

IMPACT Phase 2b MASH Trial - Topline Results

Pemvidutide: Designed to be the Treatment of Choice for Liver and Cardiometabolic Diseases

June 26, 2025



Forward-looking statements

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IMPACT Phase 2b MASH Trial

Screening/Randomization

Key Eligibility Criteria

- MASH (F2/F3)
- LFC[†] ≥ 8%
- BMI ≥ 27.0 kg/m²

Key Endpoints

Primary

MASH resolution or fibrosis improvement^{††}

Secondary

- MASH resolution and fibrosis improvement
- Non-invasive tests
- Weight Loss

Placebo weekly

1.2 mg weekly*

1.8 mg weekly*

**No dose titration used in IMPACT trial*

Week 24

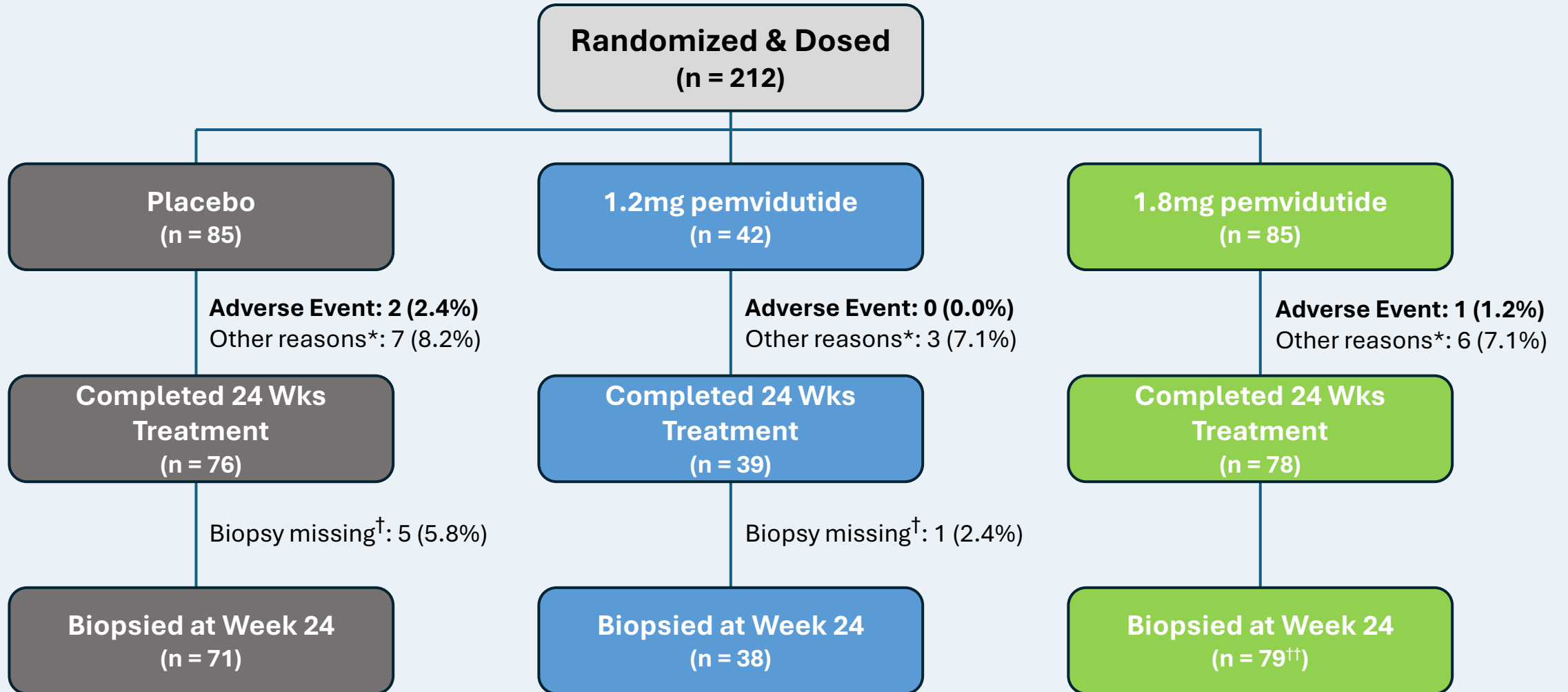
Liver Biopsy
NITs
Weight Loss

Week 48

NITs
Weight Loss

Study Disposition

High Study Completion Rates with Minimal AE Discontinuations



IMPACT Baseline Demographics and Disease Characteristics

Characteristic	Placebo (n = 85)	1.2 mg (n = 42)	1.8 mg (n = 85)
Age - years	52.8 (\pm 11.8)	54.4 (\pm 13.9)	53.4 (\pm 12.4)
Female sex - n (%)	47 (55.3)	26 (61.9)	50 (58.8)
Body weight - kg	109.1 (\pm 27.5)	112.0 (\pm 27.3)	107.7 (\pm 21.3)
BMI - kg/m ²	38.0 (\pm 7.9)	39.8 (\pm 9.2)	38.7 (\pm 6.9)
Diabetic - n (%)	37 (43.5)	19 (45.2)	36 (42.4)
F3 Fibrosis - n (%)	40 (47.1)	17 (40.5)	39 (45.9)
ELF	9.7 (\pm 0.8)	10.0 (\pm 0.8)	9.9 (\pm 1.0)
VCTE - kPa	12.5 (\pm 4.4)	12.4 (\pm 3.6)	12.8 (\pm 4.4)
Liver Fat Content - %	19.6 (\pm 6.4)	19.9 (\pm 7.0)	19.0 (\pm 6.8)
ALT - IU/L	56.9 (\pm 32.8)	66.7 (\pm 54.3)	67.6 (\pm 43.0)

Plus-minus values are means \pm SD

Two Methods of Biopsy Reading Employed

Pathologist reading

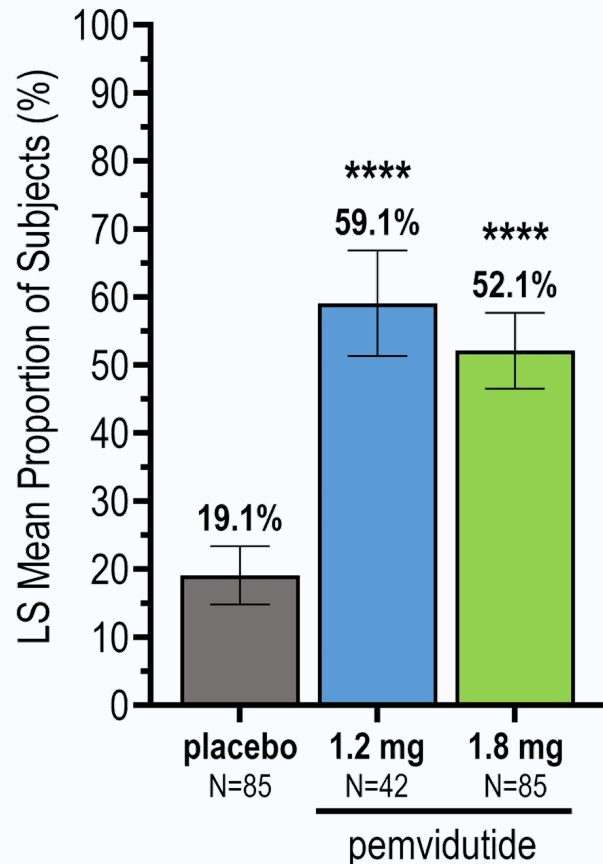
- Biopsies independently scored by three pathologists using the mode method
- Pathologists blinded to subject, treatment, and timepoint (sequence of sampling)

Supplemental AI-based reading

- Blindly scored biopsies without knowledge of treatment assignment or timepoint of treatment
- Analyses limited to fibrosis quantification

First Incretin to Demonstrate Statistically Significant MASH Resolution at 24 Weeks

MASH Resolution without Worsening of Fibrosis ITT Analysis¹



**** p < 0.0001 vs. placebo (Chi-Square Test)

	Placebo (n=71)	1.2mg (n=38)	1.8mg (n=79)
Completer Analysis	23.2%	66.6% p < 0.0001	56.0% p < 0.0001

	Placebo (n=85)	1.2mg (n=42)	1.8mg (n=85)
Multiple Imputations Analysis	19.3%	66.0% p < 0.0001	55.9% p < 0.0001

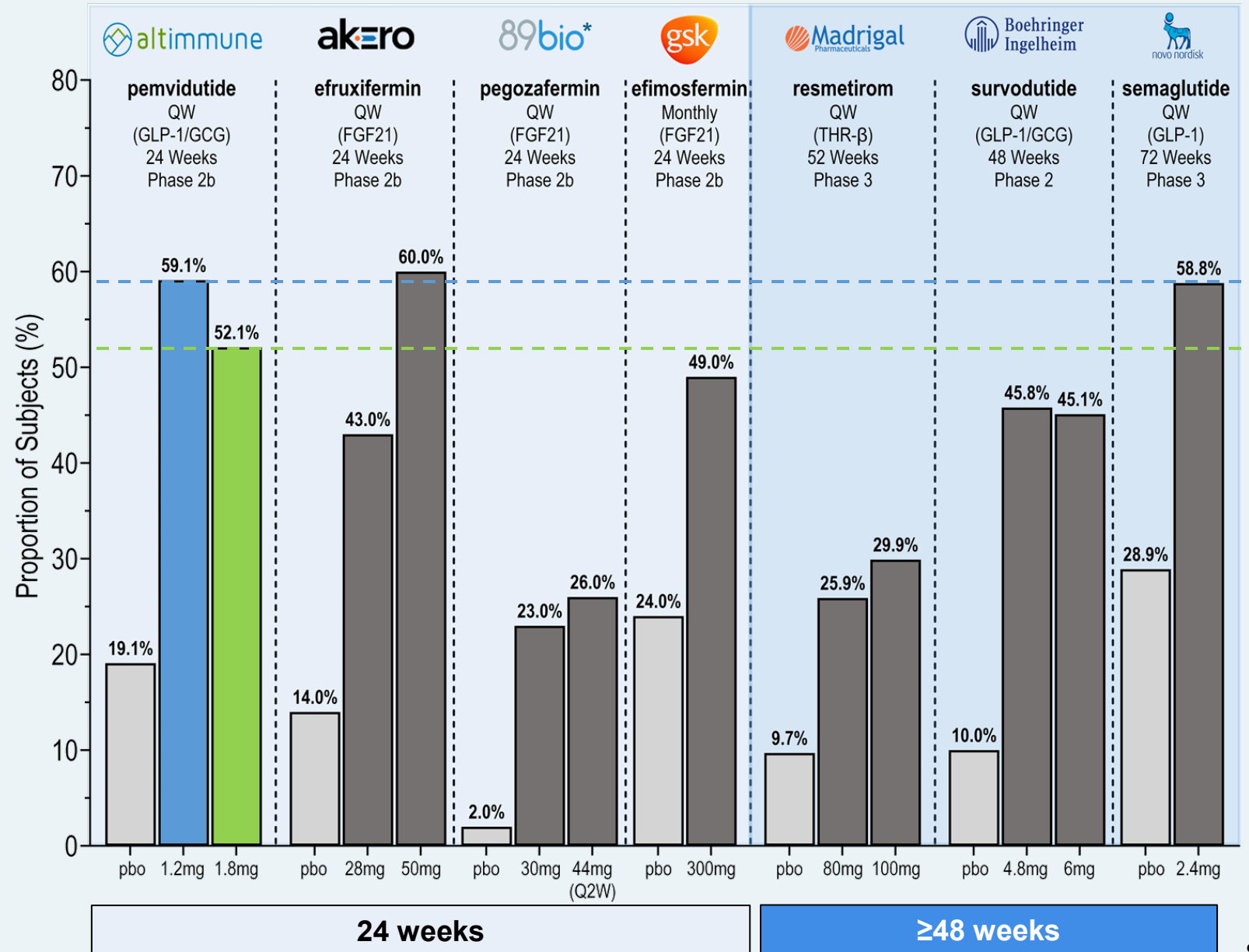
Pemvidutide: Potential for Class Leading MASH Resolution

Response achieved at 24 weeks better than or comparable to other therapies, including those assessed at later timepoints

No head-to-head studies of pemvidutide to other MASH products or product candidates have been conducted; the data regarding other MASH products and product candidates is based on published data. Because of differences in patient populations, study designs, and numerous other factors, cross-trial comparisons must be interpreted with caution and no conclusions can be drawn. Actual results may materially differ.



MASH Resolution w/o Worsening of Fibrosis ITT Analyses*

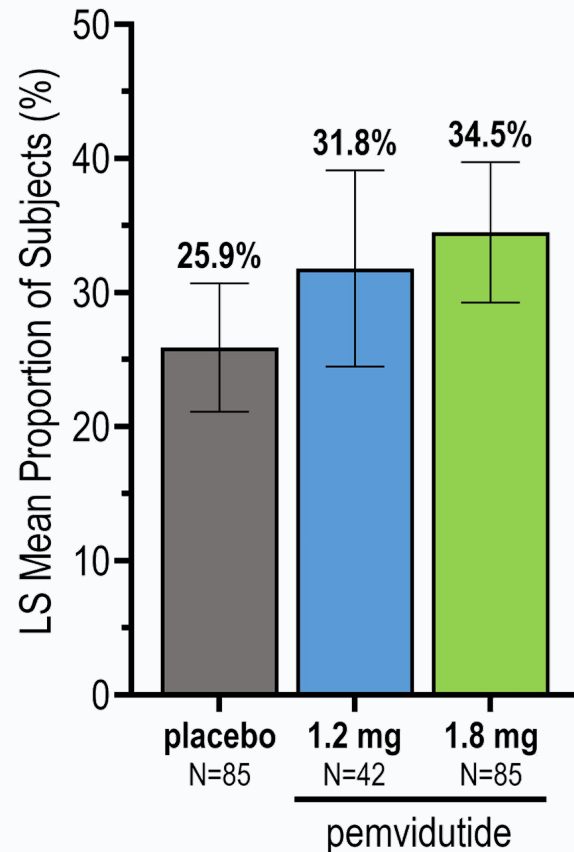


* Pegozafermin data generated with multiple imputations; calculated efimosfermin; See slide 22 for full citations

Pemvidutide: Fibrosis Improvement at 24 Weeks

Fibrosis Improvement without Worsening of MASH

ITT Analysis



NS vs. placebo (Chi-Square Test)

	Placebo (n=71)	1.2mg (n=37*)	1.8mg (n=79)
Completer Analysis	30.9%	35.6%	37.0%

	Placebo (n=85)	1.2mg (n=42)	1.8mg (n=85)
Multiple Imputations Analysis	26.8%	34.7%	36.8%

* 1 biopsy was interpretable for MASH resolution but not for fibrosis improvement

Fibrosis Improvement with Pemvidutide

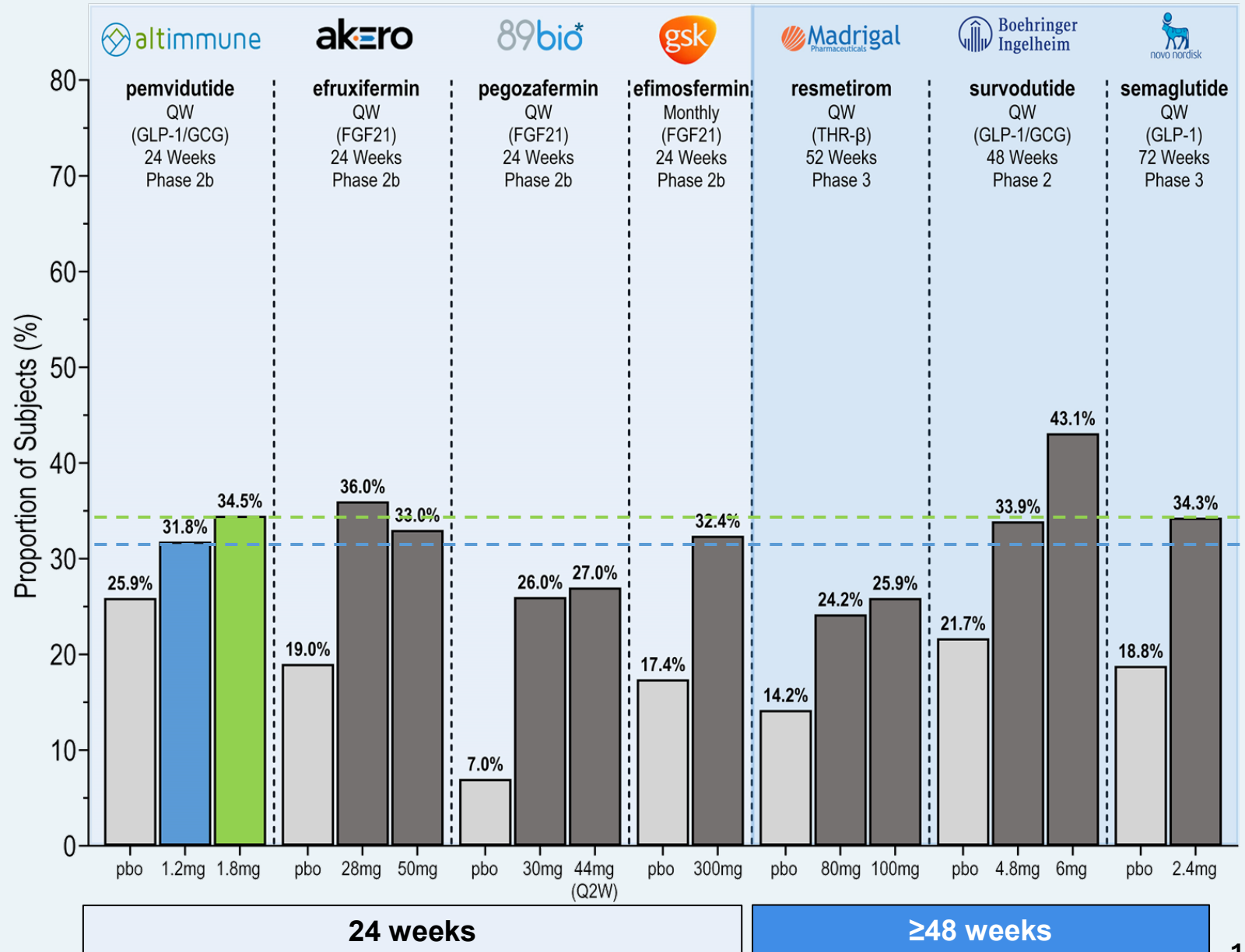
Absolute fibrosis improvement comparable or more favorable to most other MASH therapies

No head-to-head studies of pemvidutide to other MASH products or product candidates have been conducted; the data regarding other MASH products and product candidates is based on published data. Because of differences in patient populations, study designs, and numerous other factors, cross-trial comparisons must be interpreted with caution and no conclusions can be drawn. Actual results may materially differ.



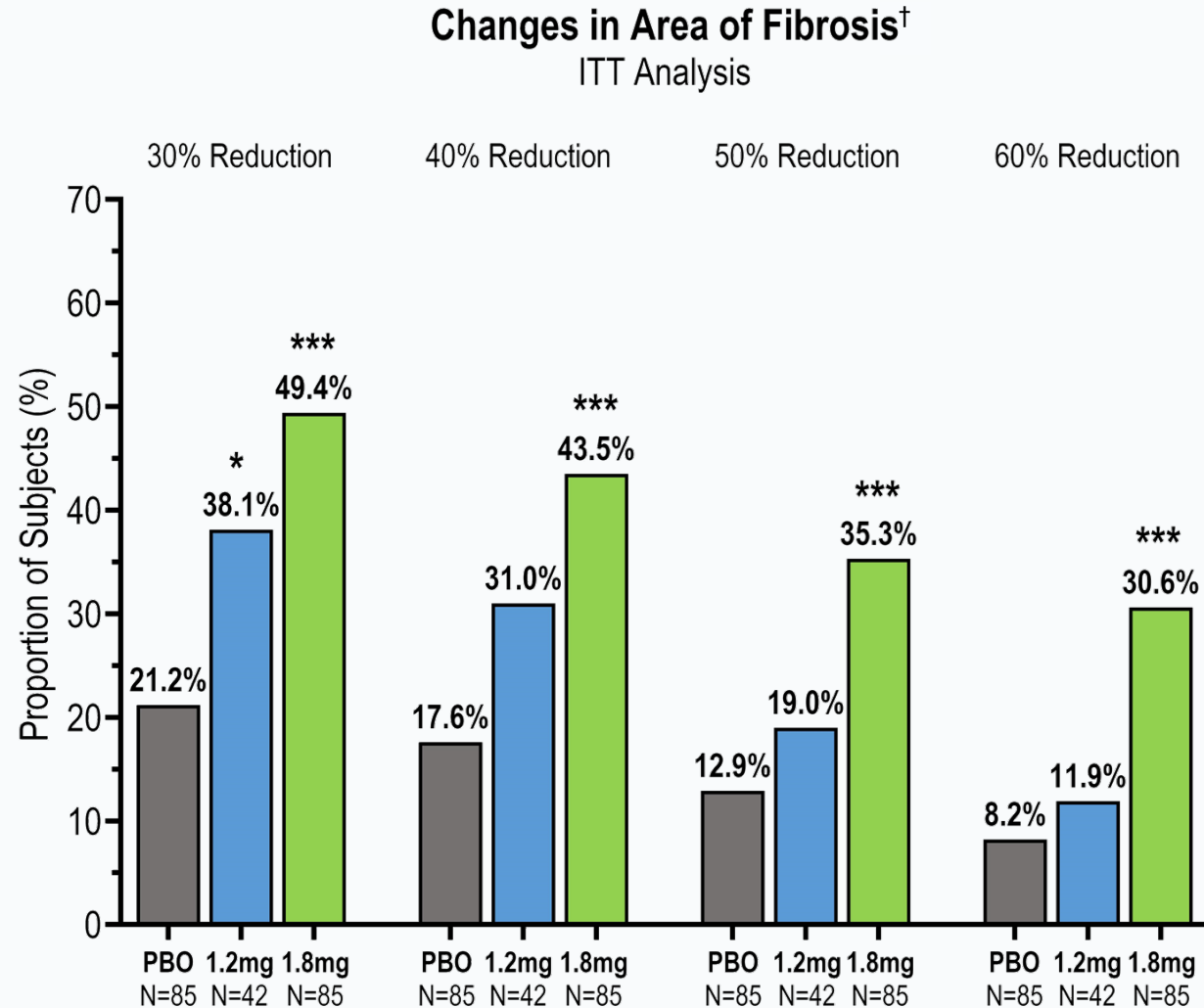
Fibrosis Improvement w/ No Worsening in MASH

ITT Analyses*



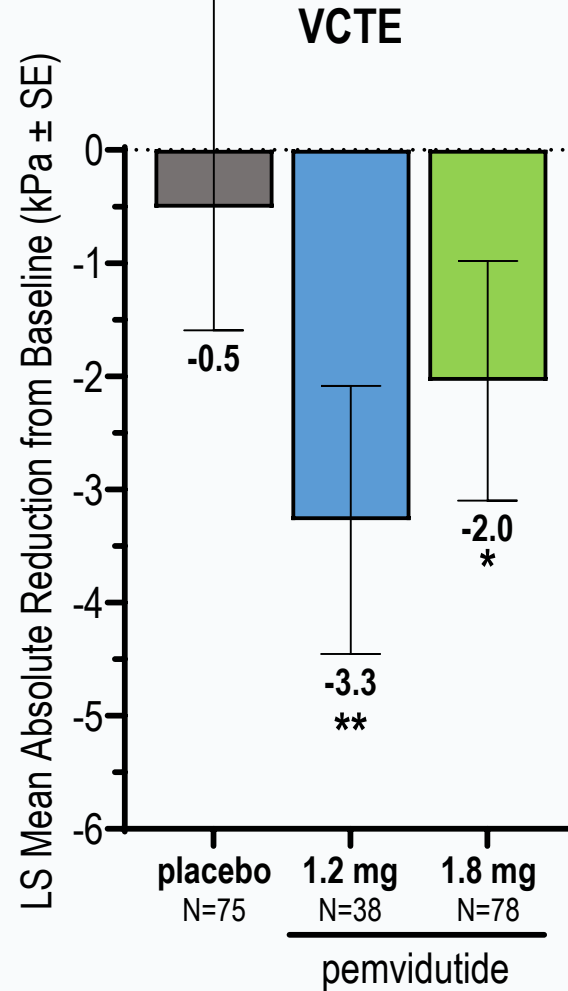
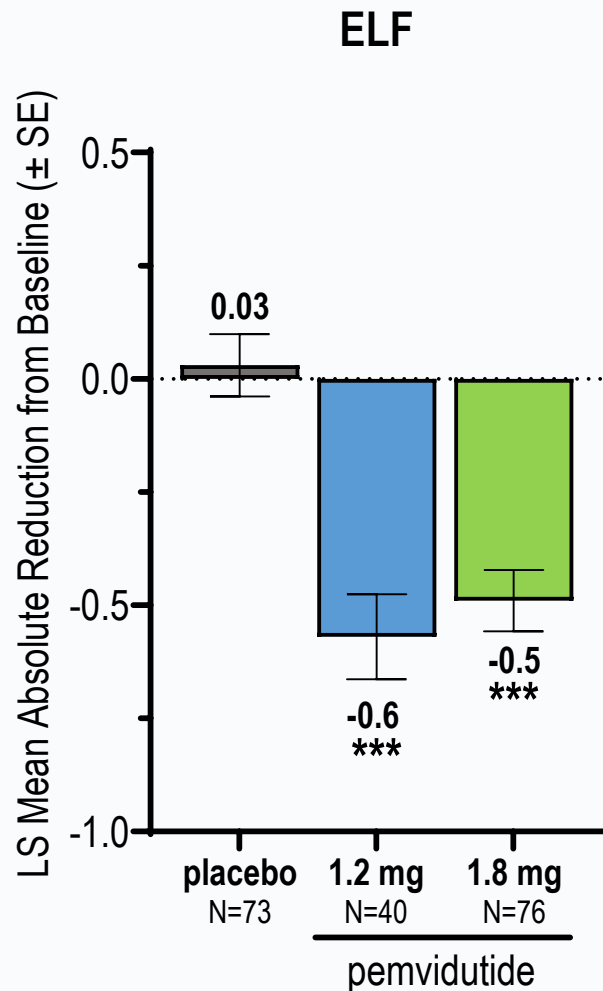
* Pegozafermin data generated with multiple imputations; calculated efimosfermin; See slide 22 for full citations

Significant Reductions in Fibrosis by AI-Based Supplemental Analysis

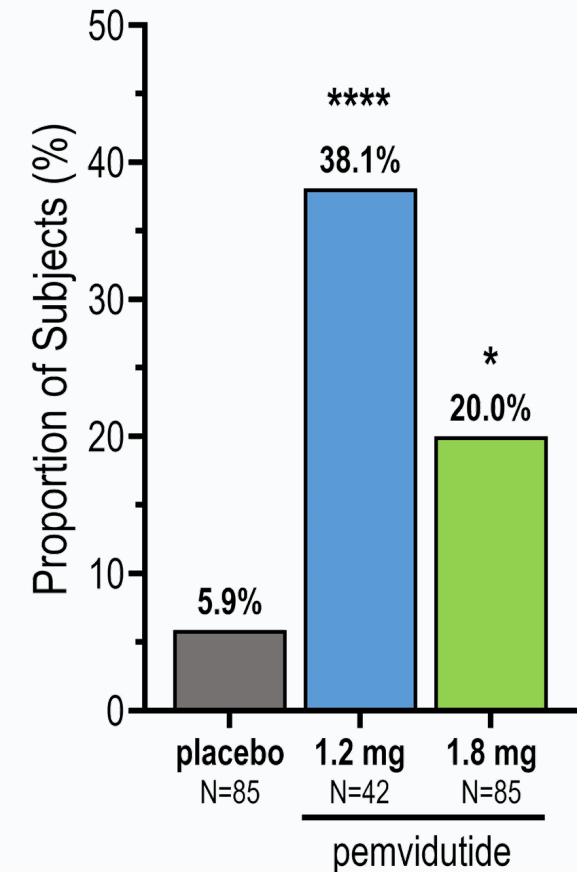


Analyses employing Liver Explore (Path AI) to evaluate the proportions of liver involved with pathological fibrosis

Significant Changes in Non-invasive Tests of Fibrosis at 24 Weeks

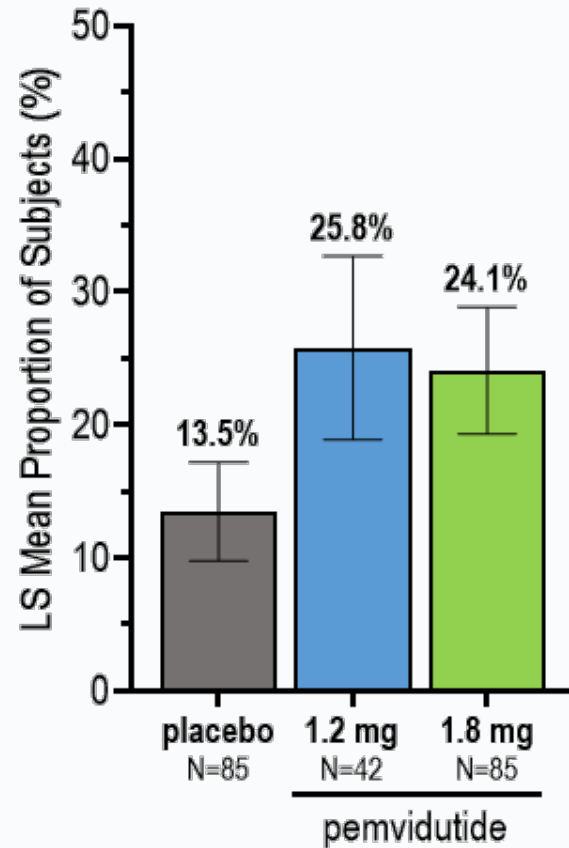


>0.5 ELF Reduction + 25% VCTE Reduction ITT Analysis



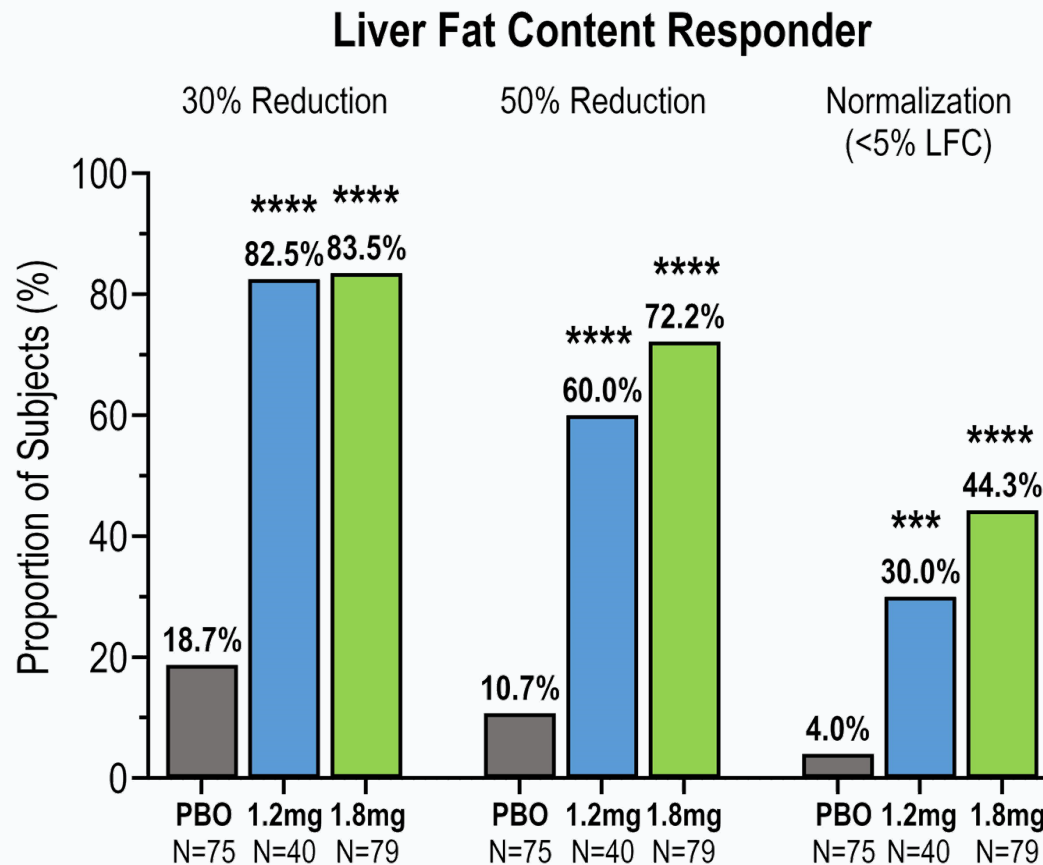
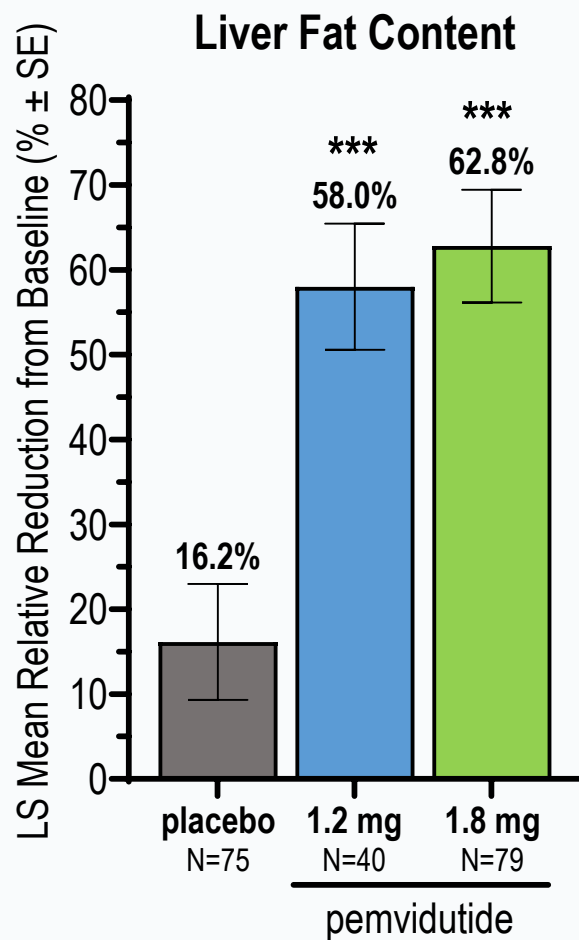
Composite Endpoint of MASH Resolution and Fibrosis Improvement at 24 Weeks

MASH Resolution and Fibrosis Improvement
ITT Analysis

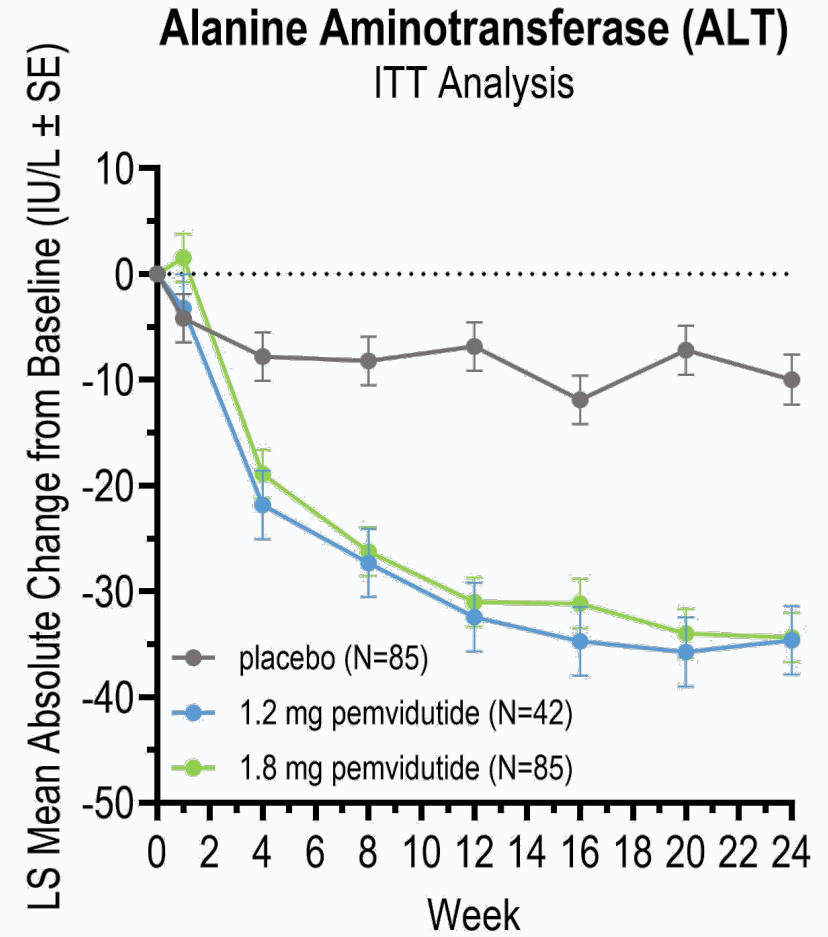
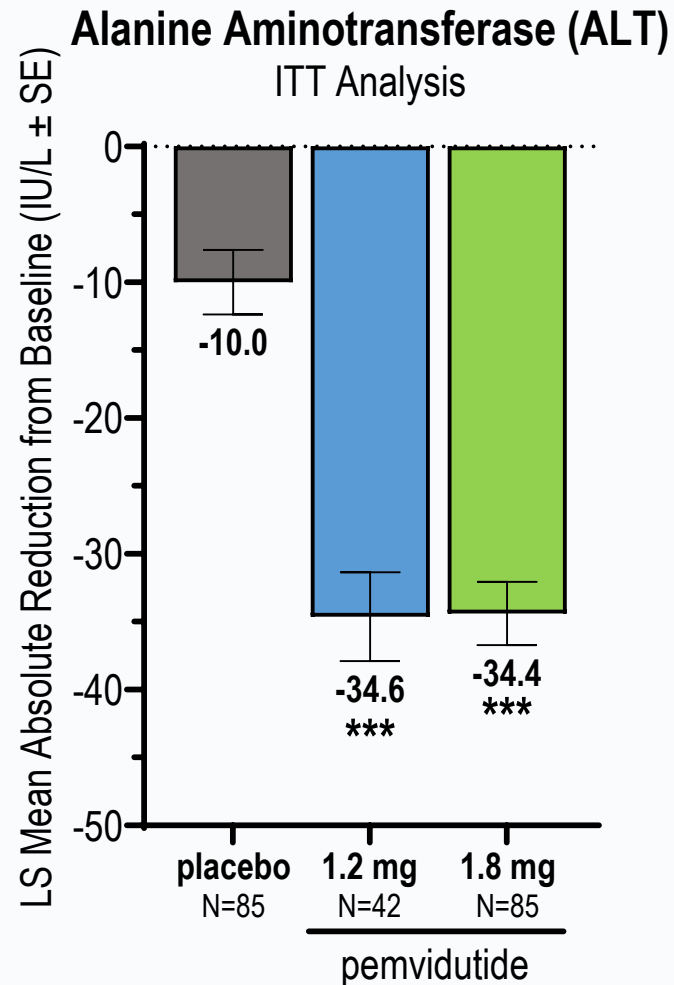


Placebo effect reduced with more stringent endpoint of MASH resolution and fibrosis improvement

Pemvidutide Reduced Liver Fat Content by up to 62.8%



Significant Reductions in Alanine Aminotransferase (ALT) Demonstrated Meaningful Liver Effects

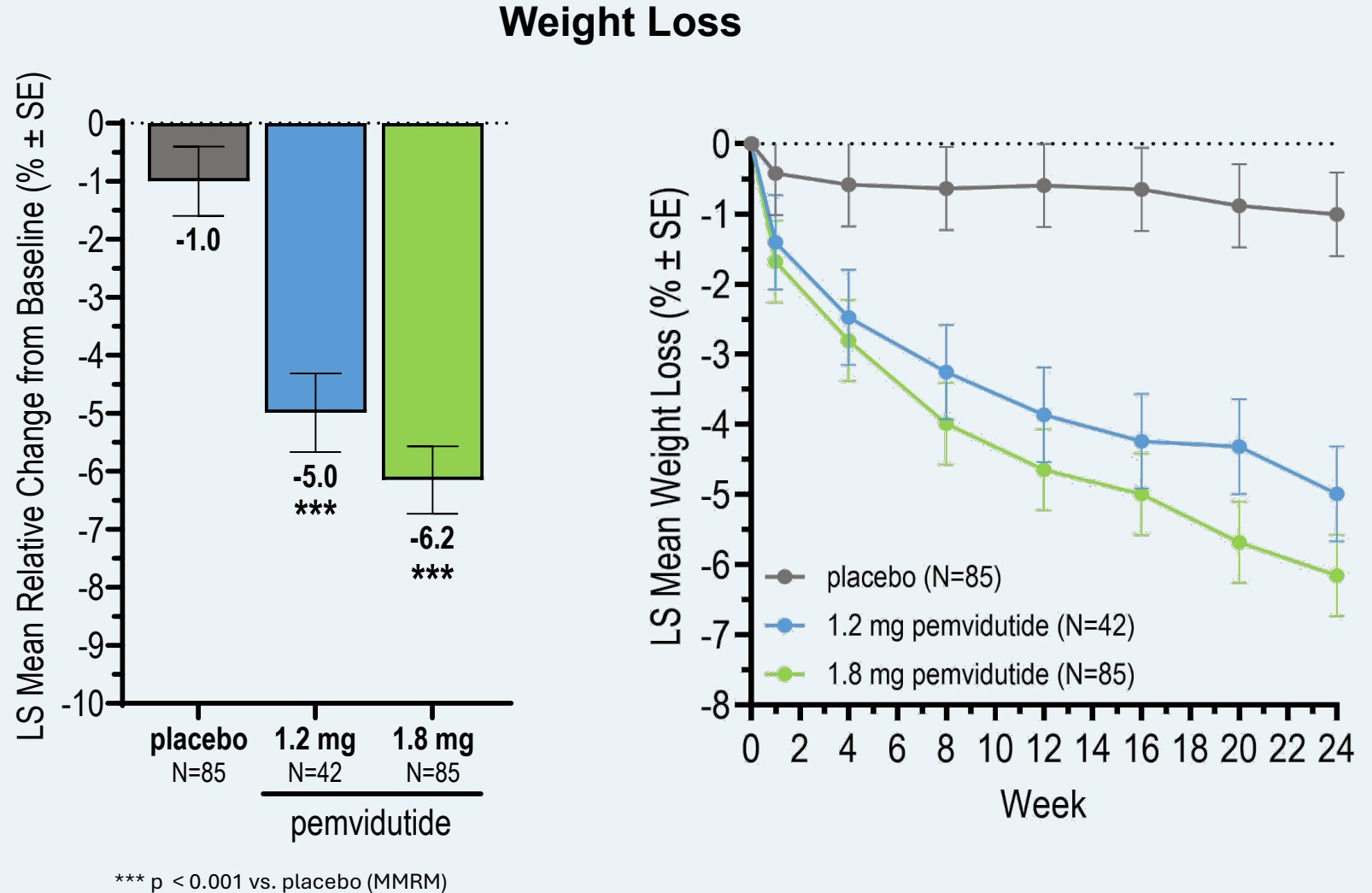


Significant Weight Loss at 24 weeks

Weight loss has been shown to be a critical element in MASH therapy¹

Weight loss continuing at week 24 with no plateauing

Opportunity to achieve greater weight loss with 2.4 mg dose in Phase 3



Potentially Class Leading Tolerability without Dose Titration

Less than 1% of subjects receiving pemvidutide discontinued treatment due to AEs

	Placebo (n = 85)	1.2 mg (n = 42)	1.8 mg (n = 85)
Serious AEs	3 (3.5%)	1 (2.4%)	3 (3.5%)
Serious AEs related to study med	0 (0.0%)	0 (0.0%)	0 (0.0%)
Severe AEs	2 (2.4%)	1 (2.4%)	4 (4.7%)
AEs leading to treatment discontinuation	2 (2.4%)	0 (0.0%)	1 (1.2%)
AEs of Special Interest	0 (0.0%)	0 (0.0%)	0 (0.0%)

Favorable GI Tolerability

Adverse Events	Placebo (n = 85)	1.2 mg (n = 42)	1.8 mg (n = 85)
Nausea	12 (14.1%)	9 (21.4%)	35 (41.2%)
Vomiting	2 (2.4%)	2 (4.8%)	7 (8.2%)
Diarrhea	7 (8.2%)	4 (9.5%)	18 (21.2%)
Constipation	8 (9.4%)	5 (11.9%)	11 (12.9%)

Majority of AEs were mild in severity

Maintenance of HbA1c Regardless of Diabetes Status

Change in HbA1c from Baseline, Week 24	Placebo (n = 85)	1.2 mg (n = 42)	1.8 mg (n = 85)
All Subjects, %, LSM (SE)	0.00 (0.19)	-0.09 (0.21)	-0.12 (0.18)
Diabetic, %, LSM (SE)	0.23 (0.35)	0.05 (0.42)	-0.03 (0.36)
Non-diabetic, %, LSM (SE)	-0.02 (0.10)	-0.04 (0.11)	0.00 (0.10)

LSM, Least Squares Mean
NS, ANCOVA

Blood Pressure Reduction without Changes in Heart Rate

Change from Baseline, Week 24	Placebo (n = 85)	1.2 mg (n = 42)	1.8 mg (n = 85)
Systolic Blood Pressure mmHg, LSM (SE)	-1.1 (1.9)	-6.6 (2.2)**	-5.9 (1.9)**
Diastolic Blood Pressure mmHg, LSM (SE)	-1.3 (1.2)	-2.4 (1.4)	-2.8 (1.1)
Heart Rate bpm, LSM (SE)	0.4 (0.9)	-0.7 (1.3)	1.0 (0.9)

LSM, Least Squares Mean

**p < 0.01 vs. placebo (MMRM)

Pemvidutide IMPACT Phase 2b MASH Trial Summary

First Product Candidate to Demonstrate Significant MASH Effects and Weight Loss at 24 Weeks

- Trial met its primary endpoint with statistically significant and potentially class leading MASH resolution without worsening of fibrosis of up to 59.1% at 24 weeks
- Fibrosis improvement without worsening of MASH of up to 34.5% at 24 weeks
- Supplemental AI-based analysis demonstrated reductions in area of fibrosis
- Statistically significant improvement in widely used non-invasive tests (NITs) of fibrosis
- Robust liver fat reduction of up to 62.8%
- Weight loss of up to 6.2% continuing at 24 weeks with no plateauing

Potentially Best in Class Tolerability with No Dose Titration

- Less than 1% discontinuation rate due to adverse events in subjects receiving pemvidutide
- No heart rate increases or difference in cardiac AEs between pemvidutide and placebo
- Maintenance of HbA1c regardless of diabetes status

References

- **MASH Resolution w/o Worsening of Fibrosis**
 - Efruxifermin: Harrison et al. Lancet 2023 (Fig 2B). ITT analysis
 - Pegzofermin: Loomba et al. NEJM2023 (Fig. 1B). Multiple imputations
 - Efimosfermin: 11/2024 Phase 2 Results Deck (calculated based on completer data; Pbo N=41, 300mg N=43). Calculated ITT
 - Resmetirom: Harrison et al. NEJM 2024 (Fig 1A) . ITT analysis
 - Survodutide: Sanyal et al NEJM 2024 (Figure S7B). ITT analysis
 - Semaglutide: Sanyal et al NEJM 2025 (Table S4). ITT analysis
- **Fibrosis Improvement with No worsening in MASH**
 - Efruxifermin: Harrison et al. Lancet 2023 (Fig 2B). ITT analysis
 - Pegzofermin: Loomba et al. NEJM2023 (Fig. 1B). Multiple imputations
 - Efimosfermin: 11/2024 Phase 2 Results Deck (calculated internally based on completer data; Pbo N=41, 300mg N=43). Calculated ITT
 - Resmetirom: Harrison et al. NEJM 2024 (Fig 1A) . ITT analysis
 - Survodutide: Sanyal et al NEJM 2024 (Figure S7B). ITT analysis
 - Semaglutide: Sanyal et al NEJM 2025 (Table S4). ITT analysis



Thank you