

LPCN 1144

for Non-Cirrhotic NASH

LiFT Key Topline Results

August 2021



Forward-Looking Statements

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Summary of *LiFT* Results

Study Demonstrates Treatment Potential of LPCN 1144 in NASH

- Primary endpoint met – Change in liver fat via MRI-PDFF at Week 12
- Both LPCN 1144 treatment arms met with statistical significance the pre-specified histology based regulatory endpoint of NASH resolution with no worsening of fibrosis
- Treatment effect observed on fibrosis improvement needs confirmation in a larger study
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- LPCN 1144 was well tolerated with an overall safety profile comparable to placebo
- Positive topline results support LPCN 1144 development for regulatory approval

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

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

Study Design

- Biopsy confirmed male NASH subjects with F1-F3
Three-arm, blinded, placebo-controlled
 - 1:1:1 randomization
 - Treatment A: 142 mg eq. T twice daily
 - Treatment B: 142 mg eq. T + 238 mg d-alpha tocopherol twice daily
 - Placebo: twice daily
- Treatment duration of 36 weeks

Primary Endpoint:

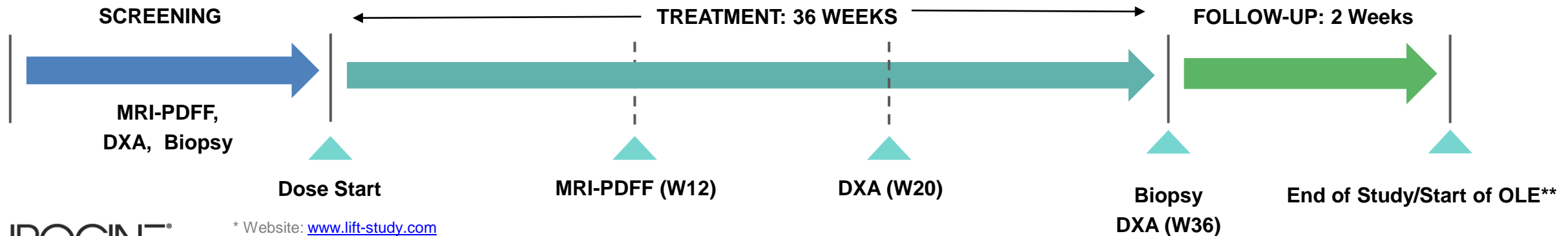
- ✓ Change in hepatic fat fraction via MRI-PDFF (W12)

Key Secondary Endpoints:

- Change in NASH activity and fibrosis via liver biopsy scoring (W36)
- Change in body composition, liver injury markers

Analysis Sets:

- Safety Set: All randomized subjects (ITT)
- Biopsy Set: All subjects with baseline and EOS biopsies
- NASH Resolution Set: Biopsy set with NAS ≥ 4 and at least 1 point in both inflammation and ballooning



Histopathological Assessment Methodology

Techniques Employed

Histopathological Slides (H&E and Trichrome Staining)	One Central Independent Hepatopathologist		Digitalized Stained Slides Reading (Quantitative Artificial Intelligence)
	NASH CRN Scoring	Paired Reading (Separately from CRN)	
Screening / Baseline (BL)	<ul style="list-style-type: none"> Read as it is available 	<ul style="list-style-type: none"> BL and EOS read as pairs and compared Blinded to treatment and timepoint Evaluated as 'Better', 'Same' or 'Worse' 	<ul style="list-style-type: none"> All (BL and EOS for all subjects) slides read as one group Blinded to treatments Continuous quantitative scoring* for disease severity
End of Study (EOS)	<ul style="list-style-type: none"> Read as part of tranches along with a few baseline slides Blinded to treatment and timepoint 		
Parameters Evaluated	<ul style="list-style-type: none"> Graded for NASH (steatosis, inflammation & ballooning) Staged for Fibrosis 	<ul style="list-style-type: none"> NASH (steatosis, inflammation & ballooning) and Fibrosis 	<ul style="list-style-type: none"> Fibrosis (as composite score)

*Numerous traits in three phenotypic layers (Collagen Content, Fibers Morphometry, and Fibrosis Architecture) for Fine and Assembled collagens

LiFT Study: Baseline Characteristics*

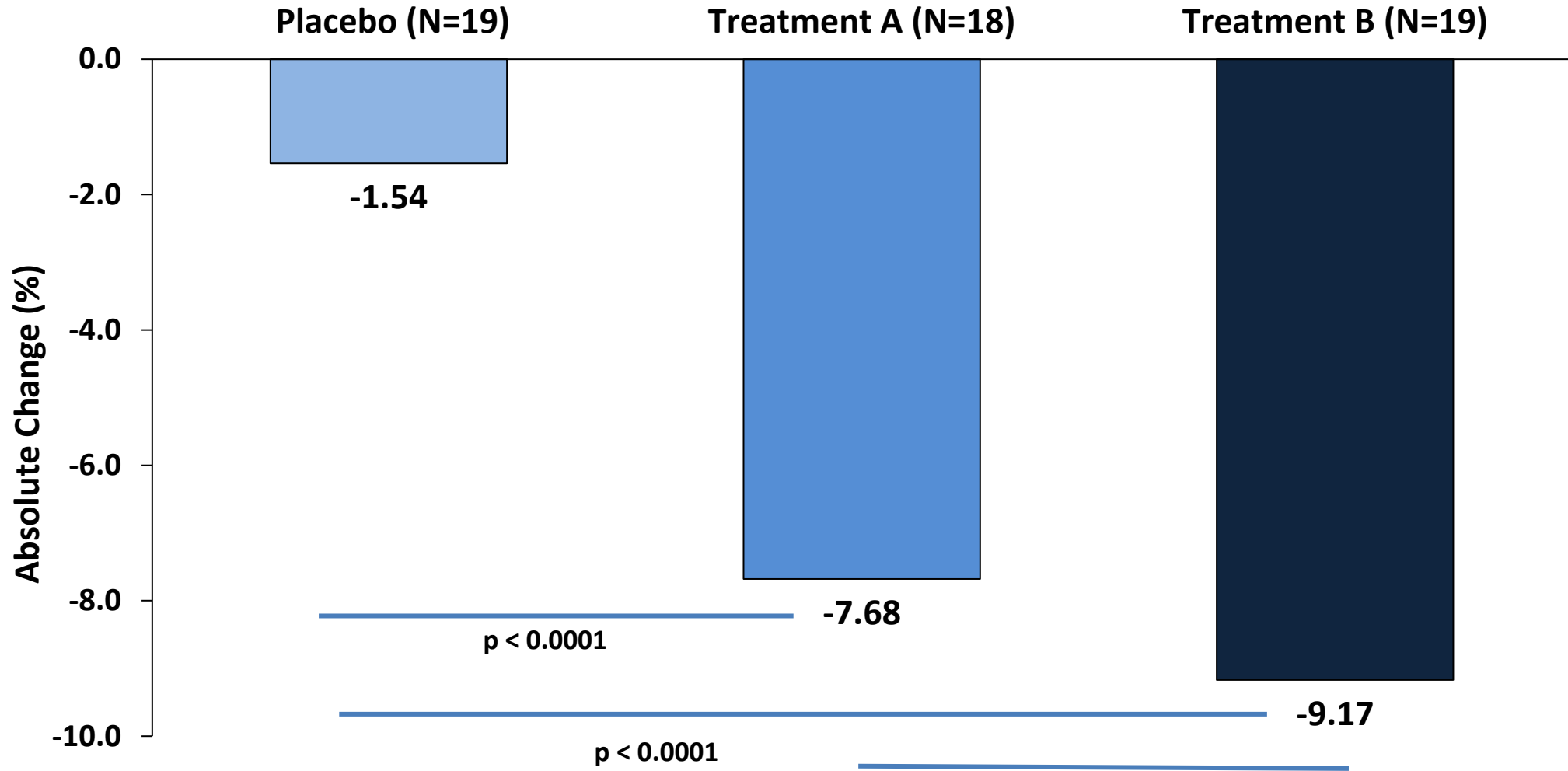
Parameter	Placebo (N=15)	Treatment A (N=15)	Treatment B (N=14)
Mean Age (years)	50.5	50.0	54.0
Mean BMI (kg/m ²)	36.7	36.5	34.7
Diabetes (%)	53.3	73.3	64.3
Hypertension (%)	73.3	60.0	57.1
Mean ALT (U/L)	49.5	58.7	53.3
Mean AST (U/L)	35.9	34.3	30.9
Mean fibrosis stage**	2.1	1.4	1.4
Mean NAFLD Activity Score	4.7	5.0	4.6

*Biopsy Set, defined as subjects with available biopsy data at baseline and EOS

**NASH CRN scoring

Primary Endpoint Met – Change in Liver Fat by MRI-PDFF at Week 12

Both LPCN 1144 Treatments Resulted in Significant Reductions in Liver Fat



Key NASH Biopsy Outcomes¹ : NASH CRN Scoring

Treatments Met NASH Resolution with No Worsening of Fibrosis End Point

	Placebo (N = 11)	Treatment A (N = 13)	Treatment B (N = 13)
NASH Resolution Responders, n (%) ²	1 (9%)	7 (54%)*	9 (69%)**
NASH Resolution with No Worsening of Fibrosis Responders, n (%)	0 (0%)	6 (46%)*	9 (69%***)

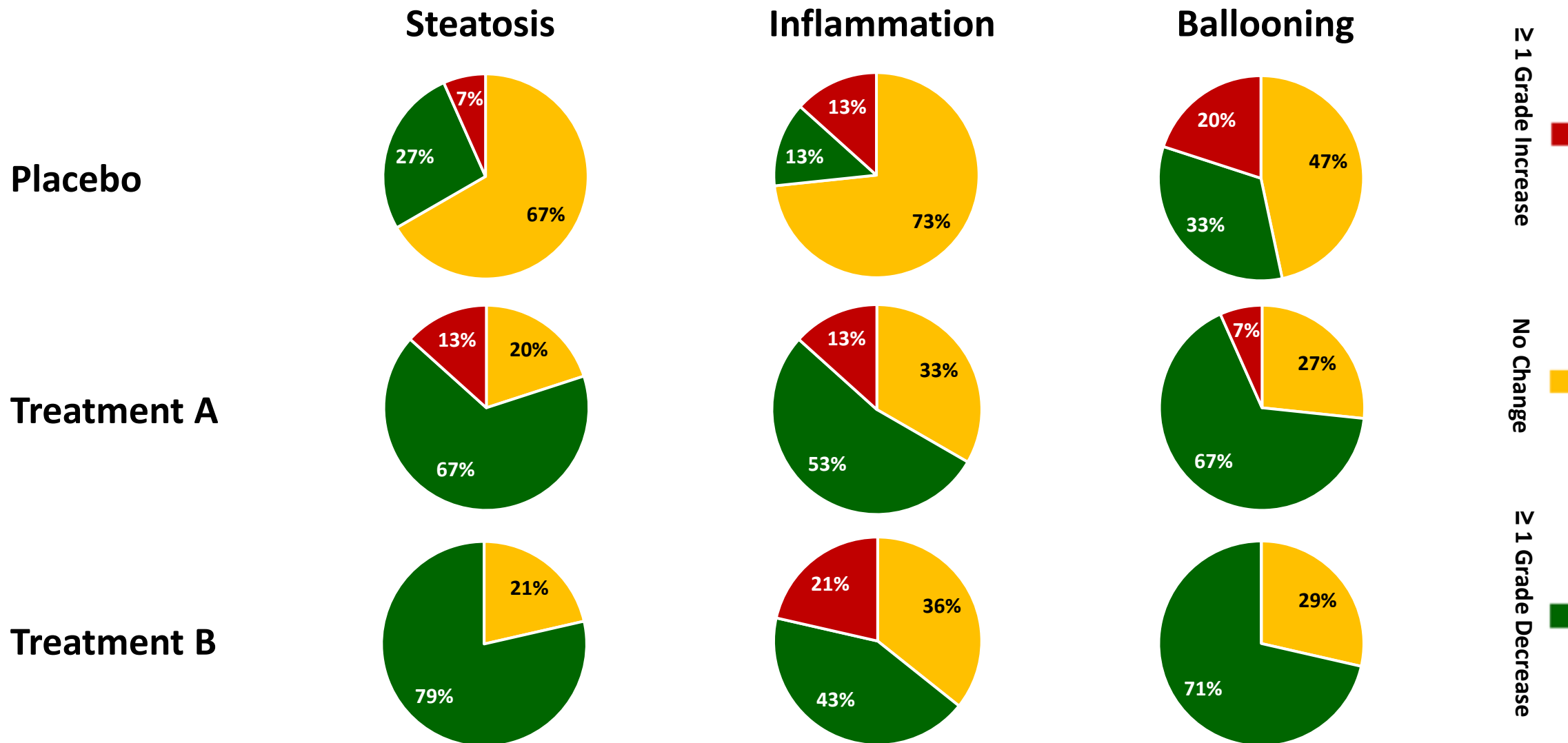
* p < 0.05 vs placebo; ** p < 0.01 vs placebo, *** p < 0.001 vs placebo

1 NASH Resolution Set includes those subjects with baseline and EOS biopsy and with NASH at baseline (NAS ≥ 4 with lobular inflammation score ≥ 1 and hepatocyte ballooning score ≥ 1) per FDA Phase 3 guidance

2 NASH resolution is defined per FDA guidance as lobular inflammation score = 0 or 1 and hepatocyte ballooning score = 0

Histological Changes in NASH Components: NASH CRN Scoring

Substantial Improvement in All NASH Components from Baseline



Key NASH Biopsy Outcomes ¹ : Paired Read Analysis

Paired Biopsy Analysis Concurs with NASH CRN Findings

	Placebo (N = 15)	Treatment A (N = 15)	Treatment B (N = 14)
Improvement in NASH ² Responders, n (%)	2 (13%)	9 (60%)*	8 (57%)*
Improvement in NASH with No Worsening of Fibrosis Responders, n (%)	2 (13%)	9 (60%)*	8 (57%)*

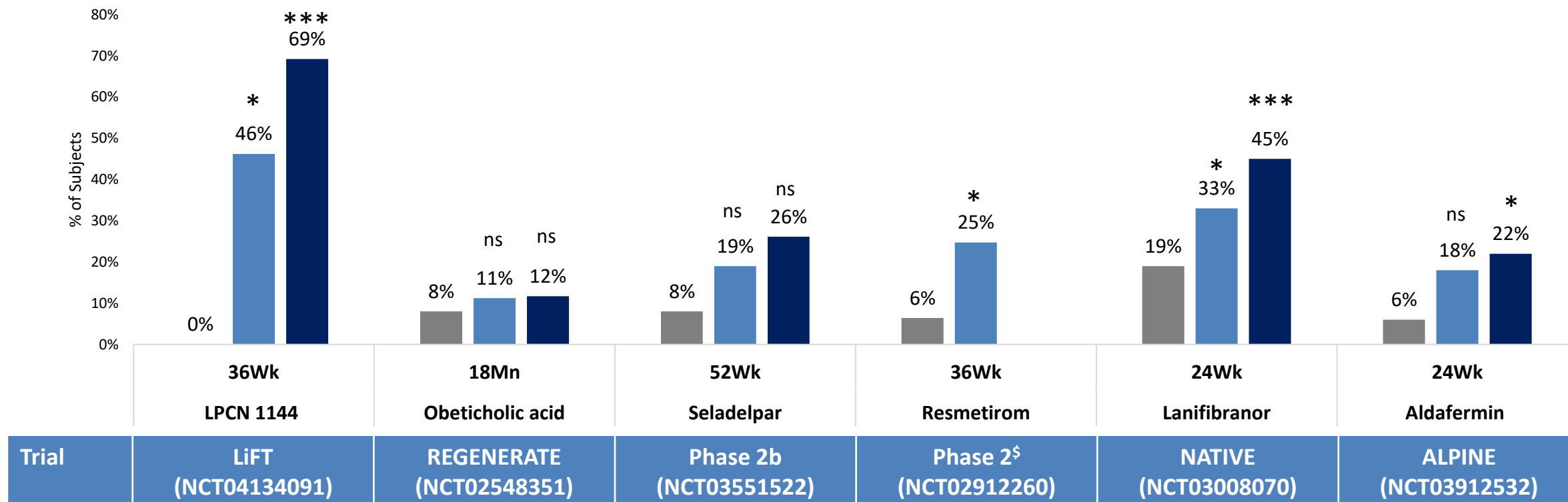
* p < 0.05 vs. placebo

Resolution of NASH with No Worsening of Fibrosis

Comparison† with Other Drug Candidates

■ Placebo ■ Dose/Treatment 1 ■ Dose/Treatment 2

* $p < 0.05$, *** $p < 0.001$ vs placebo



† Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations. No head-to-head clinical trials have been conducted.

§ Reduction 2-point on NAS or resolution of NASH without worsening of fibrosis with at least a 2-pt reduction in NAS

Fibrosis Outcomes Across Biopsy Assessment Techniques¹

Treatment Effects on Fibrosis Improvement Needs Confirmation in a Larger Study

Histopathological Assessment Techniques	Placebo (N = 15)	Treatment A (N = 15)	Treatment B (N = 14)
NASH CRN: Fibrosis Improvement \geq 1 Stage with No Worsening of NASH Responders, n (%)	6 (40%) [†]	4 (27%)	2 (14%)
Paired Reads: Fibrosis Improvement with No Worsening of NASH ² Responders, n (%)	3 (20%)	6 (40%)	8 (57%)
Digital Reads (FibroNest): Fibrosis Improvement ³ Responders, n (%)	5 (33%)	12 (80%)	6 (43%)

¹ Biopsy Set defined as all subjects with baseline and EOS biopsy

² Fibrosis improvement on paired reads defined as a score of improvement in fibrosis with a score of no worsening of ballooning, inflammation, or steatosis

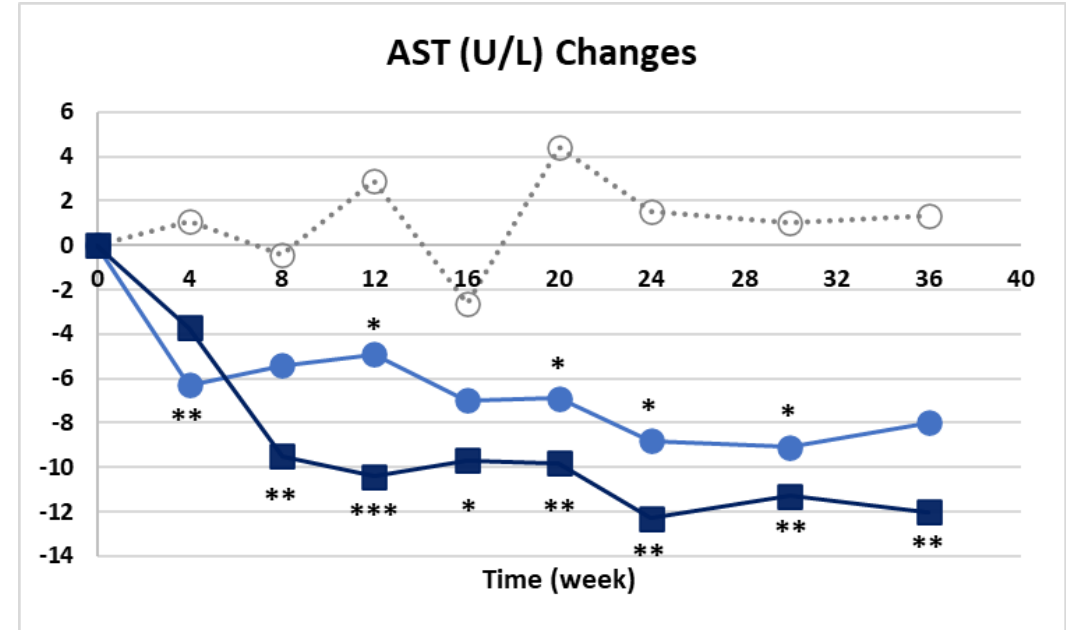
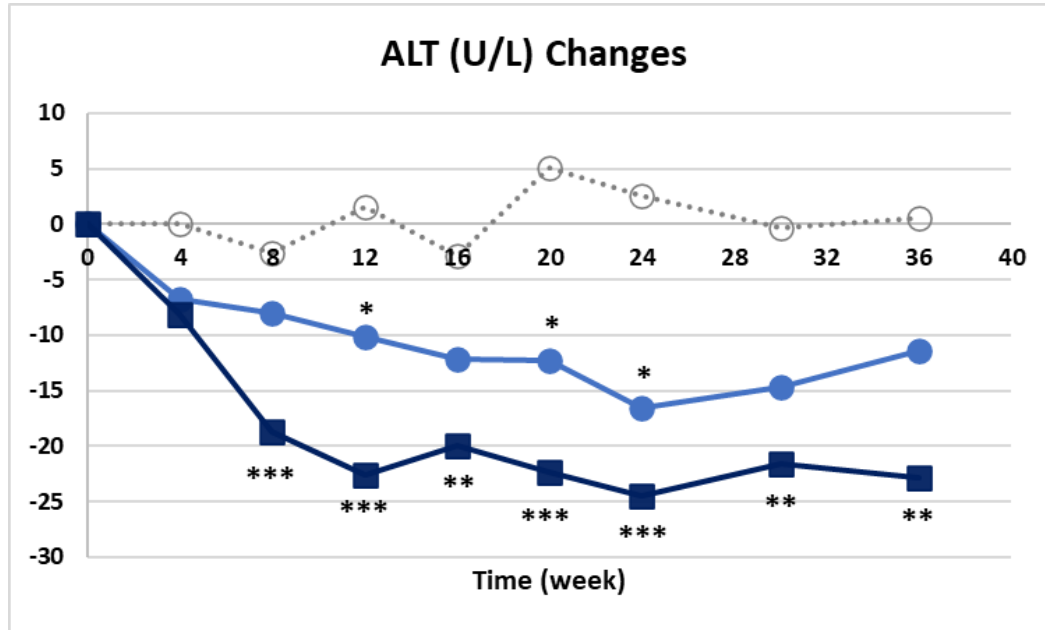
³ For Digital Reads (FibroNest - <http://www.fibronest.com>), improvement defined as a decrease in parenchymal tissue normalized phenotypic fibrosis composite score

[†] One subject in placebo is missing NASH CRN fibrosis score and is treated as a non-responder

Key Liver Injury Markers†

Early and Sustained Reductions in ALT and AST Support Beneficial Liver Effects

---○--- Placebo ●--- Treatment A ■--- Treatment B



	Placebo (N=19)	Treatment A (N=18)	Treatment B (N=19)
Mean Baseline	49.0 U/L	53.9 U/L	51.5 U/L

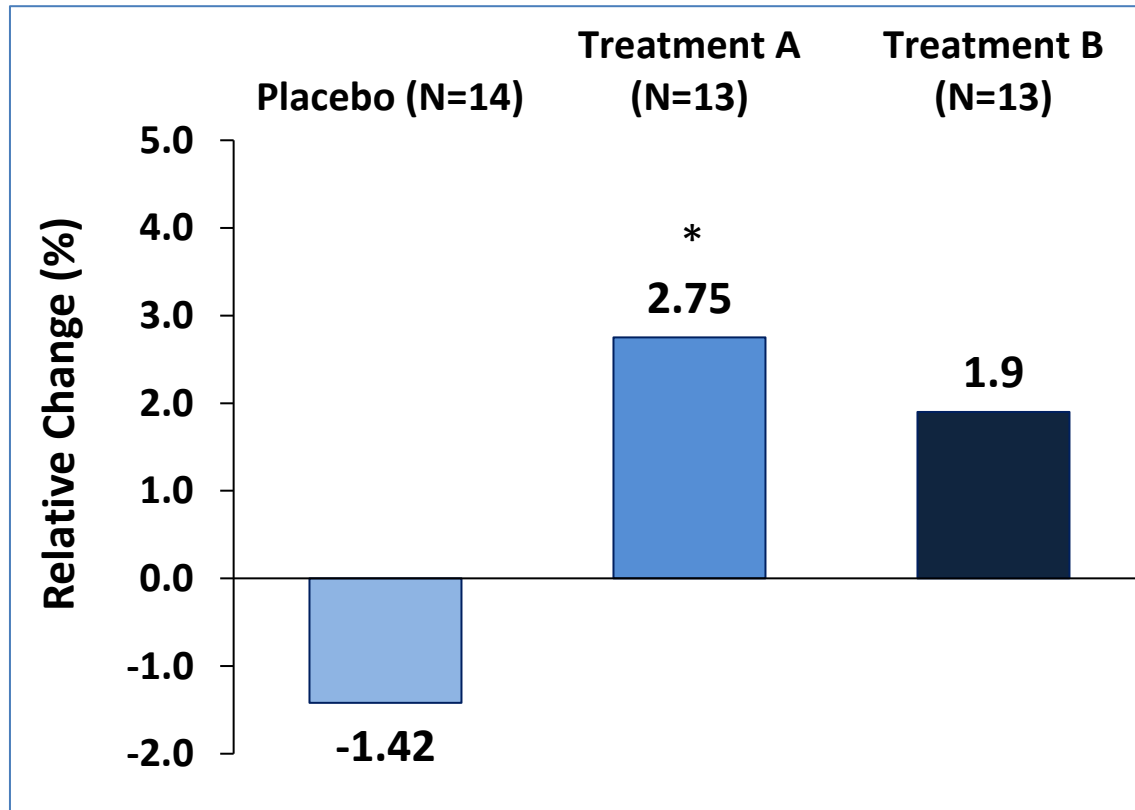
	Placebo (N=19)	Treatment A (N=18)	Treatment B (N=19)
Mean Baseline	35.4 U/L	32.4 U/L	31.9 U/L

* p < 0.05; ** p < 0.01; *** p < 0.001 vs placebo

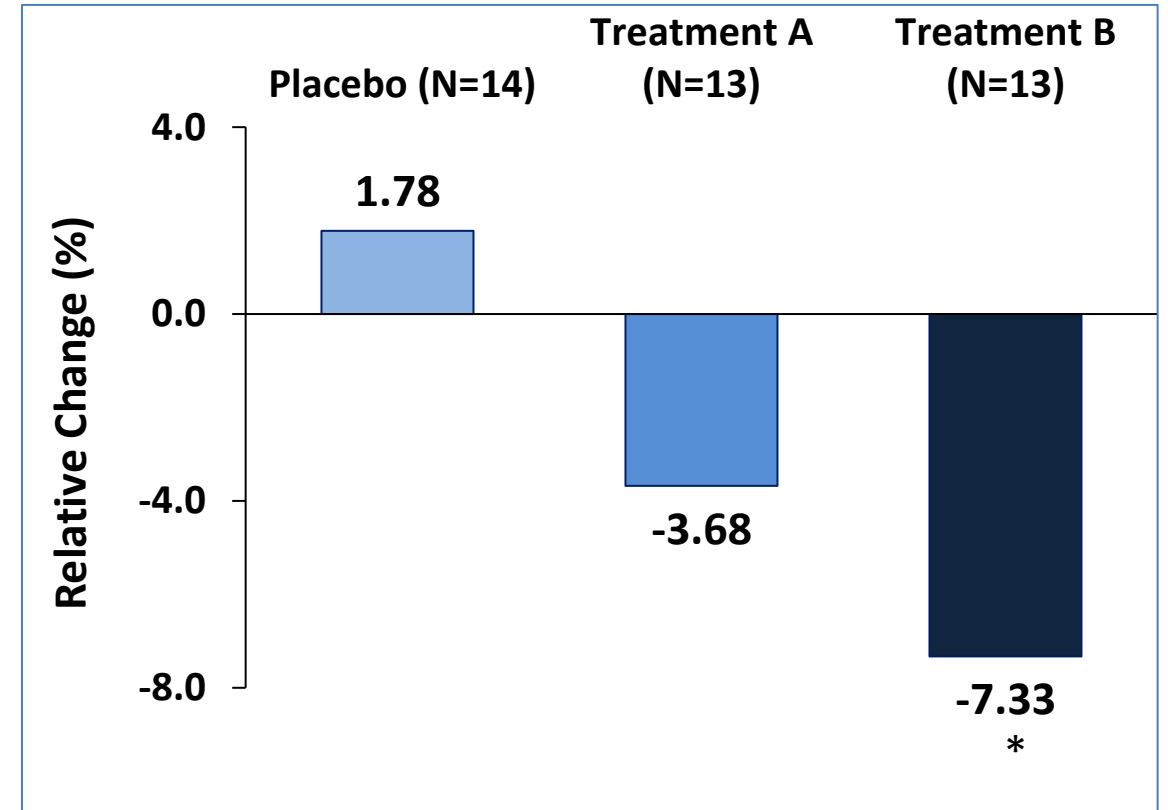
Body Composition Changes

Positive Effects in Both Treatment Arms

Relative Change in Appendicular Lean Mass



Relative Change in Whole Body Fat Mass



Safety Overview of LPCN 1144 Through Week 36

Well Tolerated with an Overall Safety Profile Comparable to Placebo

- Frequency and severity of TEAEs in both treatment arms were comparable to placebo
 - Study drug-related TEAEs were mild to moderate
- Discontinuance of study drug due to TEAEs
 - Four subjects in the placebo arm
 - One subject in total across the treatment arms
- Cardiovascular events were balanced among groups
 - Hematocrit increases averaged <2% in the treatment arms
 - No thromboembolic events were observed
 - Blood pressure changes in both treatment arms were comparable to placebo
- No reported cases of hepatocellular carcinoma or Drug Induced Liver Injury (“DILI”)
- Weight change from baseline, GI adverse events and PSA changes were comparable among groups
- No clinically meaningful changes in lipids compared to placebo
- Rates of pedal edema were low and similar in all arms, and all cases were mild to moderate

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