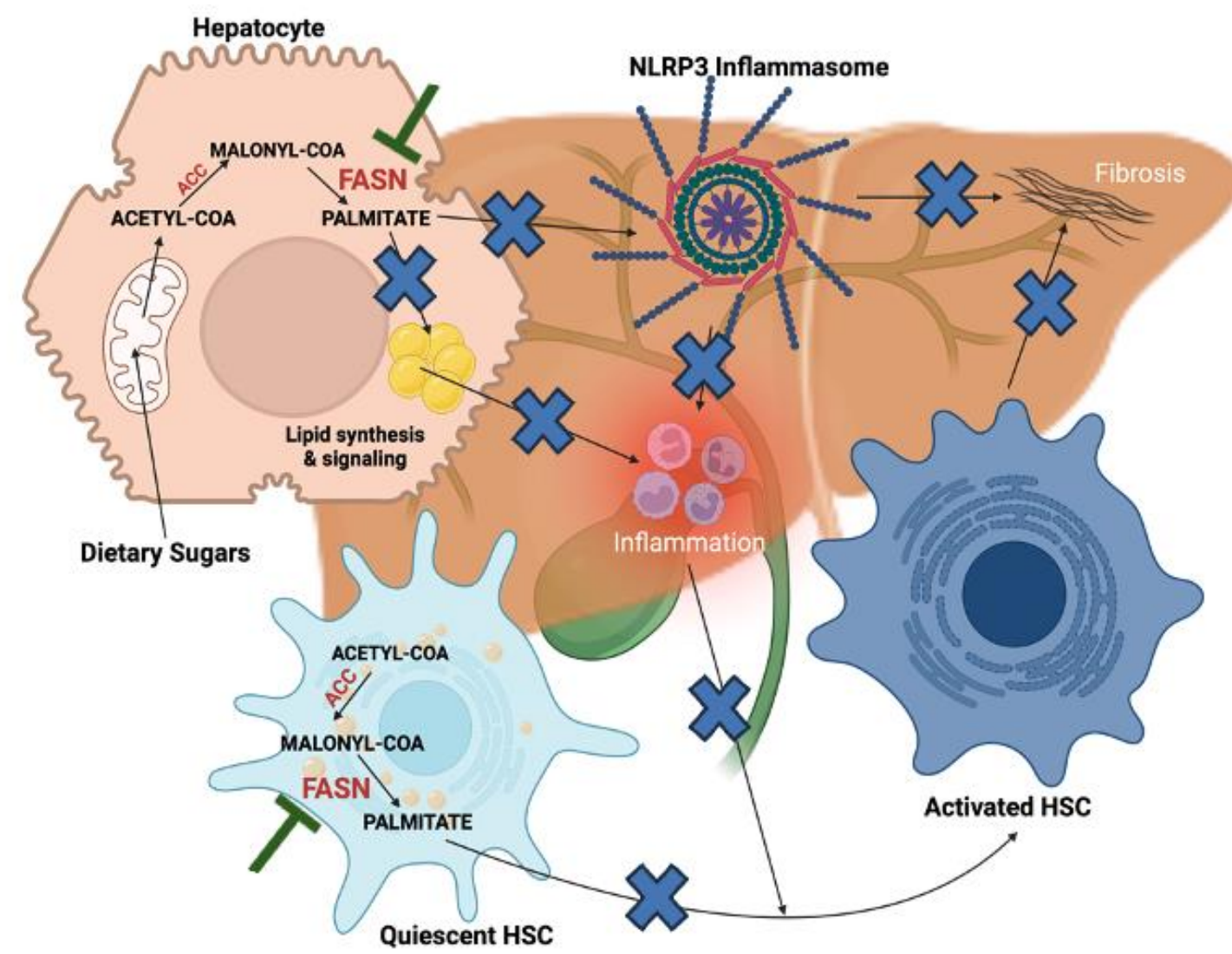


Introduction

- Denifanstat (TVB-2640) is an oral, once daily, selective FASN inhibitor in clinical development for MASH
- FASN inhibition targets 3 hallmarks of MASH¹:
 - inhibits liver fat synthesis & accumulation (hepatocytes)
 - **inhibits fibrosis (hepatic stellate cells require DNL for activation)**
 - decreases inflammation (inflammasome activation by palmitate)

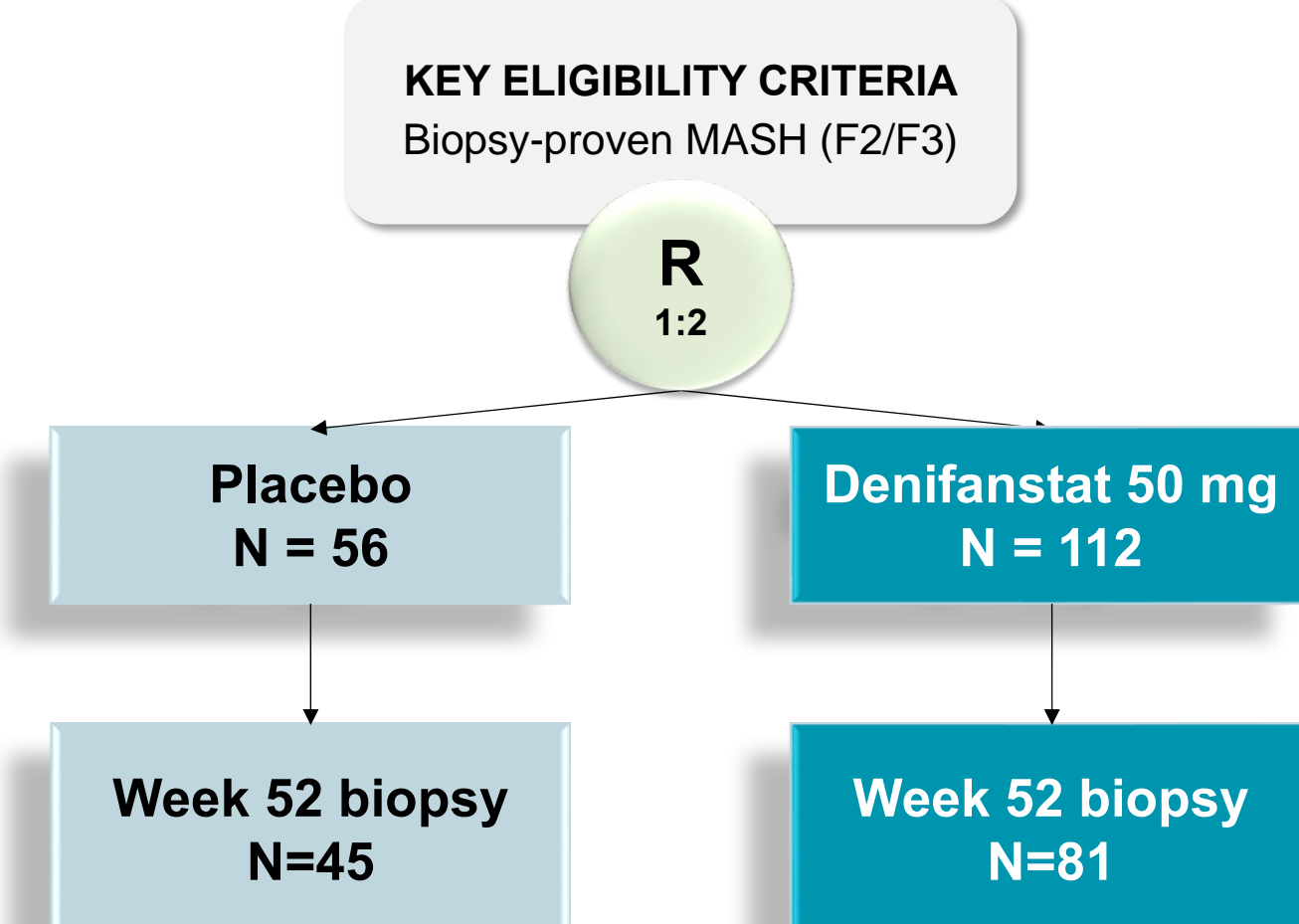


Aims

- The Phase 2b FASCINATE-2 trial met its primary endpoints as well as multiple secondary endpoints, including fibrosis improvement without worsening of MASH, and MASH resolution without worsening of fibrosis²
- This post-hoc analysis evaluated the effect of denifanstat on additional fibrosis endpoints and circulating lipids in MASH patients

Methods

- FASCINATE-2 was a 52-week randomized, double-blind, placebo-controlled Phase 2b trial²
- Primary endpoints
 - NAS \geq 2 points improvement without worsening of fibrosis
 - MASH resolution + NAS \geq 2 points improvement without worsening of fibrosis
- Selected secondary endpoints
 - Improvement in liver fibrosis \geq 1-stage without worsening of MASH
 - AI digital pathology: fibrosis evaluation with an unstained slide
- Plasma tripalmitin and extensive lipid and lipoprotein profiles were analyzed at several visits in the study (OWL Metabolomics)



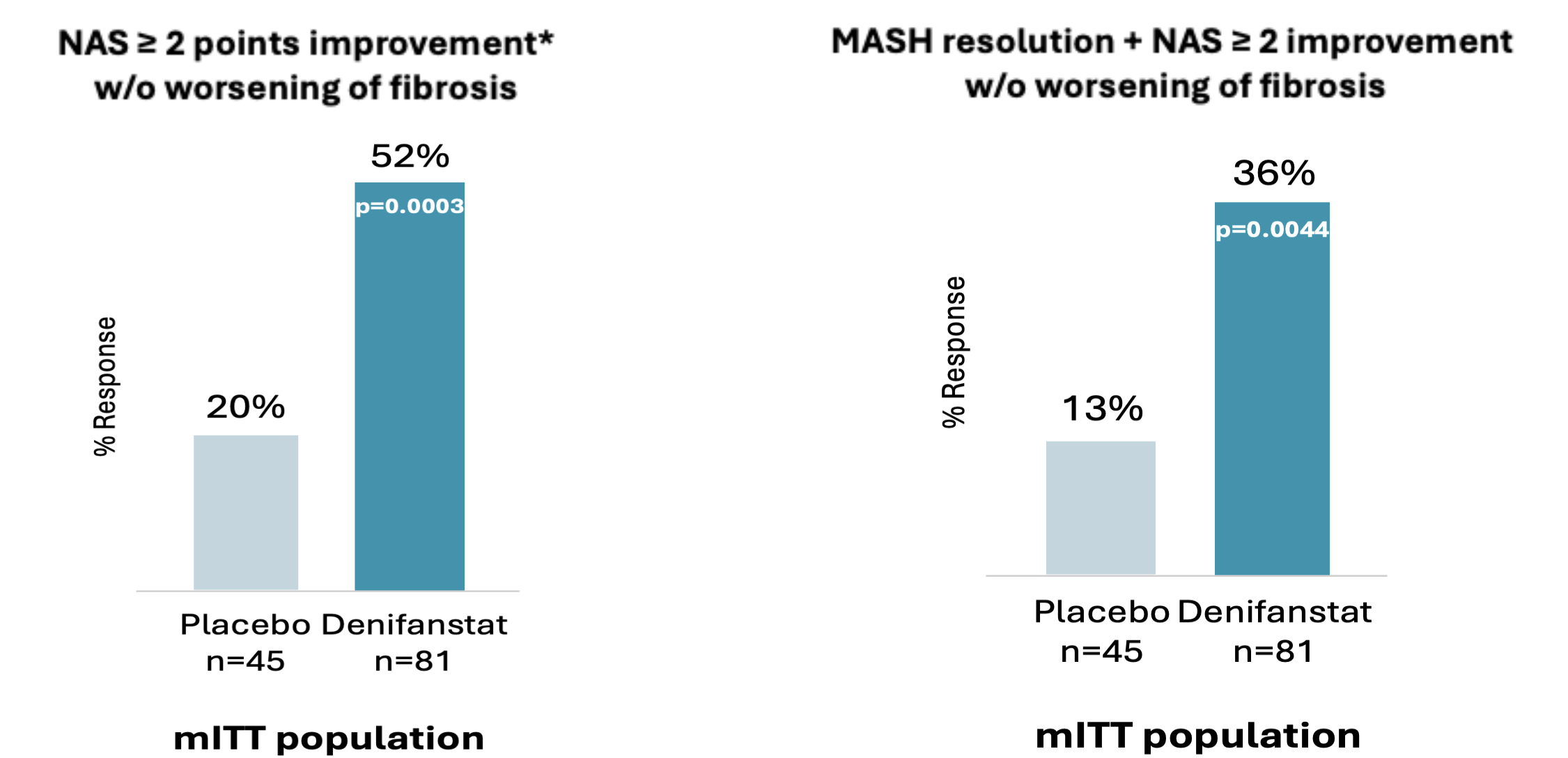
Results

Baseline Characteristics – Population with Paired Liver Biopsies

Parameter	Placebo, n=45	Denifanstat, n=81
Age, years	59.6 (+/- 10.9)	56.1 (+/- 10.8)
Sex, female	27 (60%)	48 (59%)
Ethnicity, Hispanic or Latino	15 (33%)	27 (33%)
BMI, kg/m ²	36.5 (+/- 6.7)	34.6 (+/- 6.1)
Type 2 diabetes	27 (60%)	55 (68%)
ALT, U/L	67 (+/- 33)	57 (+/- 29)
AST, U/L	52 (+/- 27)	48 (+/- 29)
ELF (Enhanced Liver Fibrosis) Score	9.8 (+/- 0.8)	9.6 (+/- 0.8)
Liver Fat Content (MRI-PDF), %	19.0 (+/- 7.0)	16.6 (+/- 7.1)
Baseline liver biopsy NAS \geq 5	34 (76%)	63 (78%)
Baseline Fibrosis		
F2	22 (49%)	34 (42%)
F3	23 (51%)	47 (58%)
qFibrosis Continuous Value	2.5 (0.64)	2.6 (0.75)

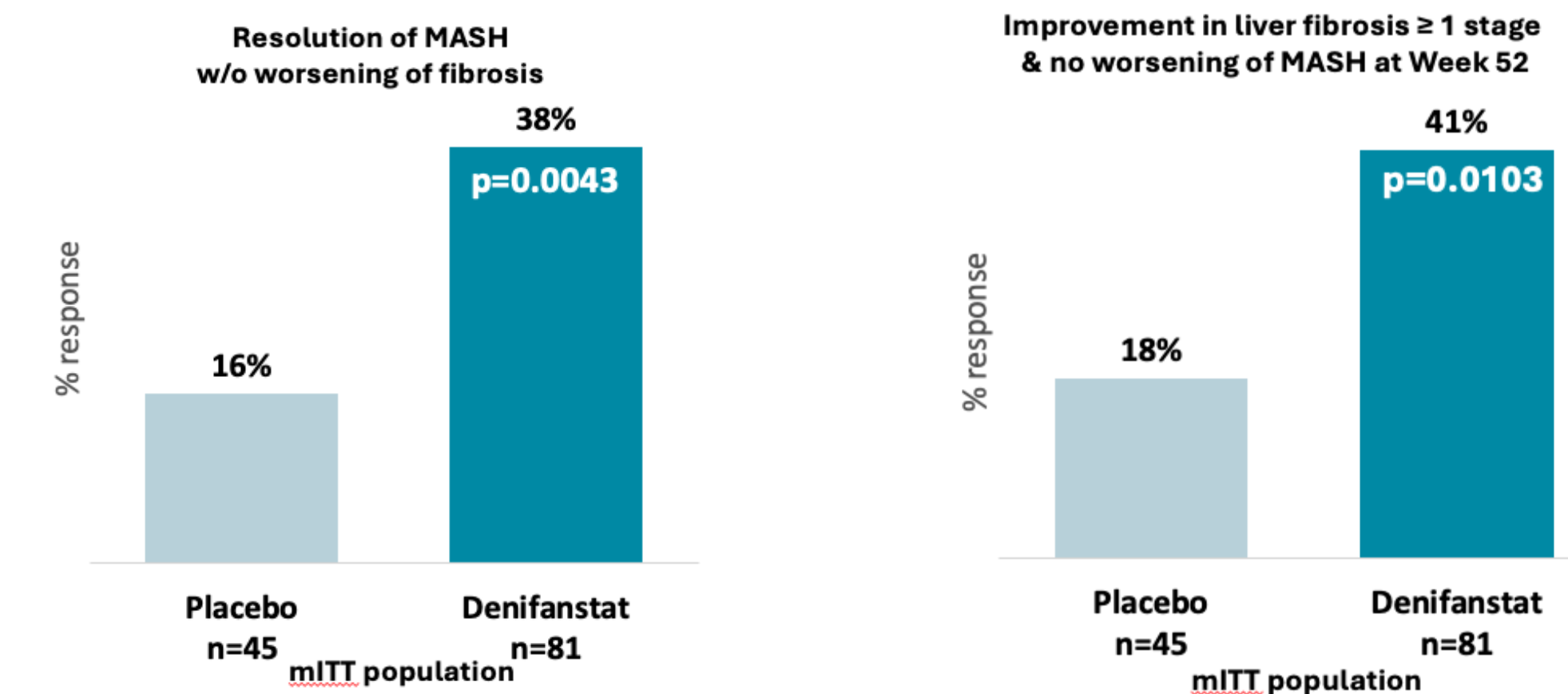
Data are mean (SD), or n (%)

Primary Endpoints



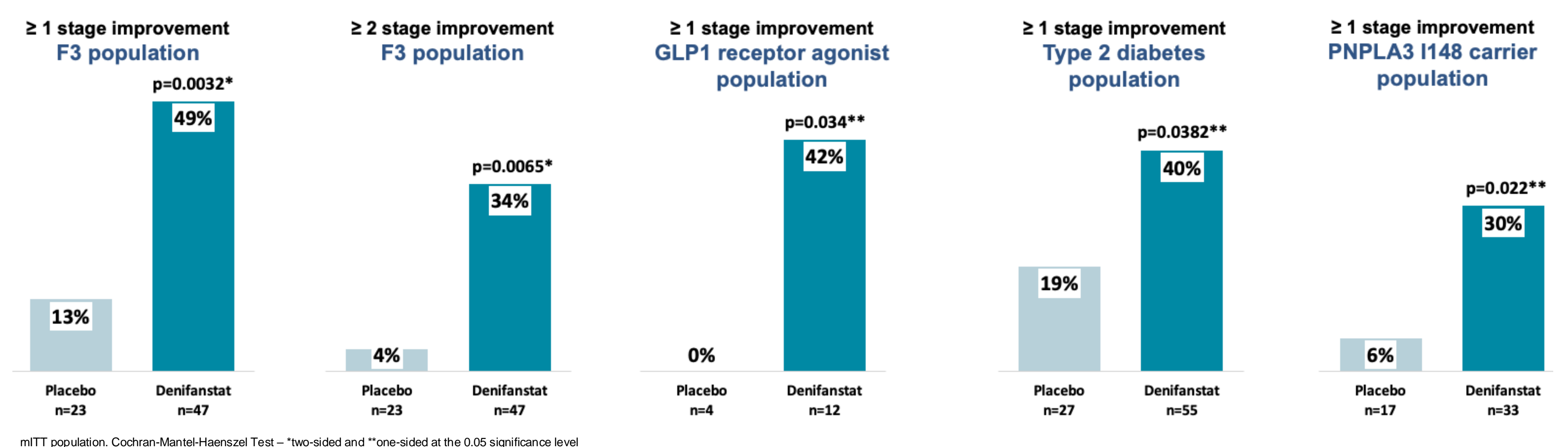
Cochran-Mantel-Haenszel Test – two sided at the 0.05 significance level. * \geq 1-point improvement in ballooning or inflammation.

Secondary Endpoints



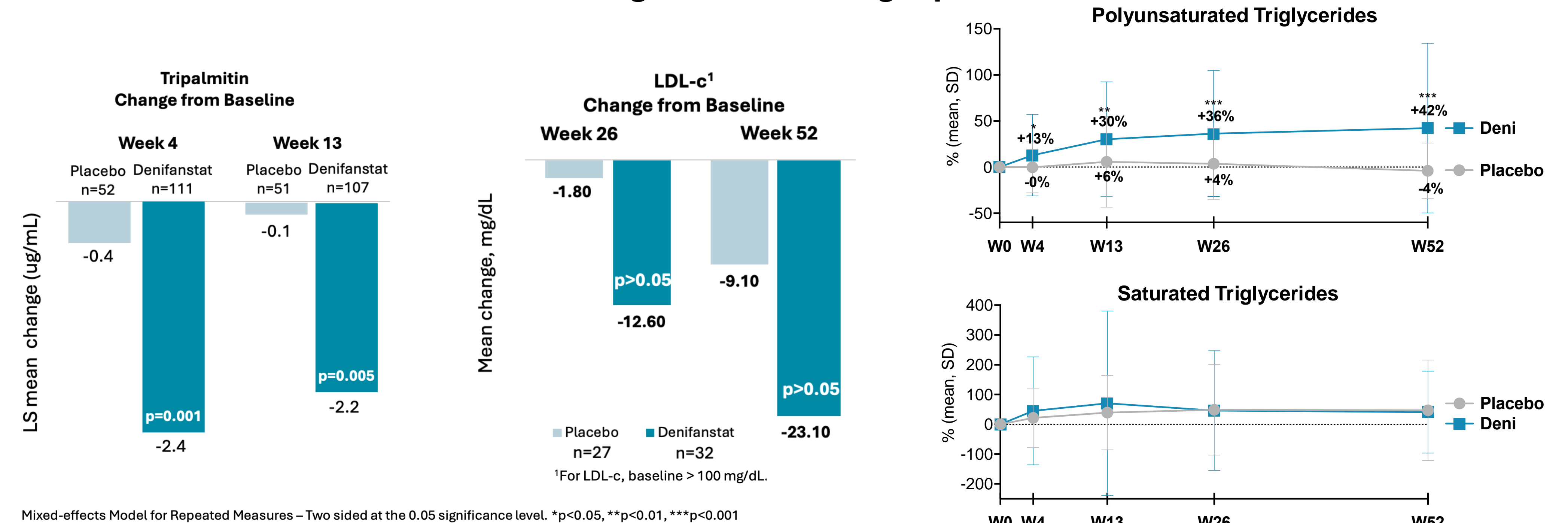
Cochran-Mantel-Haenszel Test – One sided at the 0.05 significance level

Additional Fibrosis Endpoints



mITT population, Cochran-Mantel-Haenszel Test – *two-sided and **one-sided at the 0.05 significance level

Changes in Circulating Lipids



Mixed-effects Model for Repeated Measures – Two sided at the 0.05 significance level. *p<0.05, **p<0.01, ***p<0.001

Conclusions

- Denifanstat demonstrated significant improvement in MASH resolution and fibrosis, including in difficult-to-treat subpopulations, in Phase 2b FASCINATE-2 study
- A post-hoc lipid analysis showed that denifanstat lowered LDL-cholesterol and increased polyunsaturated TG, providing potential cardiovascular benefits in MASH patients
- These data demonstrate the unique mechanism of action of denifanstat and support further clinical evaluation for denifanstat in MASH