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Announces Topline Results from Phase 2b FASCINATE-2 Clinical Trial
Webcast on Monday, January 22, 2024 at
8:00 a.m. ET / 5:00 a.m. PT

# Proven Team with Development and Commercialization Experience Across Hepatology, Metabolic Disease and Oncology

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- Cognoa: President & CEO
  Chrono Therapeutics: President & CEO
  Senior Executive and Commercial roles at Horizon, Raptor, Dynavax, Chiron
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*Executive Chairman*

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- Ph.D. – Stanford University, Dept of Microbiology & Immunology

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*CMO*

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**Elizabeth Rozek**
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  B.A. – Brown University

# Forward Looking Statements

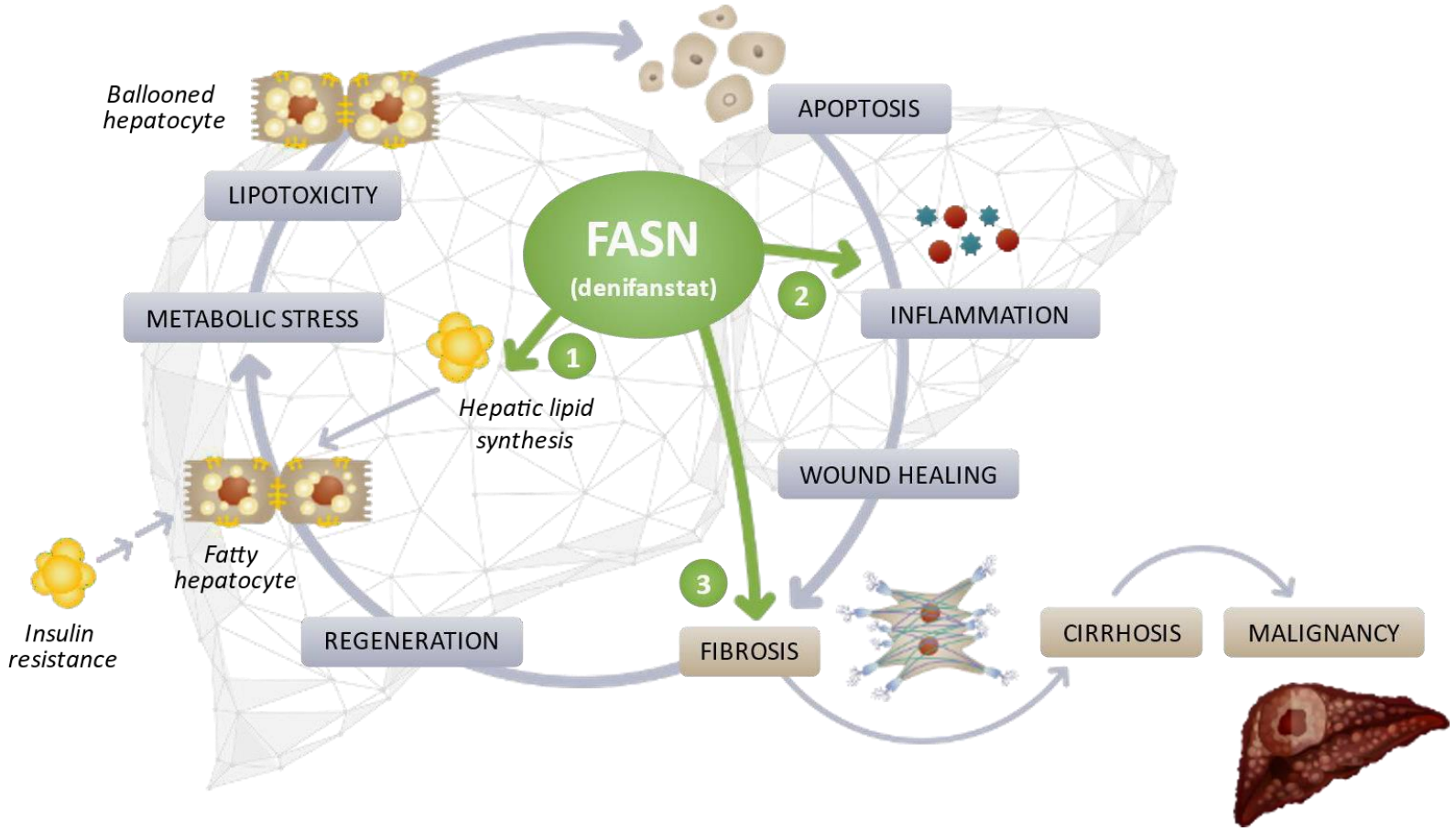
This presentation contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this document, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding possible or assumed future results of operations, business strategies, research and development plans, regulatory activities, the presentation of data from clinical trials, Sagimet's clinical development plans and related anticipated clinical development milestones, market opportunity, competitive position and potential growth opportunities are forward-looking statements. These statementsinvolve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this presentation are only predictions. These forward-looking statements speak only as of the date of this presentation and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control, including, among others: the clinical development and therapeutic potential of denifanstat or any other drug candidates we may develop; our ability to advance drug candidates into and successfully complete clinical trials, the risk the topline clinical trials may not be predictive of, and may differ from final clinical data and later-stage clinical trials; that unfavorable new clinical trial data may emerge in other clinical trials of denifanstat, including Phase 3 clinical trials; that clinical trial data are subject to differing interpretations and assessments, including by regulatory authorities; our relationship with Ascletis, and the success of its development efforts for denifanstat; the accuracy of our estimates regarding our capital requirements; and our ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of our most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements.

Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

# Denifanstat: Differentiated Mechanism Believed to Target Key Drivers of NASH

*Denifanstat has independent mechanisms designed to:*

1. Block **steatosis** via inhibiting de novo lipogenesis in hepatocytes
2. Reduce **inflammation** via preventing immune cell activation
3. Blunt **fibrosis** via inhibiting stellate cell activation






*Adapted from Wegermann et al, Clinical Liver Disease, Vol 11, No 4, April 2018, DOI: 10.1002/cld.709*

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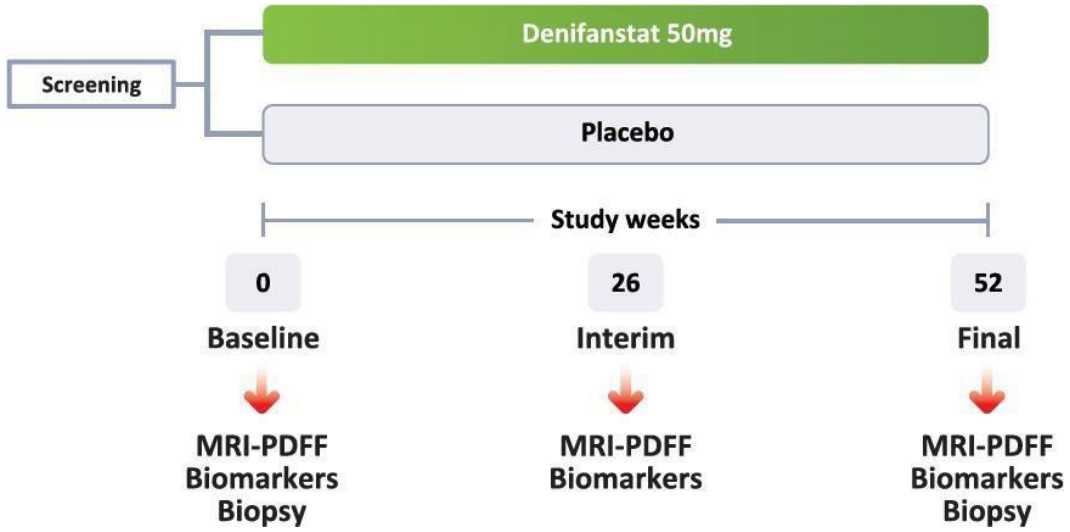
# FASCINATE-2 Phase 2b Biopsy Trial Design
## *Measuring Histological Improvement*

### FASCINATE-2 Phase 2b trial design




- Biopsy confirmed F2-F3 NASH patients
- 52 weeks, 2:1 50mg or placebo, double-blind

### Primary endpoints

- NAS ≥2 points improvement w/o worsening of fibrosis OR
- NASH resolution + NAS ≥2 improvement w/o worsening of fibrosis

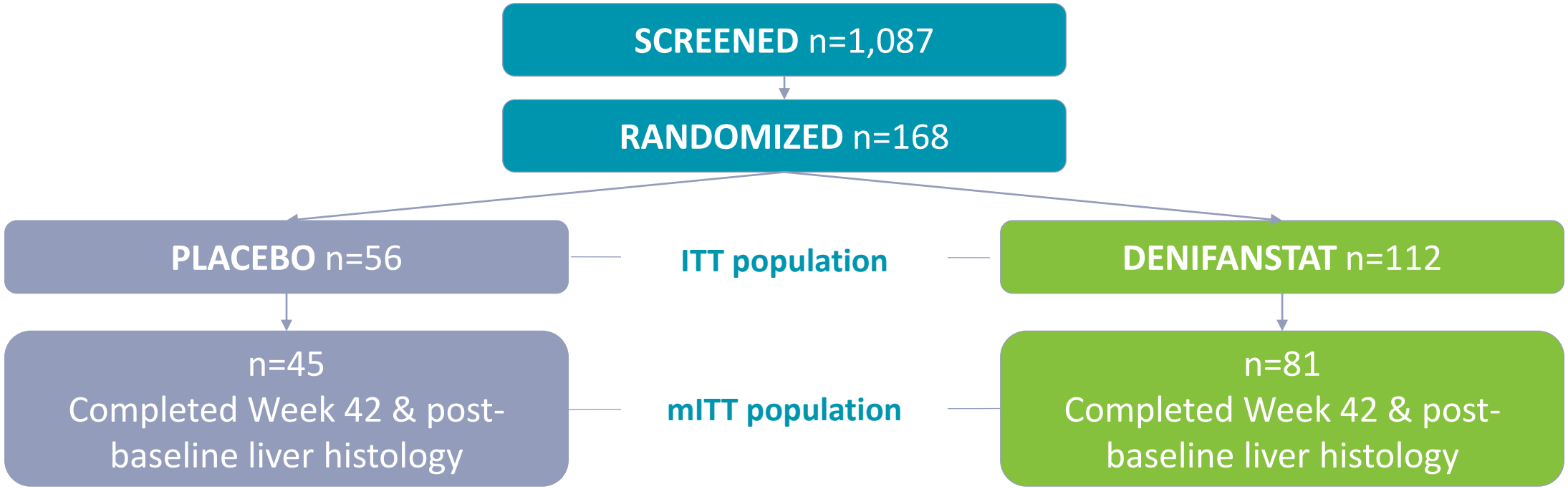
### Other selected endpoints

- Improvement in liver fibrosis ≥1 stage without worsening of NASH (Bx)
- Digital AI pathology
- MRI-PDFF: absolute decrease, % change from baseline, % pts ≥30% reduction from baseline (responders)



AI: Artificial Intelligence, Bx; biopsy, MRI-PDFF; magnetic resonance imaging derived proton density fat fraction, NAS; NAFLD Activity Score.

# FASCINATE-2: Patient Disposition



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# FASCINATE-2 Baseline Characteristics
## *Typical F2/F3 NASH Population*

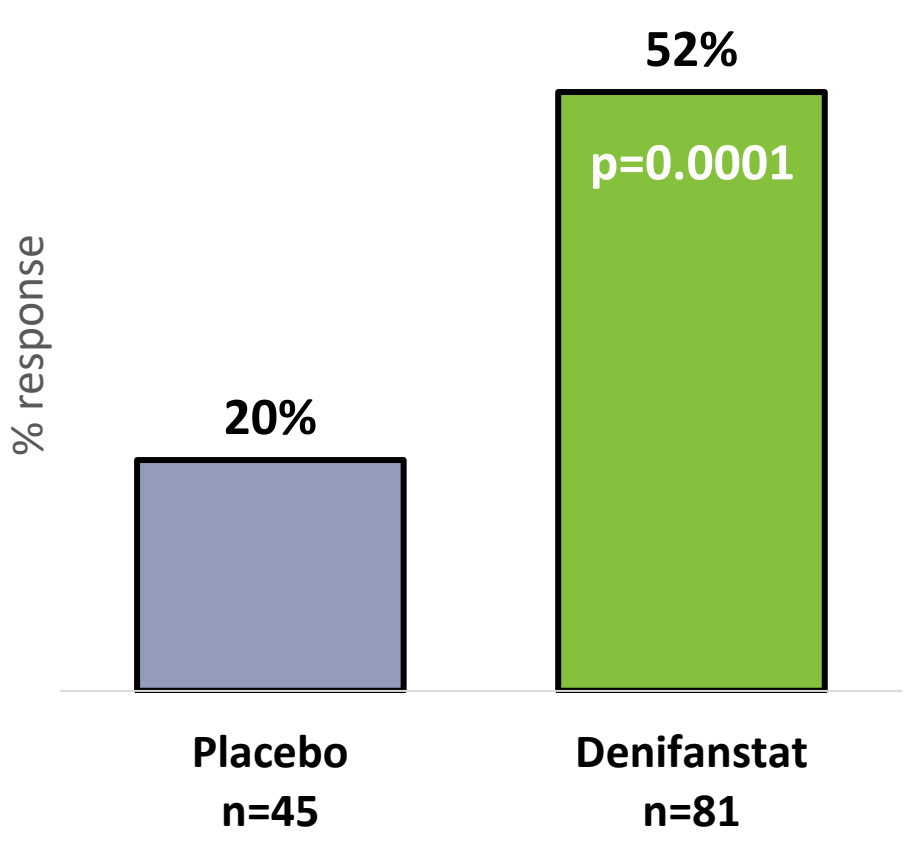
| Parameter | Placebo, n=45 | Denifanstat, n=81 |
|---|---|---|
| **Age**, years | 59.6 (+/- 10.9) | 56.1 (+/- 10.8) |
| **Sex**, female | 27 (60%) | 48 (59%) |
| **Race**, White | 41 (91%) | 73 (90%) |
| **Ethnicity**, Hispanic or Latino | 15 (33%) | 27 (33%) |
| **BMI**, $kg/m^2$ | 36.5 (+/- 6.7) | 34.6 (+/- 6.1) |
| **Type 2 diabetes** | 27 (60%) | 55 (68%) |
| **ALT (alanine aminotransferase)** U/L | 67 (+/- 33) | 57 (+/- 29) |
| **AST (aspartate aminotransferase)** U/L | 52 (+/- 27) | 48 (+/- 29) |
| **Liver Fat Content (MRI-PDFF)**, % | 19.0 (+/- 7.0) | 16.6 (+/- 7.1) |
| **Baseline liver biopsy NAS ≥ 5** | 34 (76%) | 63 (78%) |
| **Baseline liver biopsy F2/F3** | 22 (49%) / 23 (51%) | 34 (42%) / 47 (58%) |
| **Statin** (at baseline) | 21 (47%) | 38 (47%) |
| **GLP1-RA** (at baseline) | 4 (9%) | 12 (15%) |
| **LDL**, mg/dL | 103 (+/- 39) | 96 (+/- 34) |
| **Triglycerides**, mg/dL | 153 (+/- 67) | 173 (+/- 79) |
| **ELF (Enhanced Liver Fibrosis) Score** | 9.8 (+/- 0.8) | 9.6 (+/- 0.8) |
| **FAST (Fibroscan AST) Score** | 0.6 (0.19) | 0.6 (0.20) |



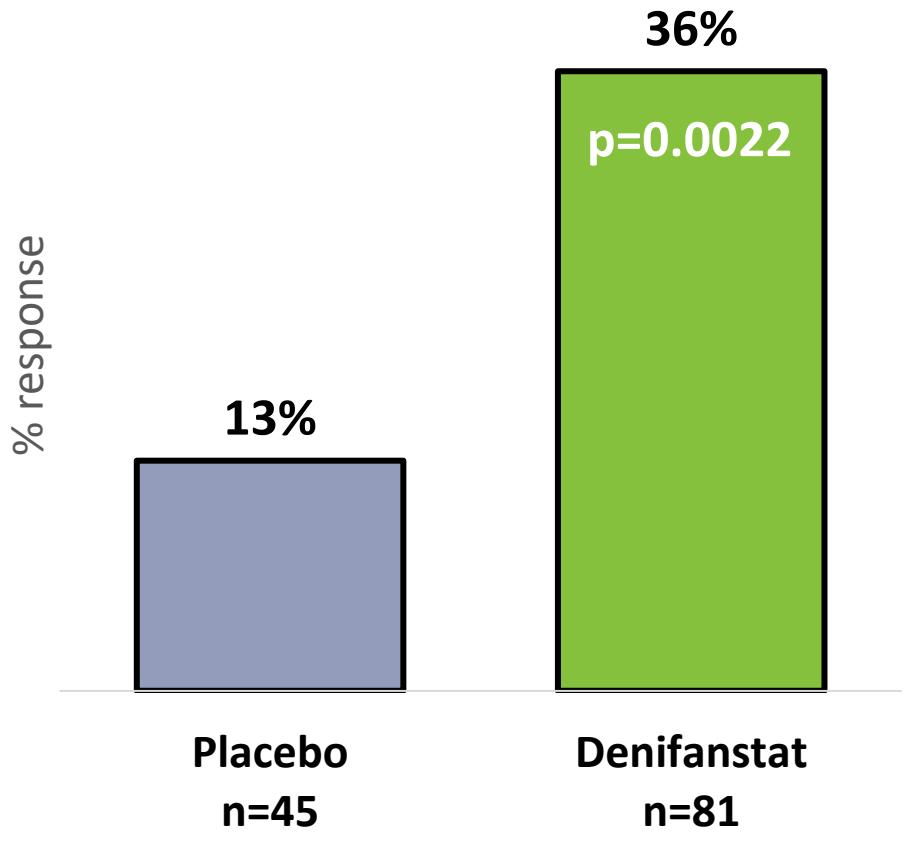
Modified intent-to-treat population (mITT) includes all patients with paired biopsies. Data are mean (SD) or n (%)

# Primary Endpoints: Liver Biopsy
## *Denifanstat Achieved Statistical Significance*

**NAS ≥ 2 points improvement***
**w/o worsening of fibrosis**




**NASH resolution + NAS ≥ 2 improvement**
**w/o worsening of fibrosis**






Cochran-Mantel-Haenszel Test – One sided at the 0.05 significance level. mITT population. * ≥1-point improvement in ballooning or inflammation.

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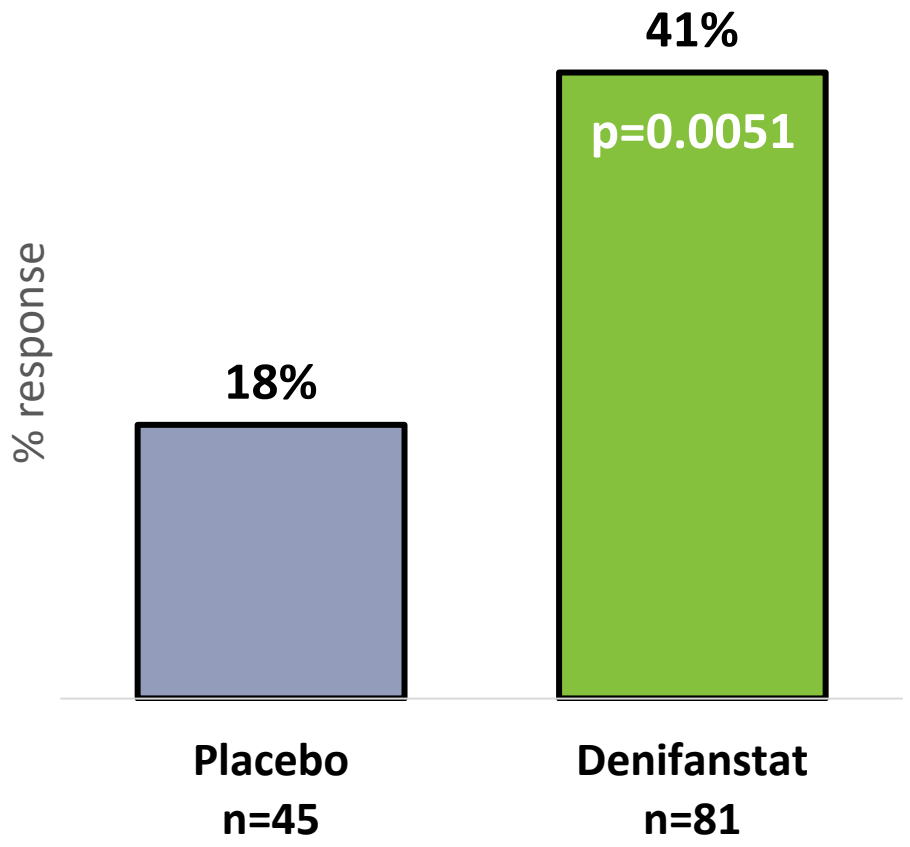
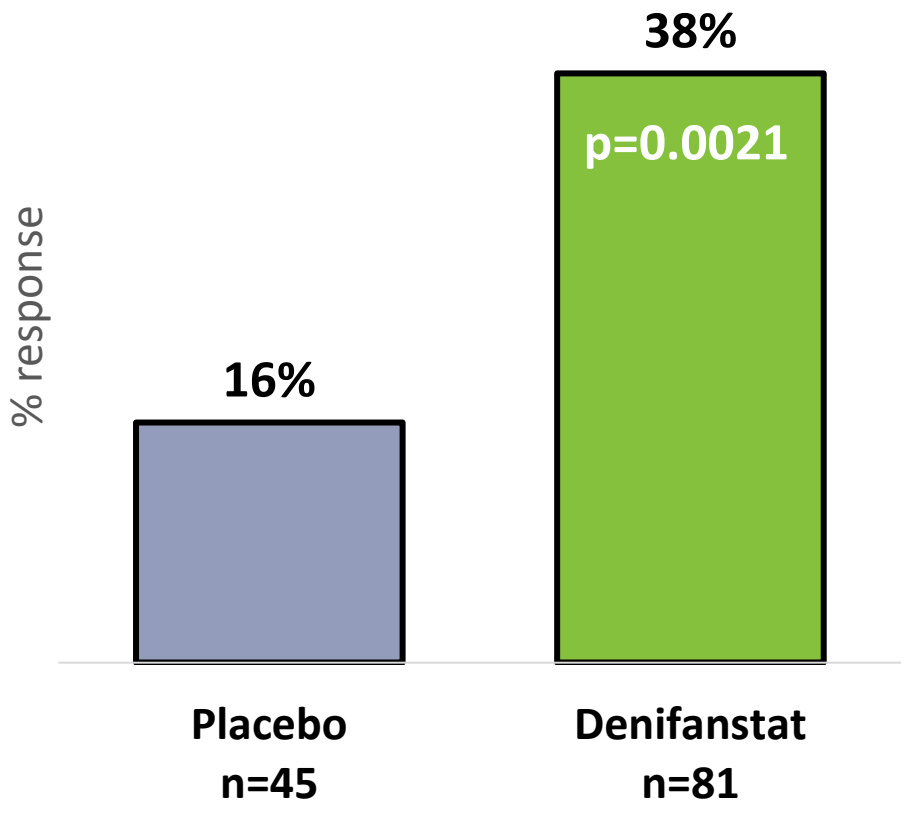
# Secondary Endpoints: Liver Biopsy
## *Denifanstat Achieved Statistical Significance*

**Improvement in liver fibrosis ≥ 1 stage w/o worsening of NASH**




**Resolution of NASH w/o worsening of fibrosis**






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

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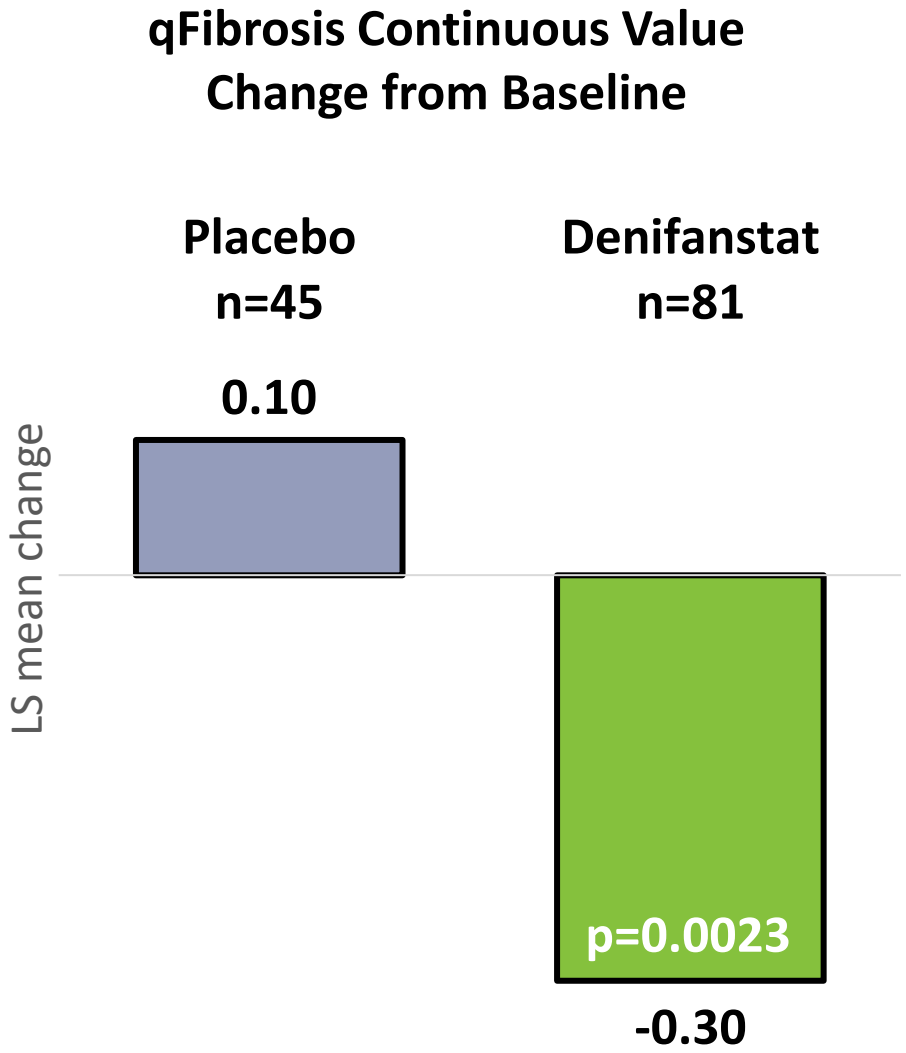
# Independent Fibrosis Analysis by AI-based Digital Pathology
## *Supporting Evidence that Denifanstat Significantly Reduced Fibrosis*






Cochran-Mantel-Haenszel Test – One sided at the 0.05 significance level. LS means; least squares mean. HistoIndex platform. mITT population.

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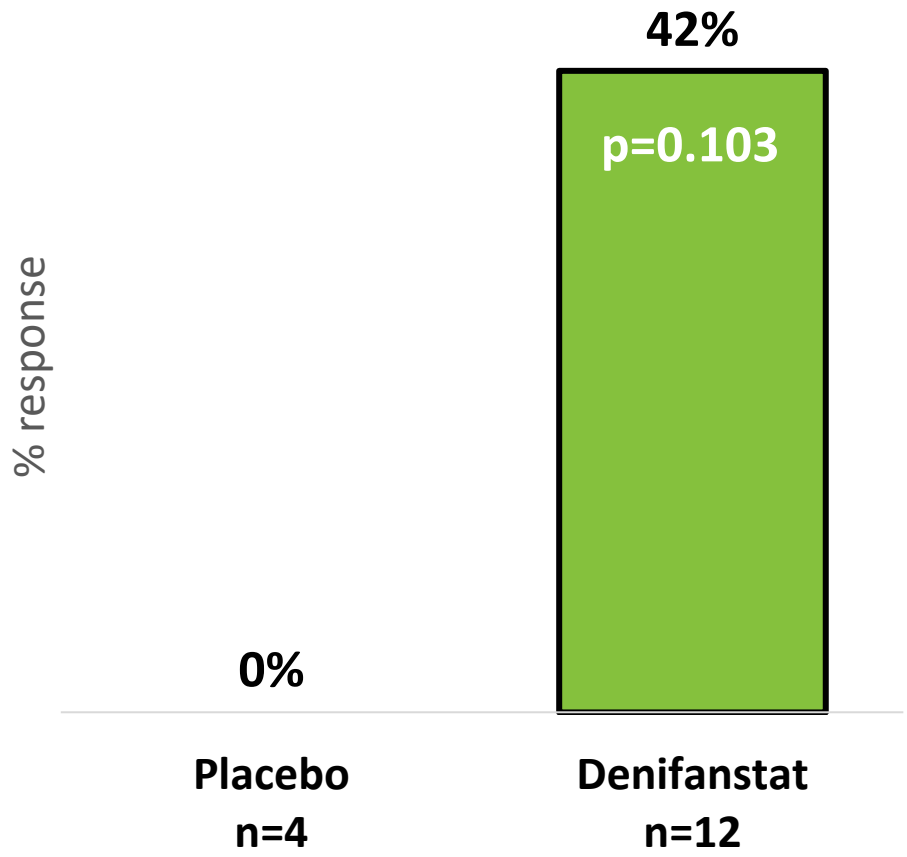
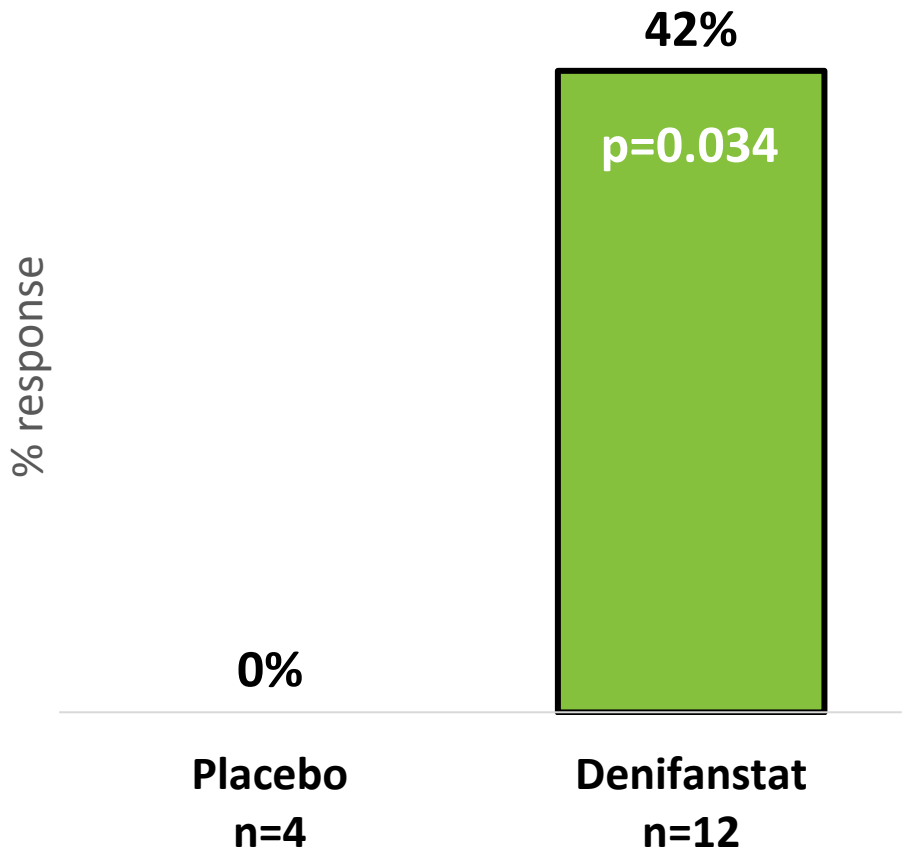
# Patient Subset on Stable GLP1-RA at Baseline: Liver Biopsy

*Denifanstat Improves NASH Resolution and Fibrosis*

**Resolution of NASH w/o worsening of fibrosis**




**Improvement in liver fibrosis ≥ 1 stage w/o worsening of NASH**






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

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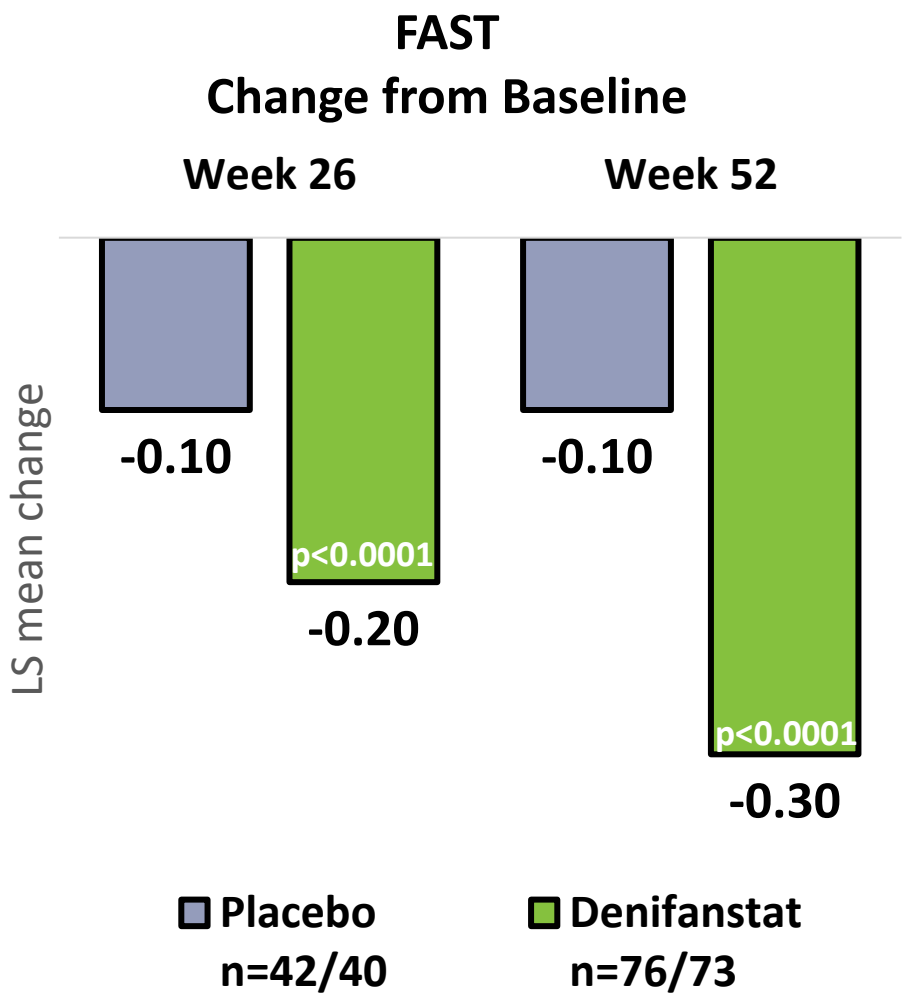
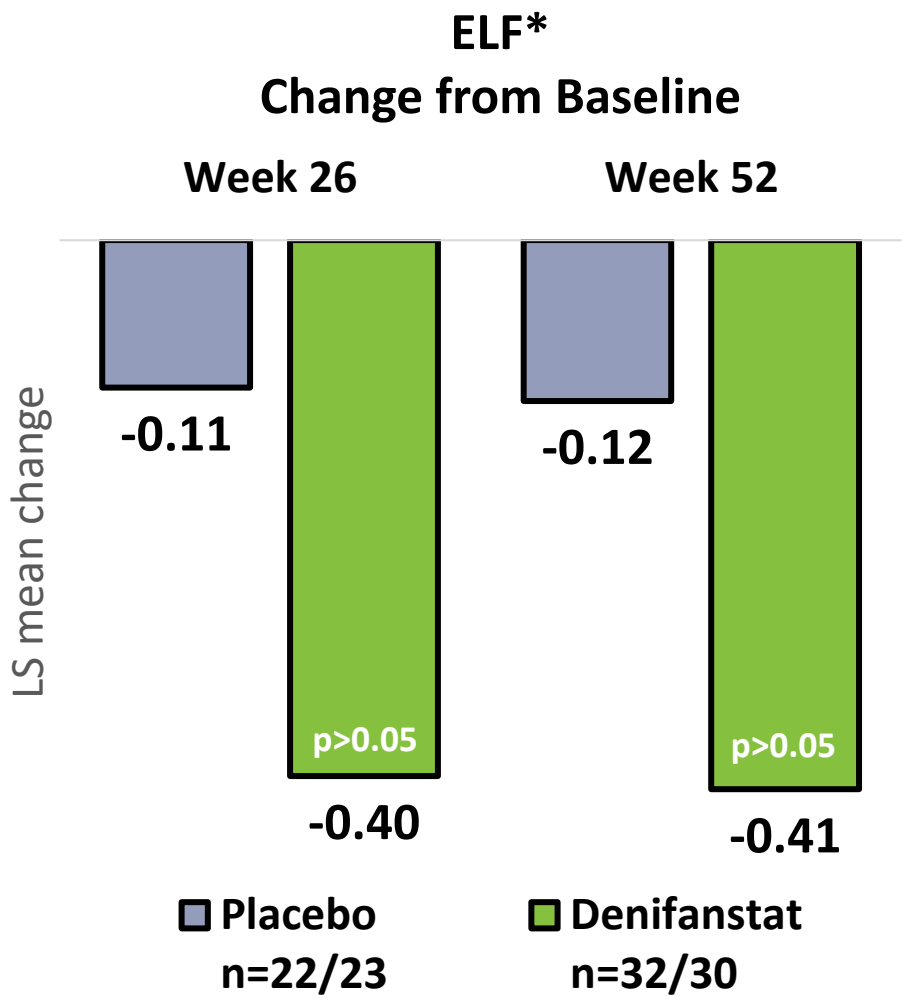
# Biomarkers of Fibrosis

## *Denifanstat Decreased FAST Score and ELF*






Mixed-effects Model for Repeated Measures – Two sided at the 0.05 significance level. mITT population. *Baseline ELF > 9.8 (mean).

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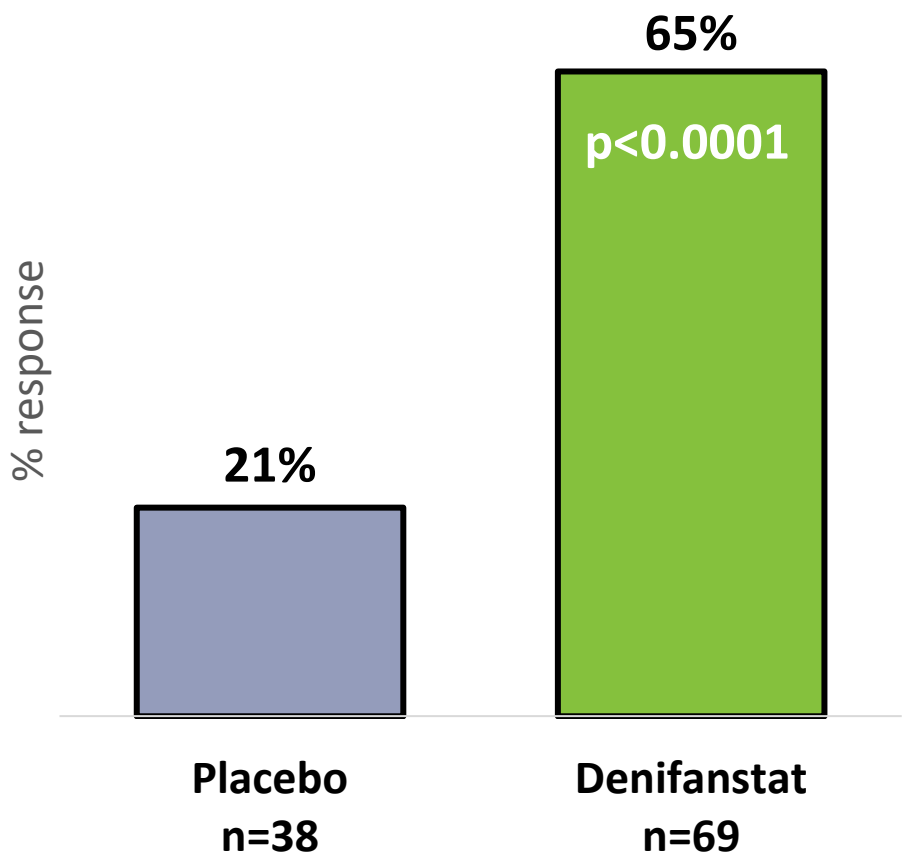
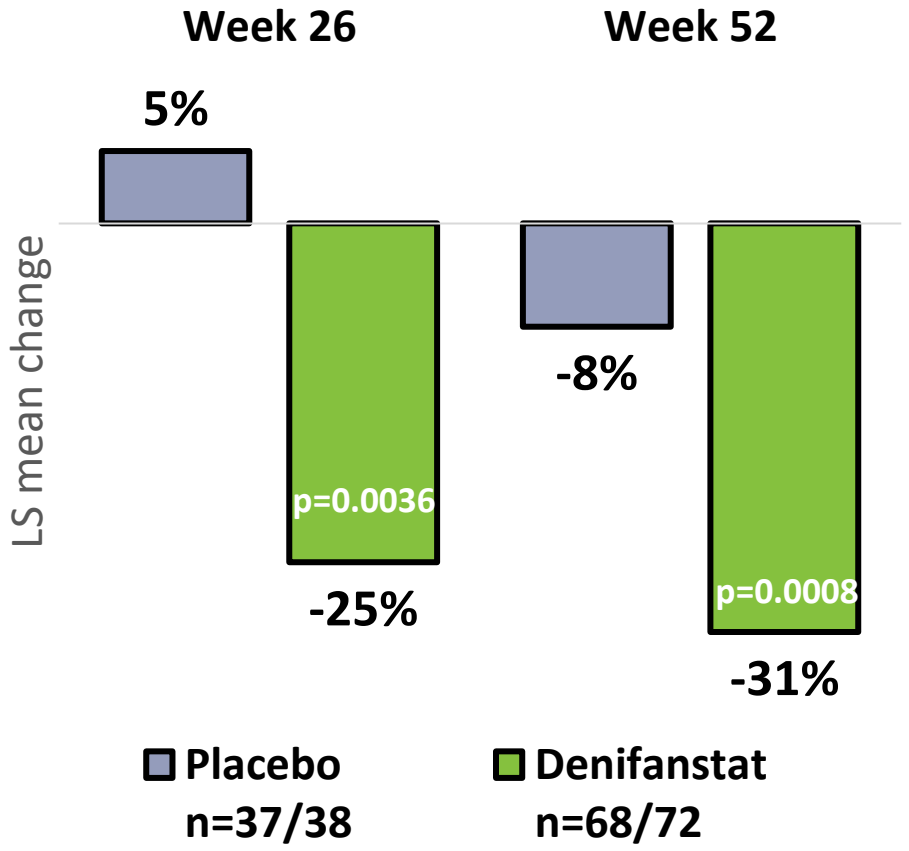
# Secondary Endpoint: Liver Fat by MRI-PDFF
## *Denifanstat Achieved Statistical Significance*

**MRI-PDFF**
**≥ 30% Relative Reduction, Week 52**




**MRI-PDFF**
**Relative Change from Baseline**






≥30% reduction: Cochran-Mantel-Haenszel Test. Relative reduction: Mixed-effects Model for Repeated Measures . mITT population

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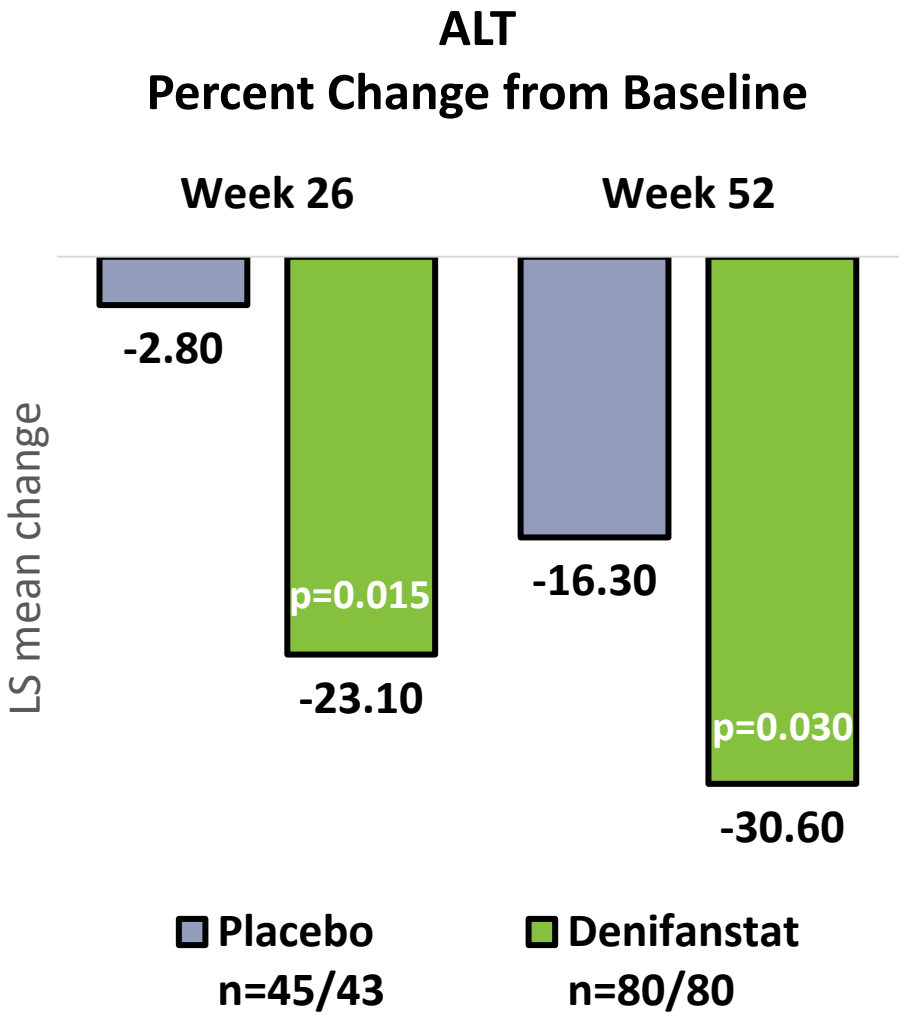
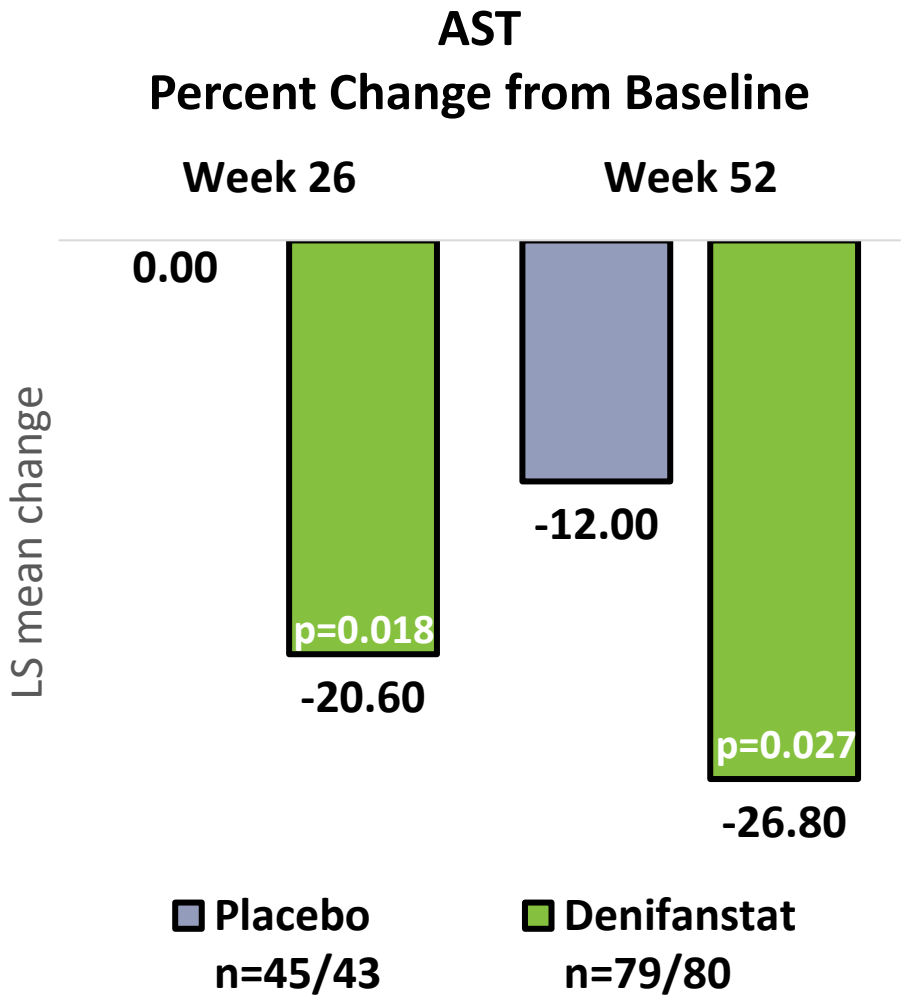
# Secondary Endpoints: Liver Enzymes
## *Denifanstat Decreased ALT and AST Levels*






Mixed-effects Model for Repeated Measures – Two sided at the 0.05 significance level. mITT population

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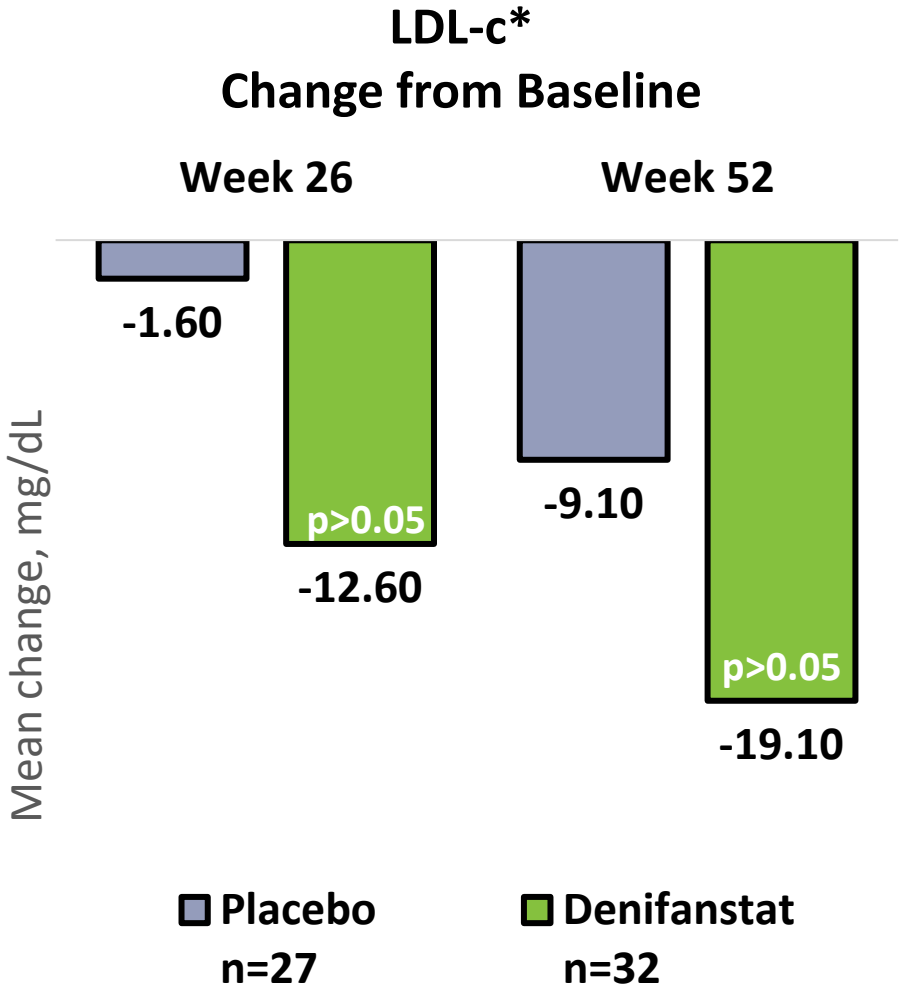
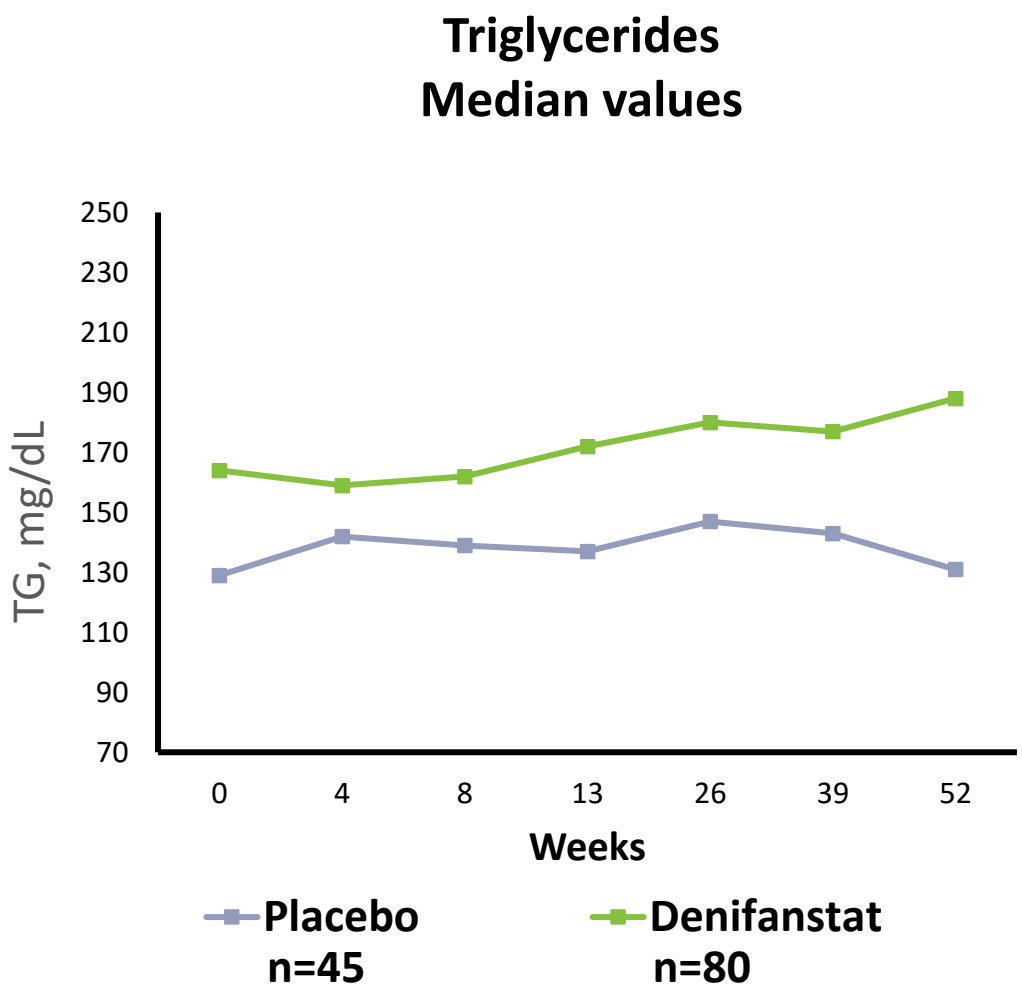
# Cardiometabolic health
## *Denifanstat Decreased LDL-c Levels*






mITT population. *For LDL-c, baseline > 100 mg/dL. Mixed-effects Model for Repeated Measures – Two sided at the 0.05 significance level.

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# FASCINATE-2: Safety
## *Denifanstat was Generally Well Tolerated*

| Parameter | Placebo n=56 | Denifanstat N=112 |
|---|---|---|
| Any TEAE (treatment emergent adverse event) | 45 (80.4%) | 96 (85.7%) |
| TEAE related to study drug | 20 (35.7%) | 51 (45.5%) |
| Most common TEAE related to study drug in ≥5% of patients by system organ class | | |
| eye disorders | 9 (16.1%) | 17 (15.2%) |
| gastrointestinal disorders | 5 (8.9%) | 13 (11.6%) |
| skin and subcutaneous tissue disorders | 4 (7.1%) | 25 (22.3%) |
| TEAE leading to study drug discontinuation | 3 (5.4%) | 22 (19.6%) |
| TEAE with CTCAE Grade 3 (Severe) or higher* | 3 (5.4%) | 13 (11.6%) |
| SAE (none related to treatment) | 3 (5.4%) | 13 (11.6%) |
| Fatal TEAE | 0 | 0 |

* No treatment-related AE was Grade 3 or higher

# Development Pipeline: Indications and Clinical Milestones

| Therapeutic Area | Indication | Stage of Development | Expected Milestone / Status |
|---|---|---|---|
| Metabolic disease | NASH - F2/F3 | TVB-2640 (Phase 2) | • Phase 2b successfully completed |
| | | TVB-2640 (Phase 1) | • Phase 1 hepatic impairment results 1Q 2024 |
| Dermatology | Acne | TVB-3567 (Preclinical) | • IND 1H 2024 filing planned |
| | | TVB-2640 (ASC40) (Phase 2 – Phase 3) | • Phase 3 clinical study initiated 4Q 2023* |
| Oncology | Solid tumors | (Phase 1 – Phase 2) | • Patient selection and trial design in FASN-dependent tumor types ongoing |
| | Recurrent glioblastoma (GBM) | TVB-2640 (ASC40) (Phase 2 – Phase 3) | • Phase 3 enrollment of 120 patients achieved in 3Q 2023; interim analysis planned* |

** Trials conducted in China by Ascletis, who has licensed development and commercialization rights to all indications in Greater China*

# End