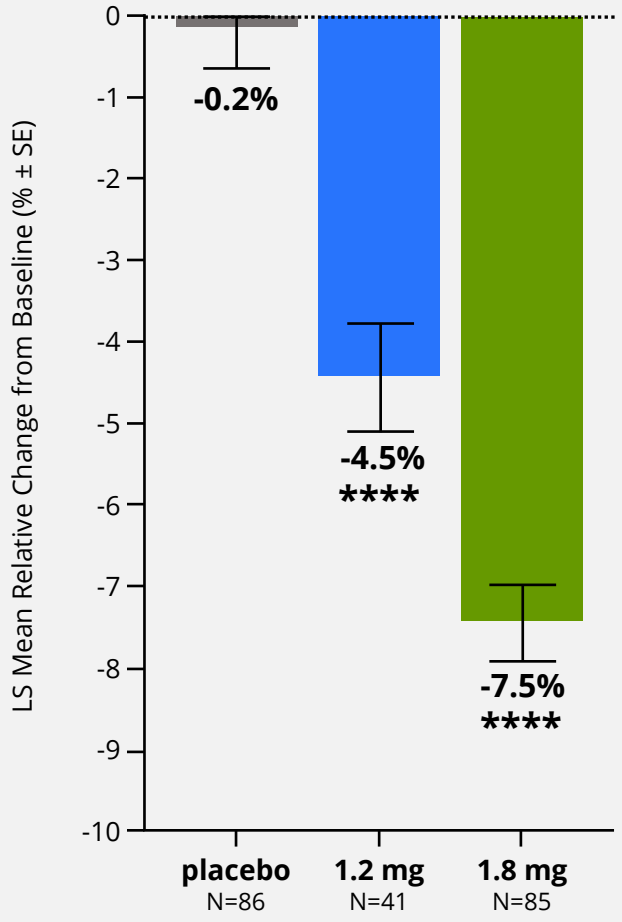
**** p < 0.0001 vs. placebo (ANCOVA)

- cT1 is a non-invasive marker of hepatic inflammation
- 80 ms reduction in cT1 is associated with 2-point reduction in NAS††

† Alkhouri et al. Journal of Hepatology; 2025; 82 (3), 438–445.
†† Dennis et al. Front Endocrinol 2020;11:575843.
NAS = Non-alcoholic fatty liver disease (NAFLD) activity score

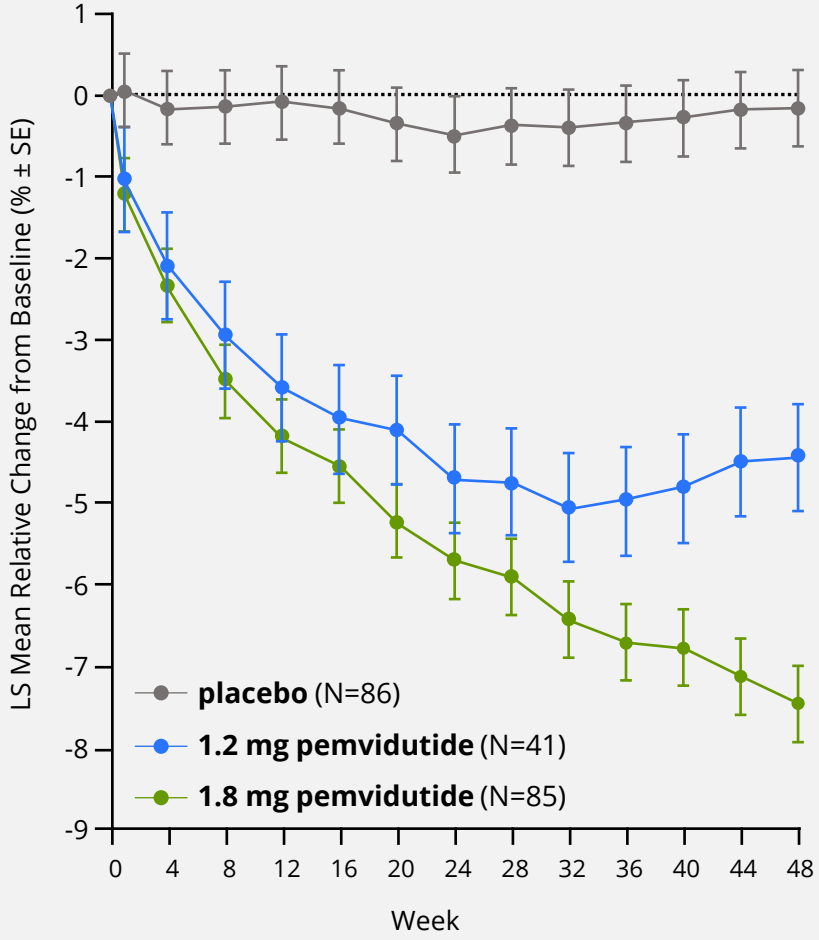
Significant and Continuing Weight Loss for 1.8 mg at 48 Weeks

Weight Loss



**** $p < 0.0001$ vs. placebo (MMRM)

Weight Loss

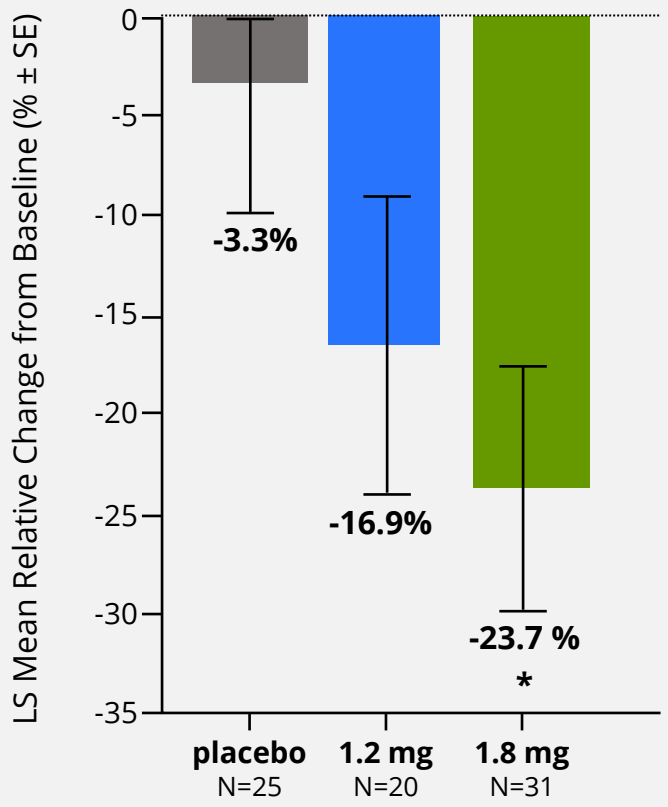


- Weight loss has been shown to be associated with MASH improvement†
- Weight loss of 7.5% at week 48 with no plateauing in 1.8 mg dose

†Vilar-Gomez et al. Gastroenterology. 2015;149(2):367-78

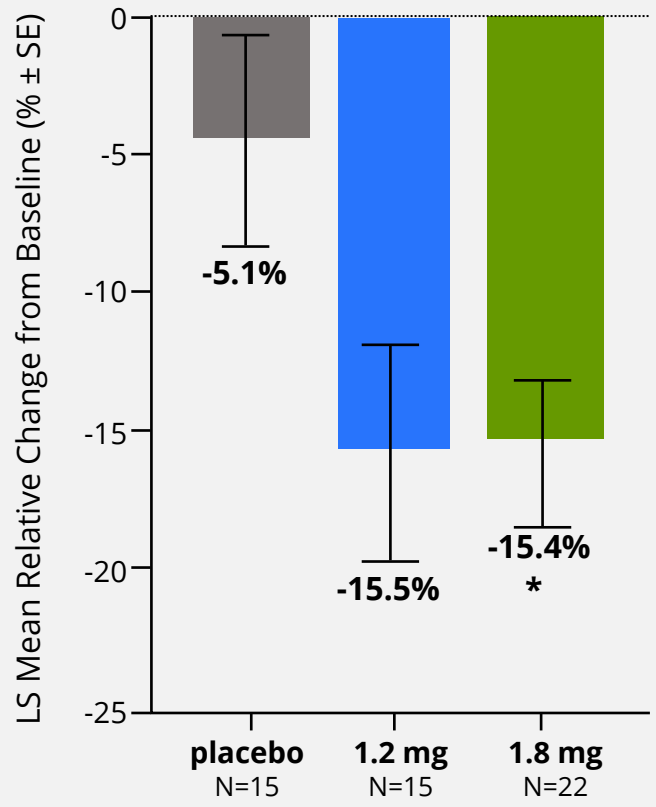
Reductions in Patients with Elevated Baseline Lipids at 48 Weeks

Triglycerides >150 mg/dL



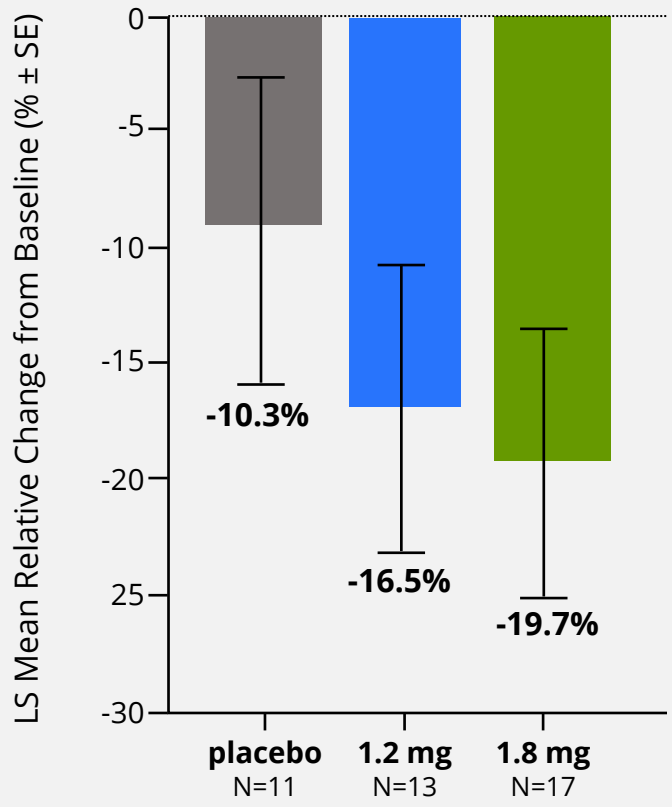
* p < 0.05 vs. placebo (ANCOVA)

Total Cholesterol >200 mg/dL



* p < 0.05 vs. placebo (ANCOVA)

LDL Cholesterol >130 mg/dL



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Safety Profile Maintained at 48 Weeks

	Placebo (N=86)	1.2 mg (N=41)	1.8 mg (N=85)
Serious AEs	5 (5.8%)	1 (2.4%)	8 (9.4%)
Serious GI AEs	1 (1.2%)	0 (0.0%)	0 (0.0%)
Serious AEs related to study med	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe AEs	2 (2.3%)	1 (2.4%)	8 (9.4%)
Severe GI AEs	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe AEs related to study med	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs of Special Interest related to study med	0 (0.0%)	0 (0.0%)	0 (0.0%)

- Majority of AEs mild to moderate in severity
- No heart rate increases or imbalances in cardiac AEs versus placebo
- Maintenance of HbA1c regardless of diabetes status

Data are presented as n (%)

Serious Adverse Events at 48 Weeks

	Placebo (N=86)	1.2 mg (N=41)	1.8 mg (N=85)
Subjects with at least one Serious TEAE	5 (5.8)	1 (2.4)	8 (9.4)
Cardiac disorders	1 (1.2)	0 (0.0)	1 (1.2)
Gastrointestinal disorders	1 (1.2)	0 (0.0)	0 (0.0)
Infections and infestations	1 (1.2)	0 (0.0)	2 (2.4)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	1 (1.2)
Metabolism and nutrition disorders	0 (0.0)	1 (2.4)	2 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0)	1 (2.4)	0 (0.0)
Nervous system disorders	0 (0.0)	0 (0.0)	1 (1.2)
Psychiatric disorders	0 (0.0)	0 (0.0)	1 (1.2)
Renal and urinary disorders	0 (0.0)	0 (0.0)	1 (1.2)
Reproductive system and breast disorders	1 (1.2)	0 (0.0)	1 (1.2)
Respiratory, thoracic and mediastinal disorders	1 (1.2)	0 (0.0)	0 (0.0)
Vascular disorders	1 (1.2)	0 (0.0)	0 (0.0)

Data are presented as n (%)

Tolerability at 48 Weeks

Adverse Events	Placebo (N=86)	1.2 mg (N=41)	1.8 mg (N=85)
Nausea	15 (17.4%)	9 (22.0%)	35 (41.2%)
Vomiting	2 (2.3%)	3 (7.3%)	10 (11.8%)
Diarrhea	7 (8.1%)	5 (12.2%)	19 (22.4%)
Constipation	10 (11.6%)	5 (12.2%)	15 (17.6%)
AEs leading to treatment discontinuation	3 (3.5%)	0 (0.0%)	1 (1.2%)

- Majority of GI AEs were mild to moderate in severity and predominantly occurred within the first 8 weeks
- Approximately 1% of total patients receiving pemvidutide discontinued treatment due to AEs

Data are presented as n (%)

Pemvidutide IMPACT Trial Summary

- Pemvidutide, a dual glucagon/GLP-1 agonist, was evaluated in the IMPACT Phase 2b trial in patients with MASH
- At 24 weeks, pemvidutide met the primary endpoint of MASH resolution without worsening of fibrosis[†]
- Pemvidutide continued to show positive results in patients with MASH at 48 weeks:
  - Robust liver fat reduction up to 55%
  - Statistically significant reductions in non-invasive tests of hepatic inflammation
  - Statistically significant reductions in non-invasive tests of hepatic fibrosis (further reductions from 24 weeks)
  - Weight loss up to 7.5%, with no evidence of plateauing
  - Generally well tolerated with AE discontinuation rates less than placebo
- Pemvidutide demonstrated statistically significant and early MASH effects and weight loss, with a generally favorable tolerability profile and no dose titration
- Efficacy and safety of pemvidutide in patients with MASH will be further assessed in a Phase 3 clinical trial

[†] *Nourredin et al. Lancet; 2025; Dec 6;406 (10520):2644-2655.*


Thank you