

# LPCN 1144

for Non-Cirrhotic NASH

LiFT Topline Results  
at Week 12

January 2021



# Forward-Looking Statements

This presentation contains forward-looking statements about Lipocine, Inc. (the “Company”). These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to the Company’s products and product candidates, the availability of additional data for week 36, the results of the *LiFT* study, clinical and regulatory processes and objectives, and potential benefits of the Company’s product candidates, all of which involve known and unknown risks and uncertainties. Actual results may differ materially from the forward-looking statements discussed in this presentation.

Accordingly, the Company cautions investors not to place undue reliance on the forward-looking statements contained in, or made in connection with, this presentation. Several factors may affect the initiation and completion of clinical trials and studies, the potential advantages of the Company’s product candidates, and the Company’s capital needs. The forward-looking statements contained in this presentation are qualified by the detailed discussion of risks and uncertainties set forth in the Company’s annual report on Form 10-K and other periodic reports filed by the Company with the Securities and Exchange Commission, all of which can be obtained on the Company’s website at [www.lipocine.com](http://www.lipocine.com) or on the SEC website at [www.sec.gov](http://www.sec.gov). The forward-looking statements contained in this document represent the Company’s estimates and assumptions only as of the date of this presentation and the Company undertakes no duty or obligation to update or revise publicly any forward-looking statements contained in this presentation as a result of new information, future events or changes in the Company’s expectations.

# Summary: Positive Topline Results

Both LPCN 1144 Treatment Arms Met the Primary Endpoint with Statistical Significance

Statistically significant reduction in liver fat was observed compared to placebo

- Up to a mean 9.2% absolute and 46.9% relative reduction in liver fat

Statistically significant reduction in markers of liver injury were observed compared to placebo

- Up to a mean 22.4 U/L decrease in alanine aminotransferase (ALT), and 10.4 U/L decrease in aspartate aminotransferase (AST)

Adverse events in both the treatment arms were comparable to the placebo arm

# LPCN 1144: *LiFT (Liver Fat Intervention with oral Testosterone)*\*

## Phase 2 Paired Biopsy Study in Men with NASH (NCT04134091)

### Study Design

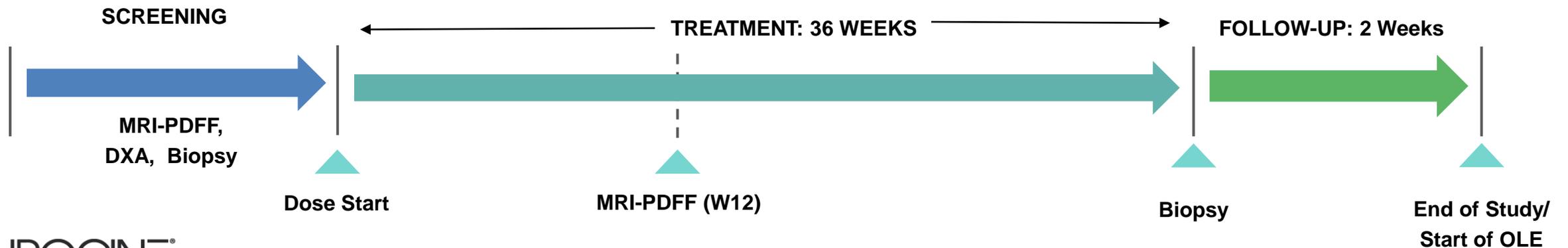
- Biopsy confirmed 56 male NASH subjects with F1-F3
- Three-arm, placebo controlled with 1:1:1 randomization
  - Treatment A: 142 mg eq. T twice daily
  - Treatment B: 142 mg eq. T + with 217 mg of d-alpha tocopherol equivalent twice daily
  - Placebo twice daily
- Treatment duration of 36 weeks

### Primary Endpoint:

- Change in hepatic fat fraction via MRI-PDFF (W12)

### Secondary Endpoints:

- Change in NASH activity and fibrosis via liver biopsy scoring (W36)
- Change in hepatic fat fraction via MRI-PDFF (W36)
- Change in liver injury markers, anthropomorphic measurements, lipids, insulin resistance, inflammatory/fibrosis markers
- Patient Reported Outcomes (PROs) including quality-of-life and patient global impression scores (PGI)

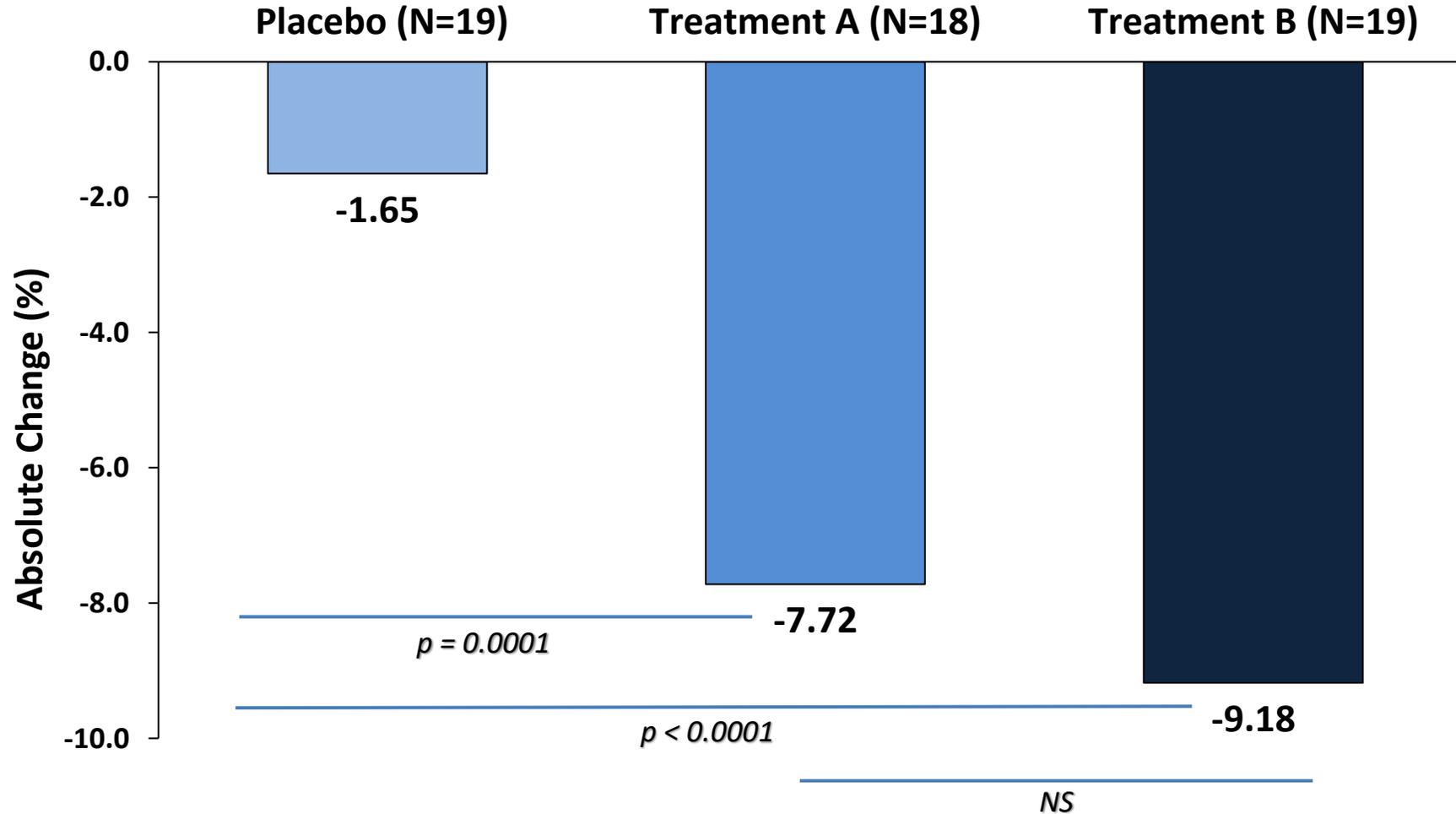


# *LiFT* Study: Baseline Characteristics

Parameter	Placebo	Treatment A	Treatment B
Started the study (N)	19	18	19
Completed WK 12 (N)	18	18	19
Age (years)	53.6	51.3	53.4
BMI (kg/m <sup>2</sup> )	37.3	36.9	34.5
Diabetes (%)	52.6	72.2	57.9
Hypertension (%)	68.4	66.7	57.9
Hepatic Fat Fraction (%)	20.06	16.73	20.87
ALT (U/L)	49.0	53.9	51.5
AST (U/L)	35.4	32.4	31.9

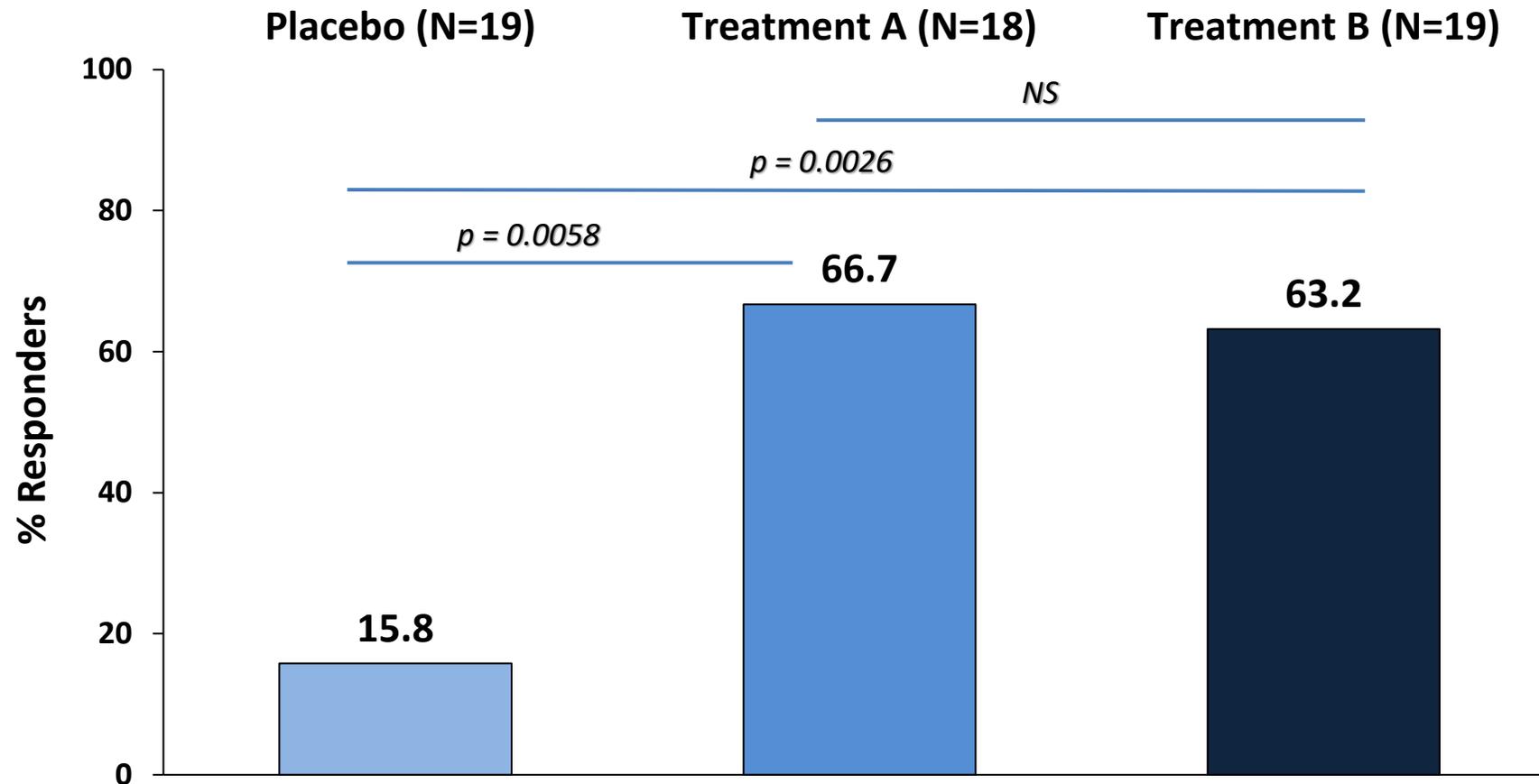
# Absolute Change in Liver Fat (%)

Baseline to Week 12\*

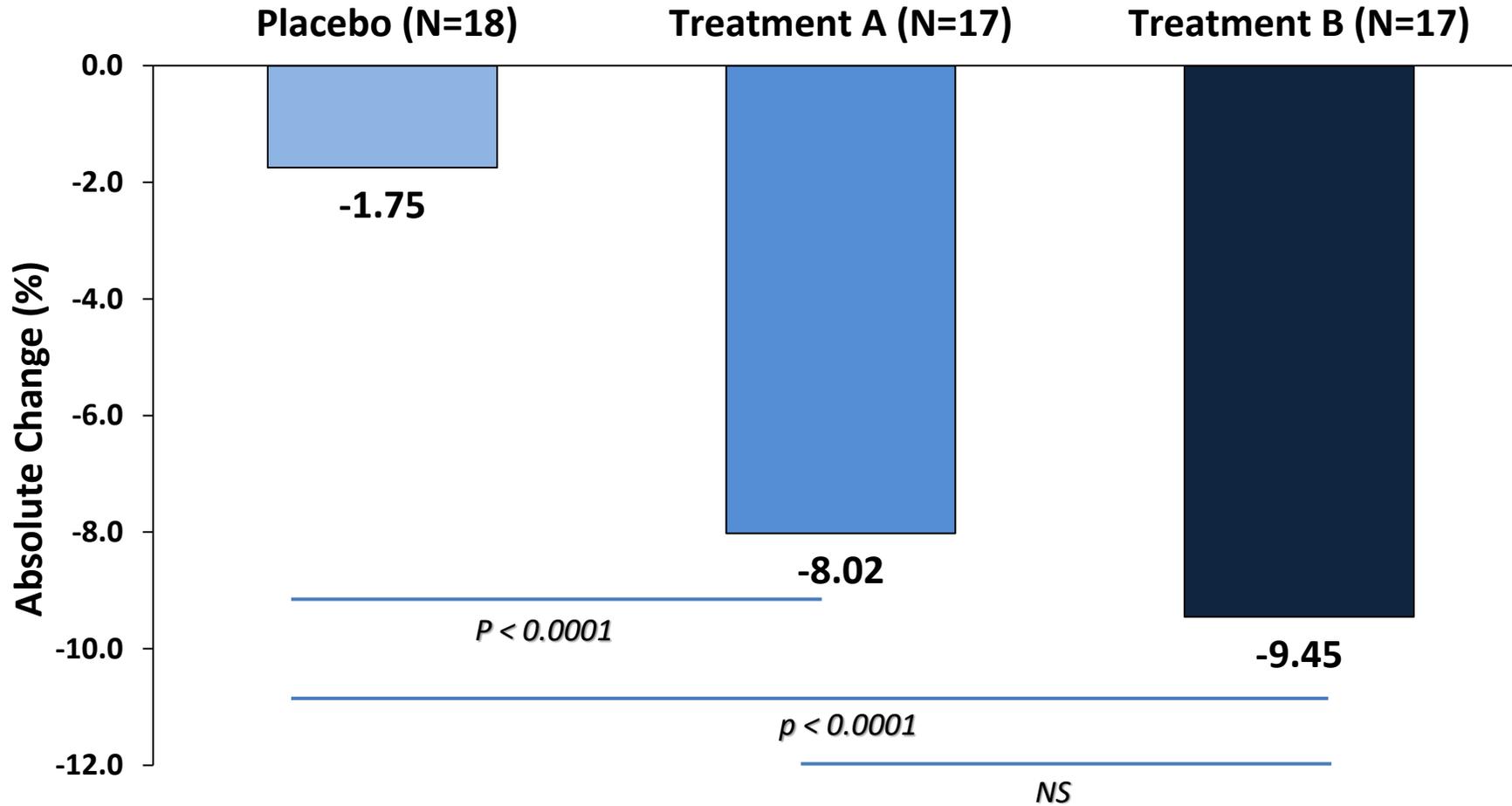


# Percent of Subjects with $\geq 30\%$ Relative Reduction in Liver Fat

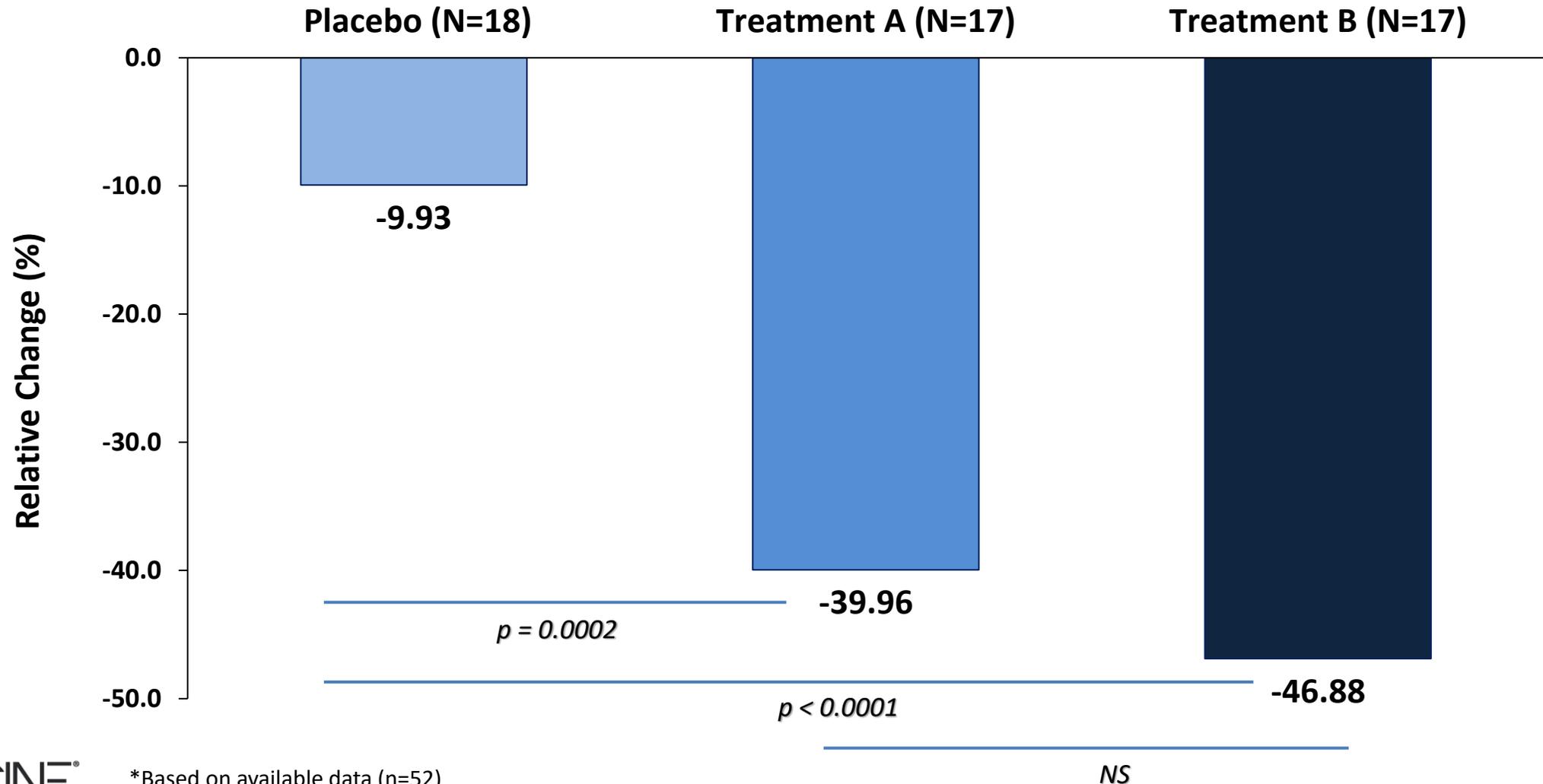
Baseline to Week 12\*



# Absolute Change in Liver Fat (%) in Subjects with Baseline Liver Fat $\geq 5\%$ Baseline at Week 12\*

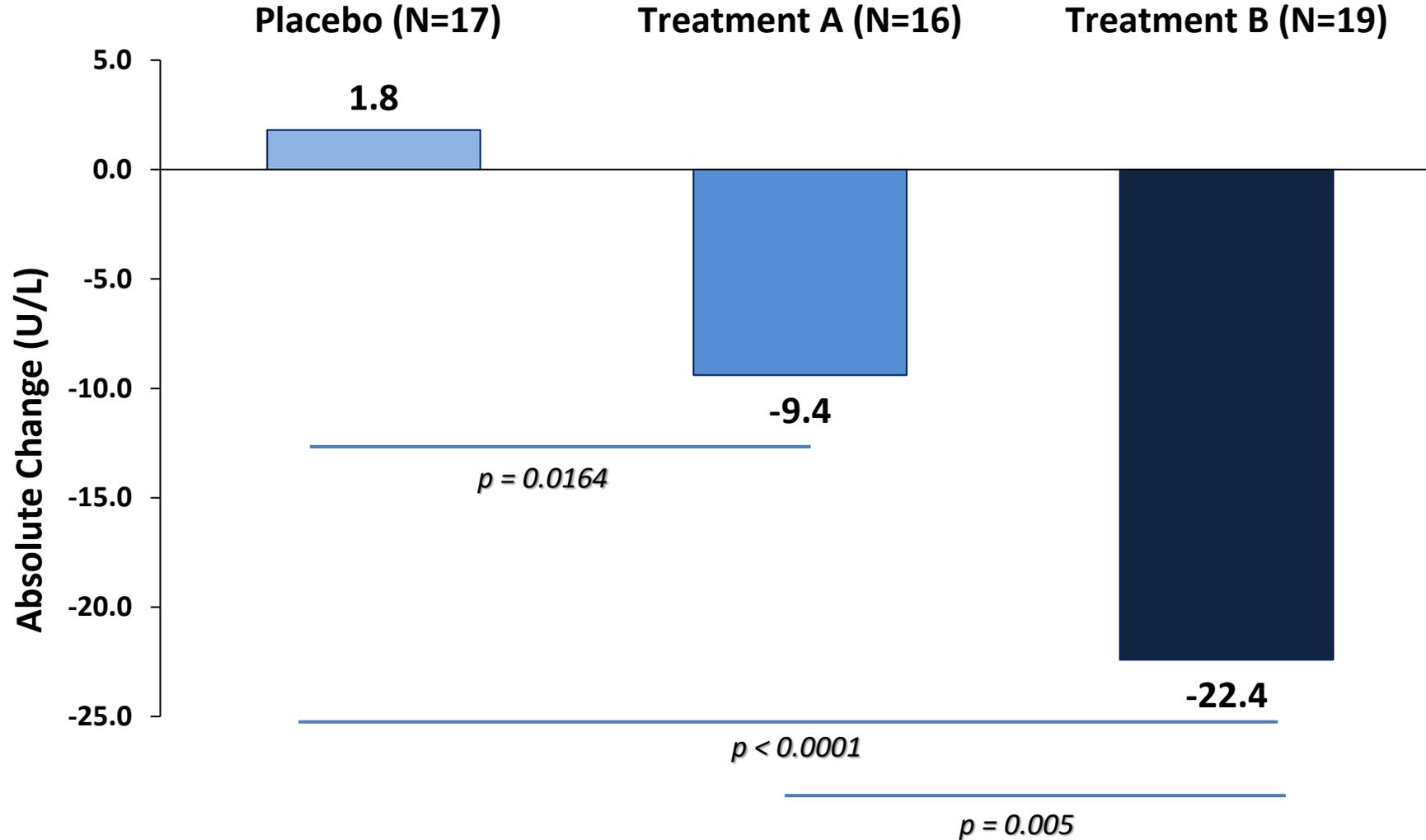


# Relative Change in Liver Fat (%) in Subjects with Baseline Liver Fat $\geq 5\%$ Baseline at Week 12\*



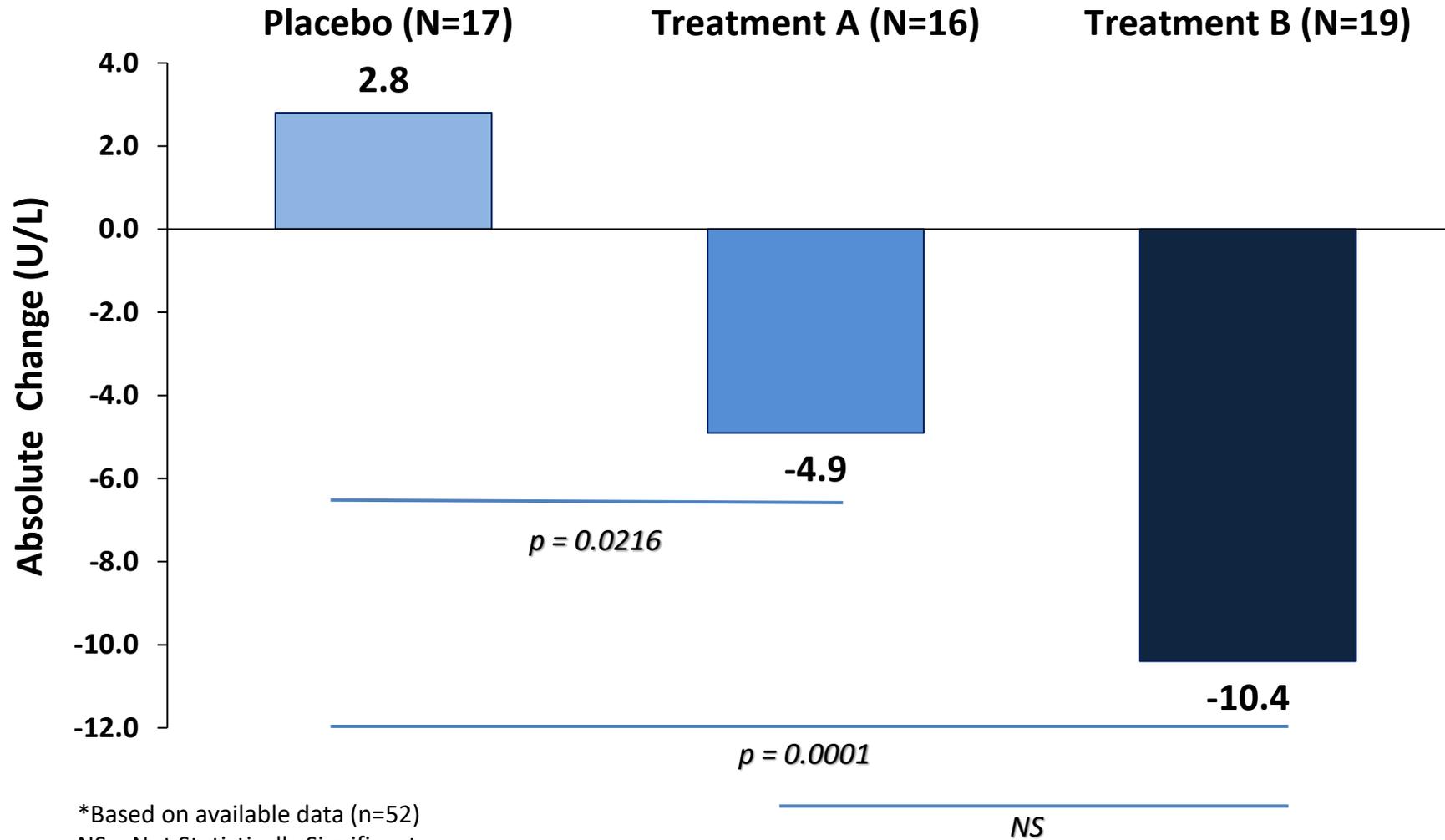
# Liver Injury Marker Changes: Alanine Aminotransferase (ALT)

Absolute Change from Baseline at Week 12\*



# Liver Injury Marker Changes: Aspartate Aminotransferase (AST)

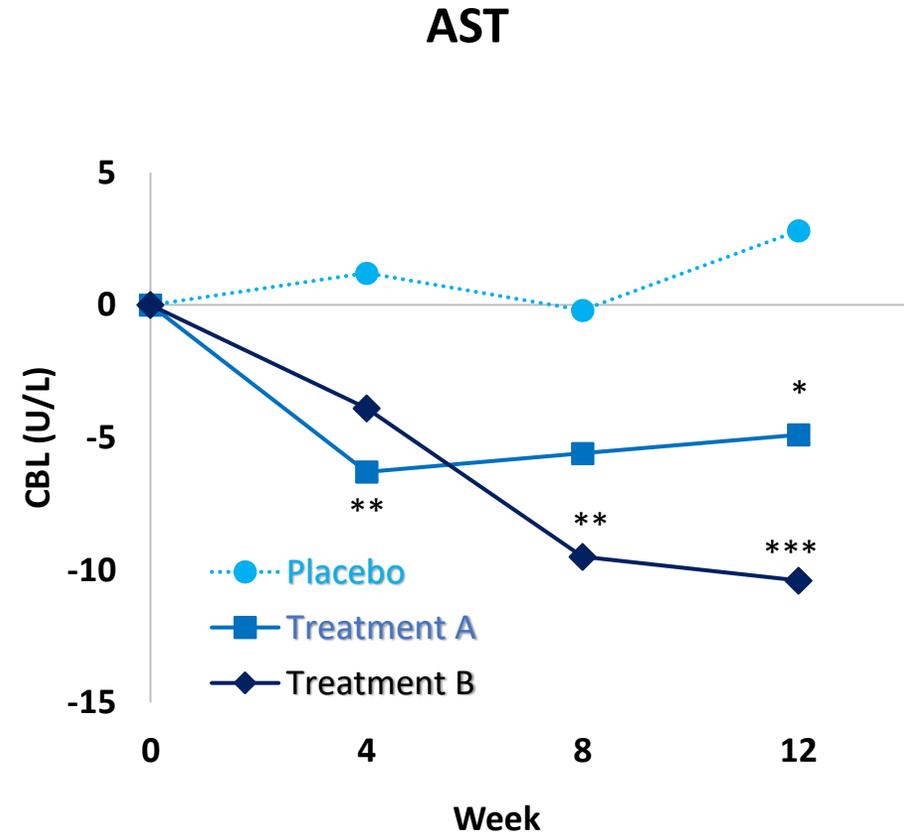
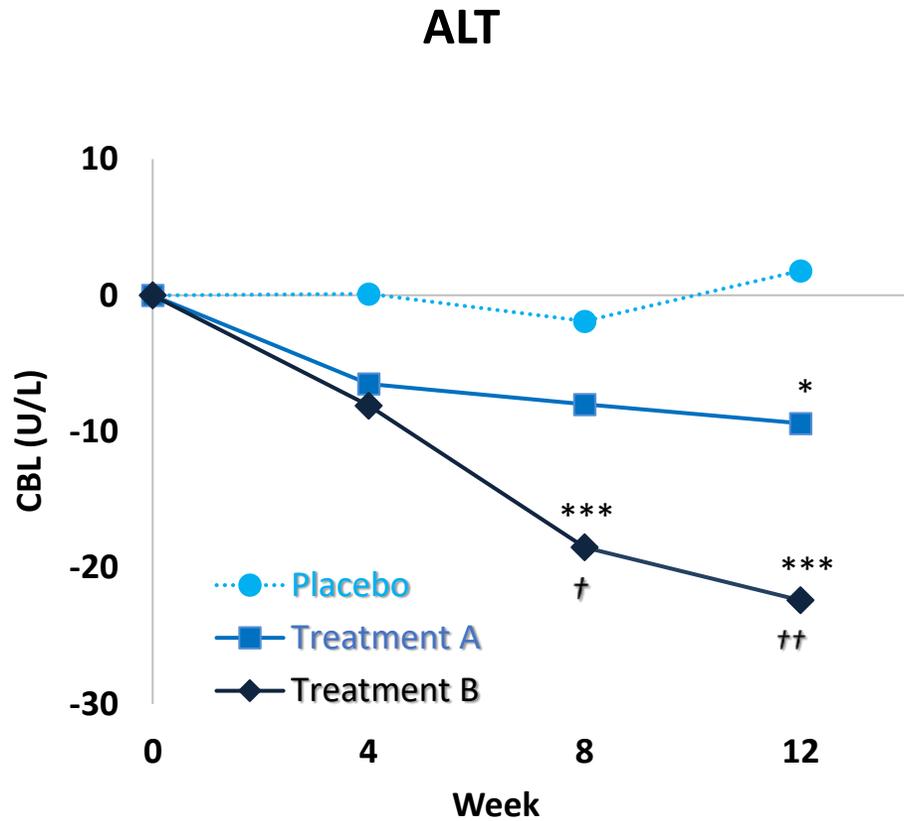
Absolute Change from Baseline at Week 12\*



\*Based on available data (n=52)  
NS = Not Statistically Significant

# Longitudinal Changes of Key Liver Injury Markers

Absolute Changes (U/L) from Baseline up to Week 12



# LiFT Study: Upcoming Data

Mid-2021



Histological change in NASH activity and fibrosis at week 36



MRI-PDF liver fat data for week 36



Body composition data from DXA scan (at 20 weeks and 36 weeks)

- Whole body lean mass, fat mass, arm leg lean mass, and bone mineral density



Liver and other markers including (fibrosis and inflammation markers) at week 36



PROs for periodic visits up to week 36

- Quality of life and patient global impression scores (PGI)