

LPCN 1144

Oral Testosterone (T)
Non Alcoholic Steatohepatitis (NASH)

Forward-Looking Statements

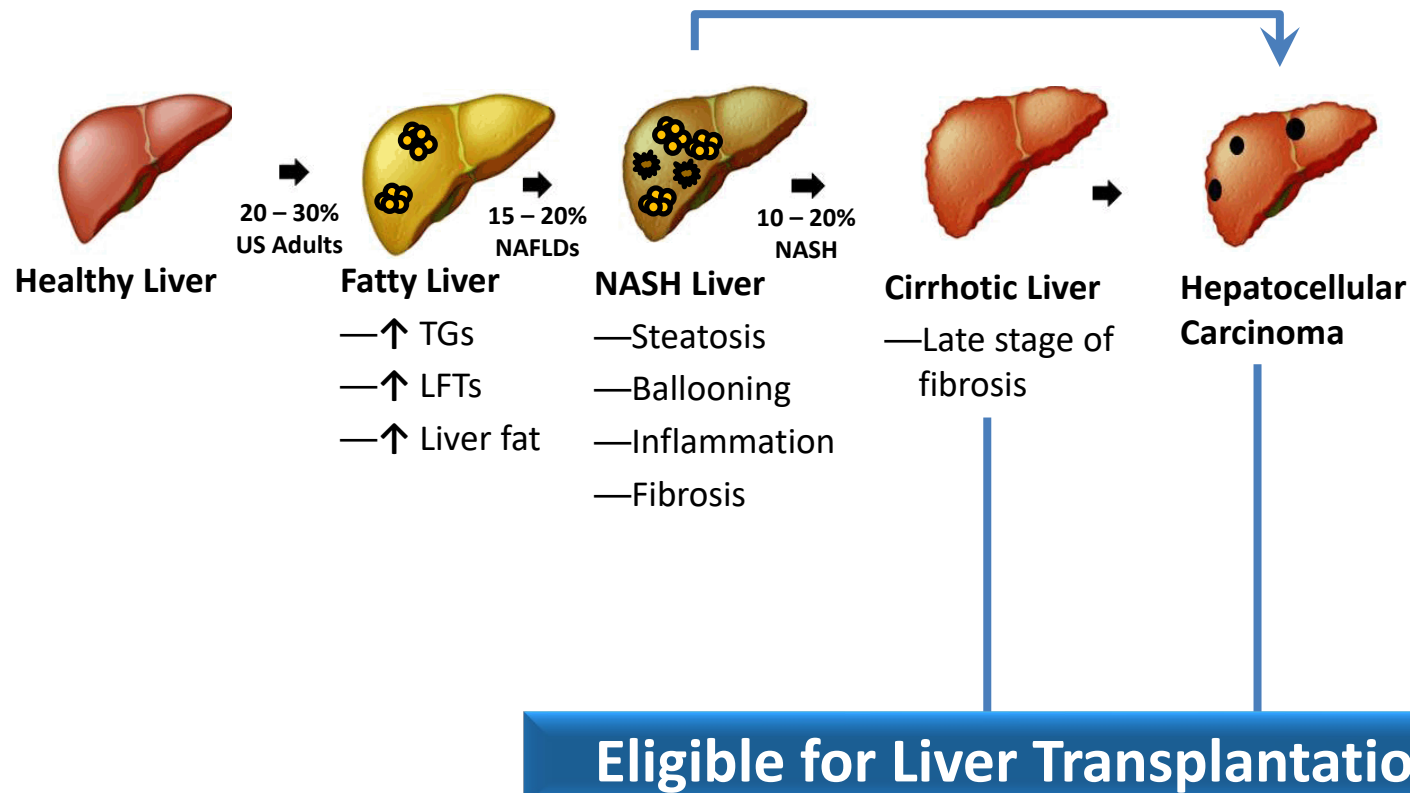
This presentation contains forward-looking statements about Lipocine Inc. (the “Company”). These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to the Company’s product candidates, the expected timing of the resubmission of the NDA for TLANDO, FDA review process related to our resubmitted NDA for TLANDO™, the expected timing of Phase 2 studies for LPCN 1144 and LPCN 1148, clinical and regulatory processes and objectives, potential benefits of the Company’s product candidates, intellectual property and related matters, 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 or on the SEC website at 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.

Non-Alcoholic Fatty Liver Disease (“NAFLD”)

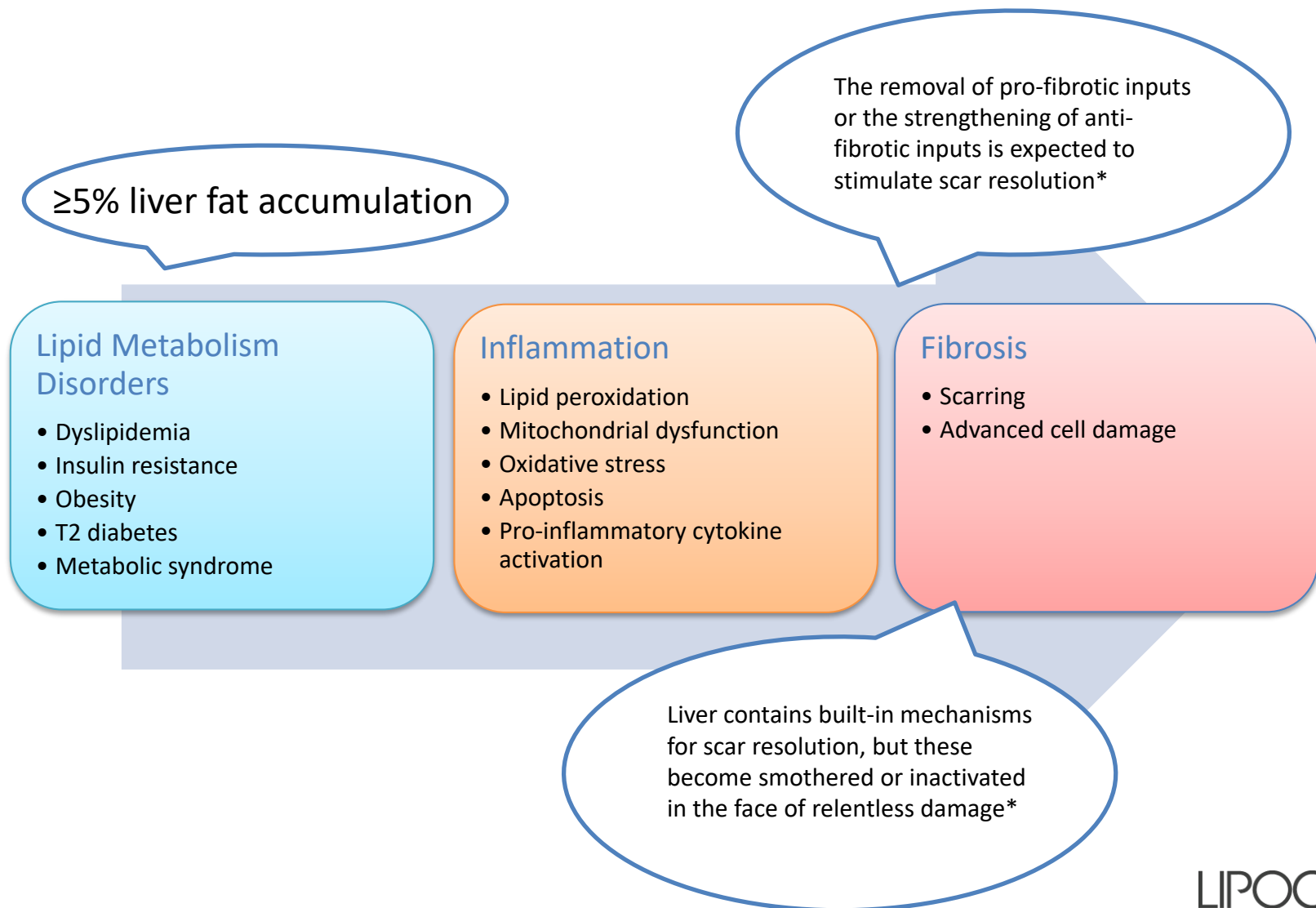
No Approved Product for the Treatment of NASH

Fatty liver is a reversible condition wherein large vacuoles of triglyceride (TG) fat accumulate in liver cells via the process of steatosis



NASH Pathogenesis

Risk Factors and Clinical Progression

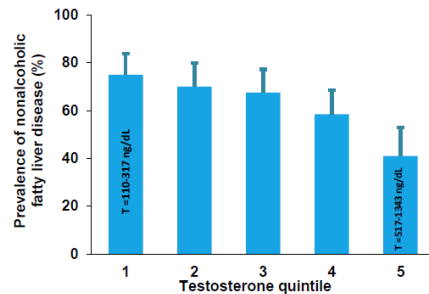
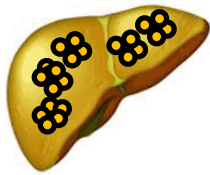


Clinical Relationship Between Testosterone and NAFLD

Across the Full Disease Spectrum

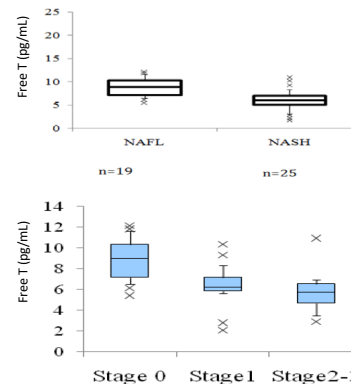
Hepatic Steatosis

“Men with low testosterone are at high risk for NAFLD.”¹



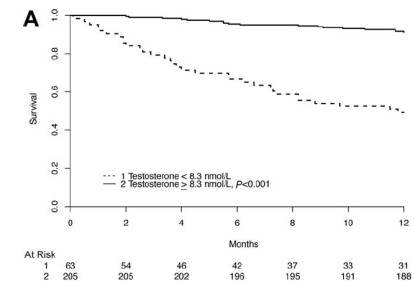
NASH

“Levels of free T decreased significantly with the increased incidence of lobular inflammation, hepatocyte ballooning, NAFLD activity score, and fibrosis.”²

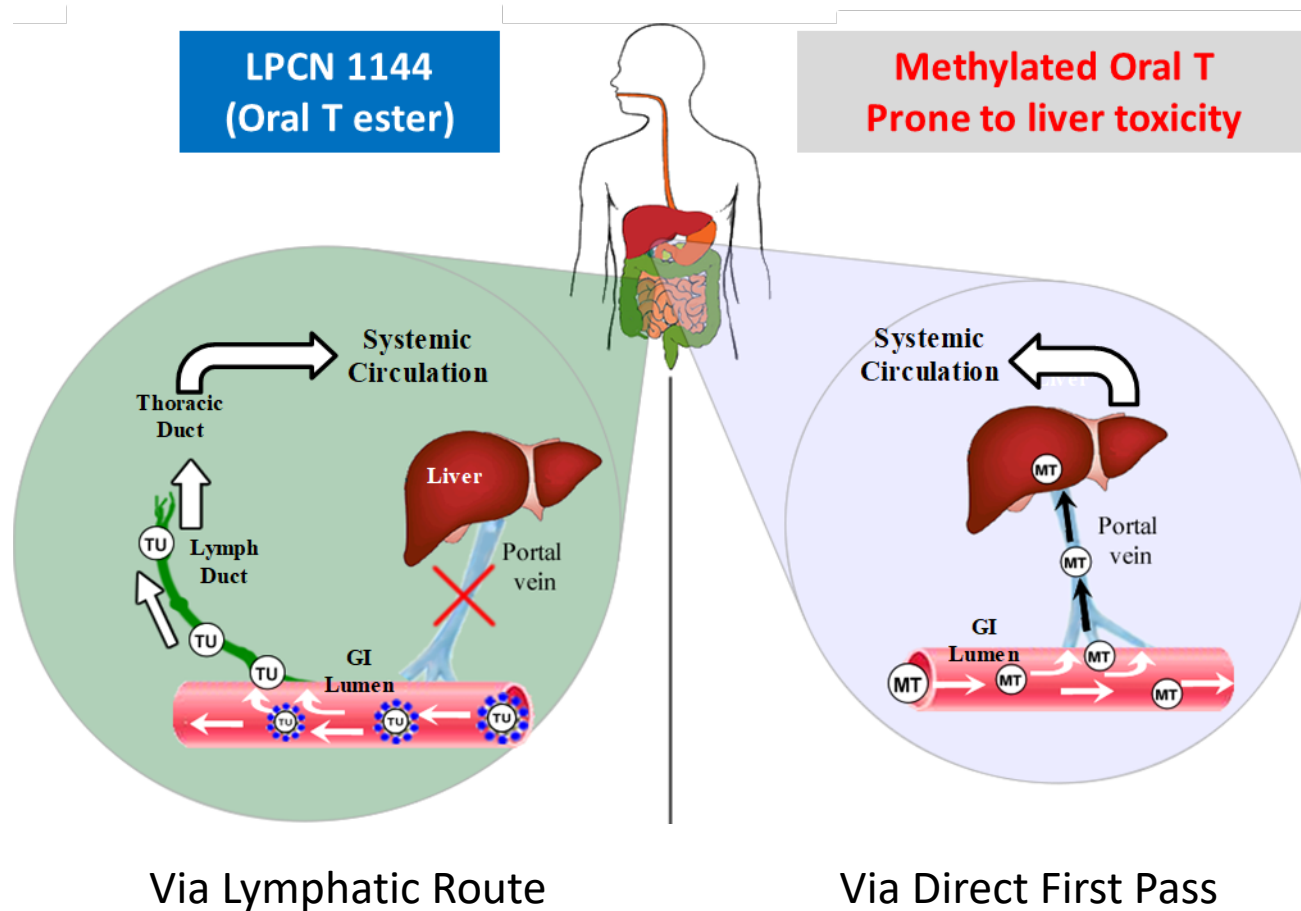


Cirrhosis

“Low T levels in cirrhotic men are associated with the combined outcome of death or transplantation.”³



LPCN 1144: Lymphatic Delivery of Oral T via Chylomicron



LPCN 1144: Oral Testosterone

Targeting The Full Spectrum of NASH Pathogenesis

A Differentiated Oral NASH Therapy Candidate

- Well tolerated - suitable for chronic use
- Favorable benefits outside the liver

Clinical Data to Advance in Phase 2 Testing

- Meaningful liver fat reductions as early as eight weeks and we believe the potential to improve upon longer treatment duration
- Substantial reductions in key elevated serum markers
- We believe there is potential for histological improvement in NASH patients

LPCN 1144: Multidimensional Mechanism of Action


Across the Full Spectrum of NASH Pathogenesis

Homeostasis Modifier ^{1, 2}	Anti-inflammatory ² / Antioxidant/Immuno- modulator ³	Regeneration Booster ^{5,6}	Anabolic Agent ⁹
<ul style="list-style-type: none">• Alter lipid, cholesterol, and glucose metabolism• Reduce visceral abdominal fat• Modify activity of hepatic lipase, and skeletal muscle/adipose lipoprotein lipase	<ul style="list-style-type: none">• Restore mitochondrial turnover and normalizes oxygen consumption⁴	<ul style="list-style-type: none">• Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation⁷• Increases circulating endothelial progenitor cells ("EPC")⁸	<ul style="list-style-type: none">• Increase muscle mass, bone density in men with liver disease¹⁰

1. Shen and Shi, Int J Endocrinol, 2015; 2. Kelly and Jones, J Endocrinol, 2013 ;
3. Sinclair et al., J Gastroenterol Hepatol, 2015; 4. Linda Vignozzi et al., University of Florence, IT, unpublished, 2018;
5. A. Francavilla et al., Digest Dis Sci, 1989; 6. Vic et al., Hepatol 1982;
7. Sinha-Hikim et al., J Clin Endocrinol Metab, 2004; 8. Liao CH et al., Andrology, 2013.
9. Gentile MA et al., J Mol Endocrine, 2010; 10. Sinclair et al., J Gastroenterol Hepatol 2016;

LPCN 1144: A Differentiated Oral NASH Therapy Candidate

Prodrug of Endogenous Testosterone

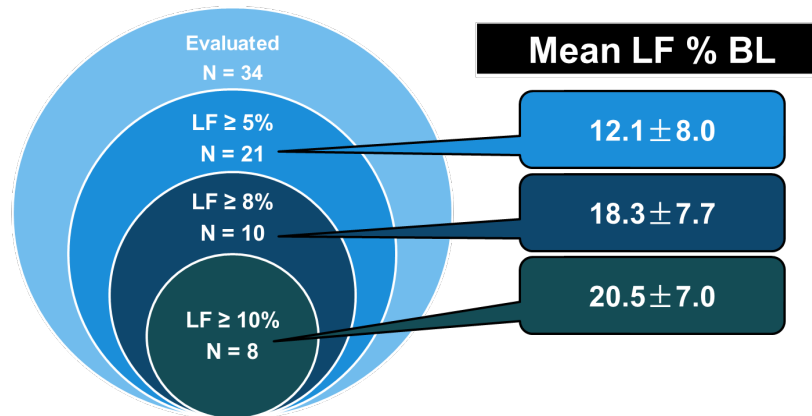
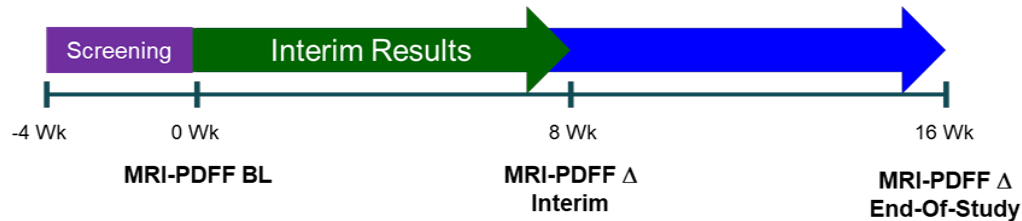


Liver Fat Reduction and Key Serum Biomarkers	<ul style="list-style-type: none">• Over 40% relative mean liver fat reduction after 16-weeks of treatment• 48% of the treated NAFLD subjects had NAFLD resolution, defined as < 5% liver fat
Potential Favorable Benefits in Systems Outside the Liver	<ul style="list-style-type: none">• T therapy known to improve muscle mass, bone density, hemopoiesis, sexual/mood dysfunction
Suitable for Chronic Use	<ul style="list-style-type: none">• Good GI tolerability• No mean LDL increase• No signs of nephrotoxicity• No signs of skeletal fragility• No signs of drug induced liver toxicity

LPCN 1144: Liver Fat Imaging Study (“LFS”)

Study Design and Baseline Liver Fat Subject Distribution

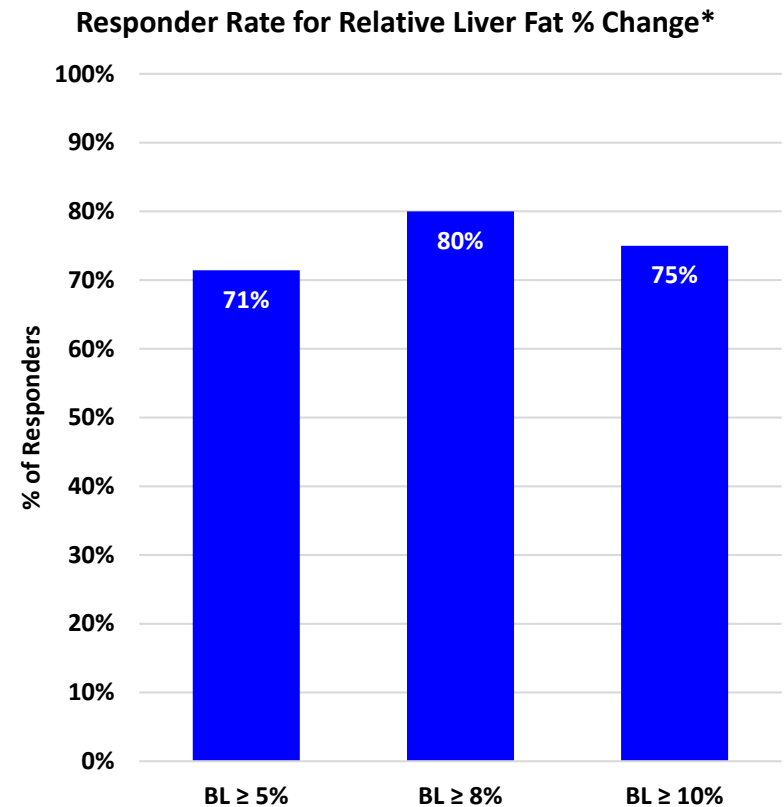
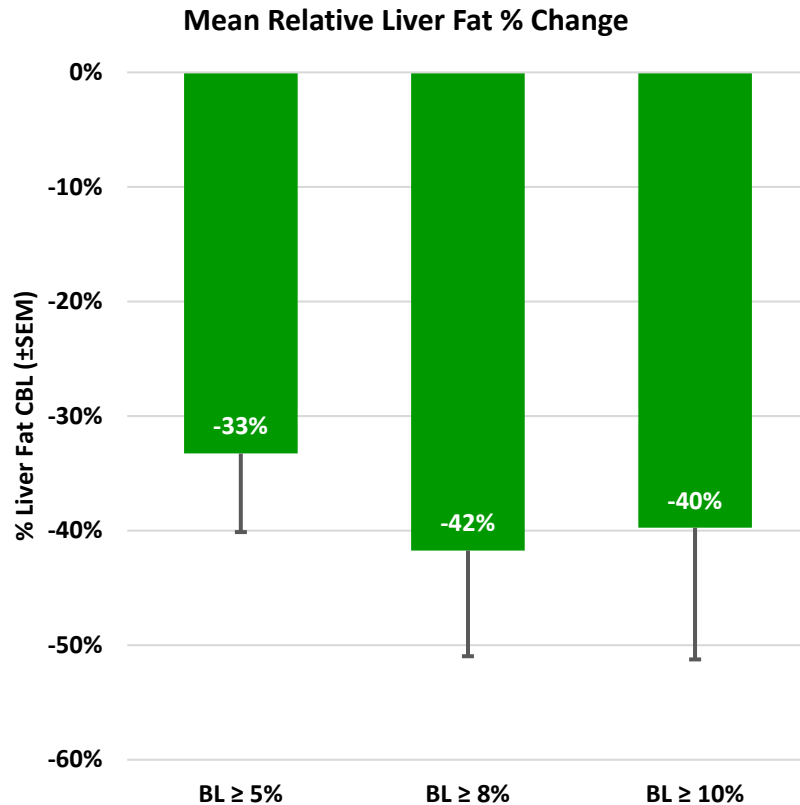
LFS was an open-label, multi-center single-arm 16-week study (N=36) with LPCN 1144 in hypogonadal males



LF = liver fat

LPCN 1144: Liver Fat Study Results

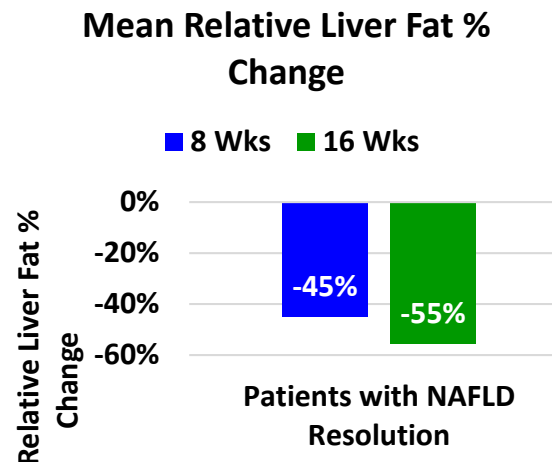
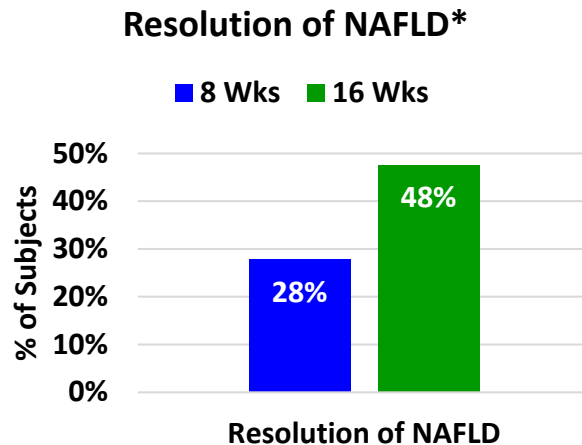
Meaningful Relative Liver Fat % Change and Responder Rate



* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.

LPCN 1144: Liver Fat Study Results

Meaningful NAFLD Resolution and Corresponding Relative Liver Fat % Reduction



100% of patients experiencing NAFLD resolution had at least 35% of relative liver fat reduction from baseline

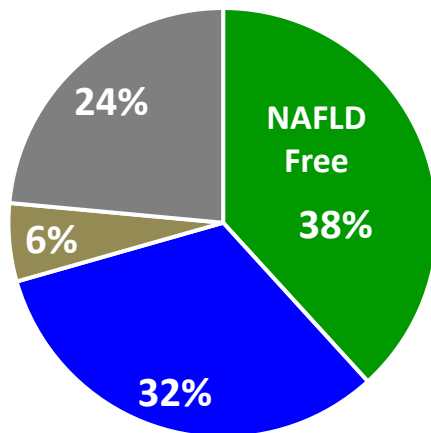
* Resolution of NAFLD is defined as when BL liver fat $\geq 5\%$ is reduced to $< 5\%$ at EOS.

LPCN 1144: Liver Fat Study Results

Liver Fat Based Subject Distribution at Each Visit

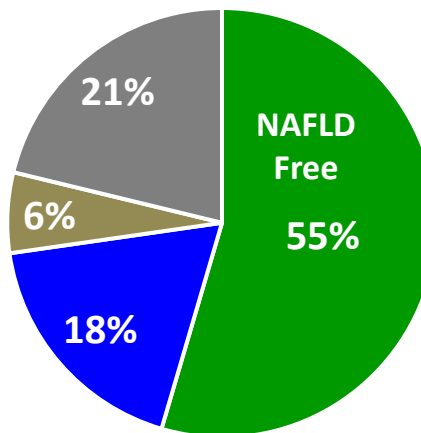
Longer Therapy Improved Liver Fat Reductions and Proportion of Subjects with Disease Resolution

Baseline Pre treatment



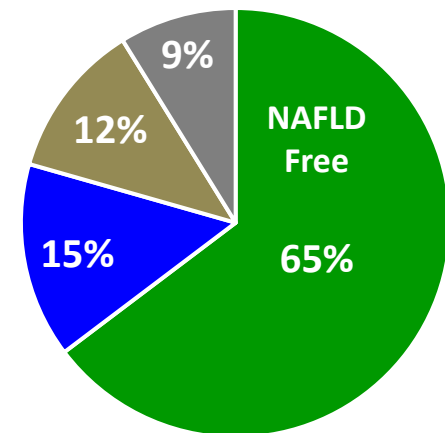
N=34

8 Week Treatment



N=33

16 Week Treatment



N=34

■ LF < 5% (NAFLD Free)

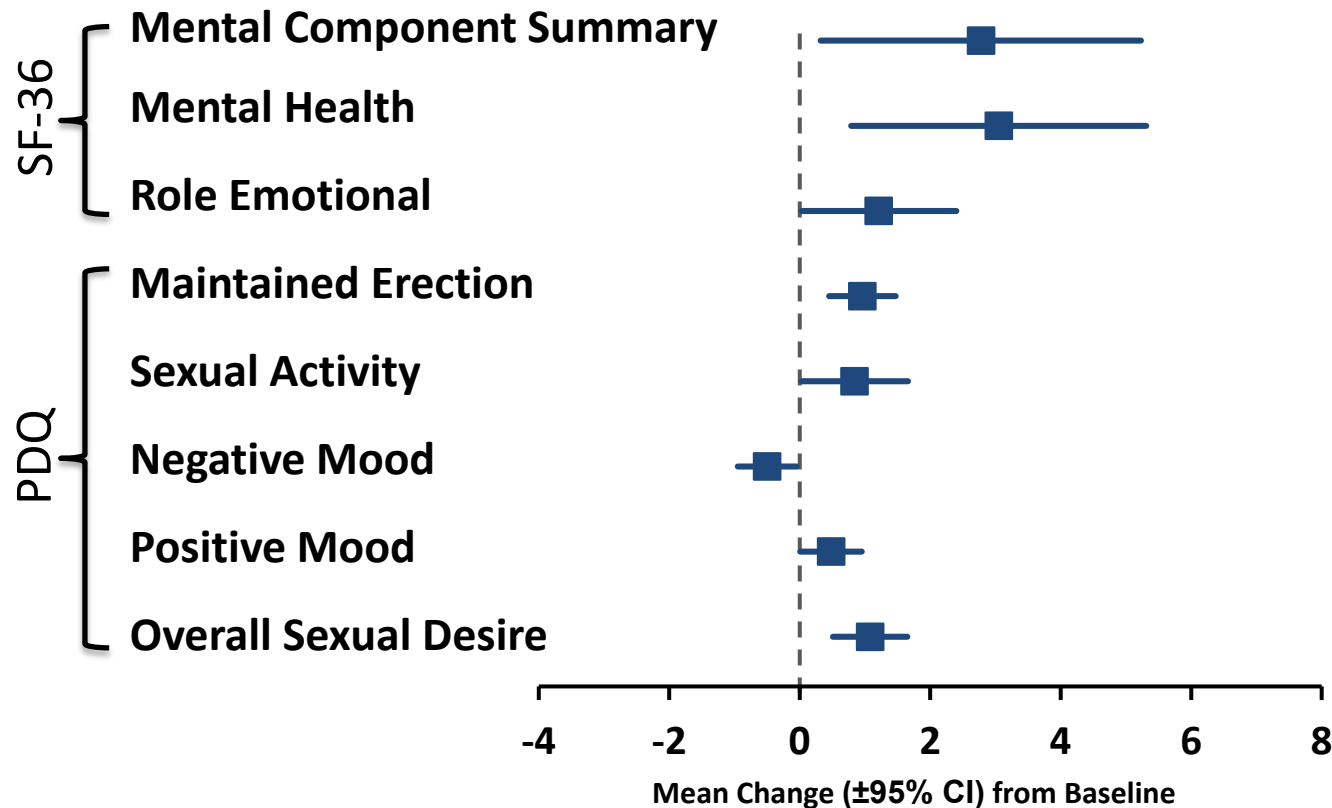
■ 5% ≤ LF < 8%

■ 8% ≤ LF < 10%

■ LF > 10%

LPCN 1144: Additional Health Benefits

Observed in Hypogonadal Subjects with Elevated ALT*



SF-36, Short Form-36 (0-100); PDQ, Psychosexual Daily Questionnaire (0-7); * ALT > 40 U/L at Baseline in 52 week SOAR Trial (N=33)

LPCN 1144: General Safety

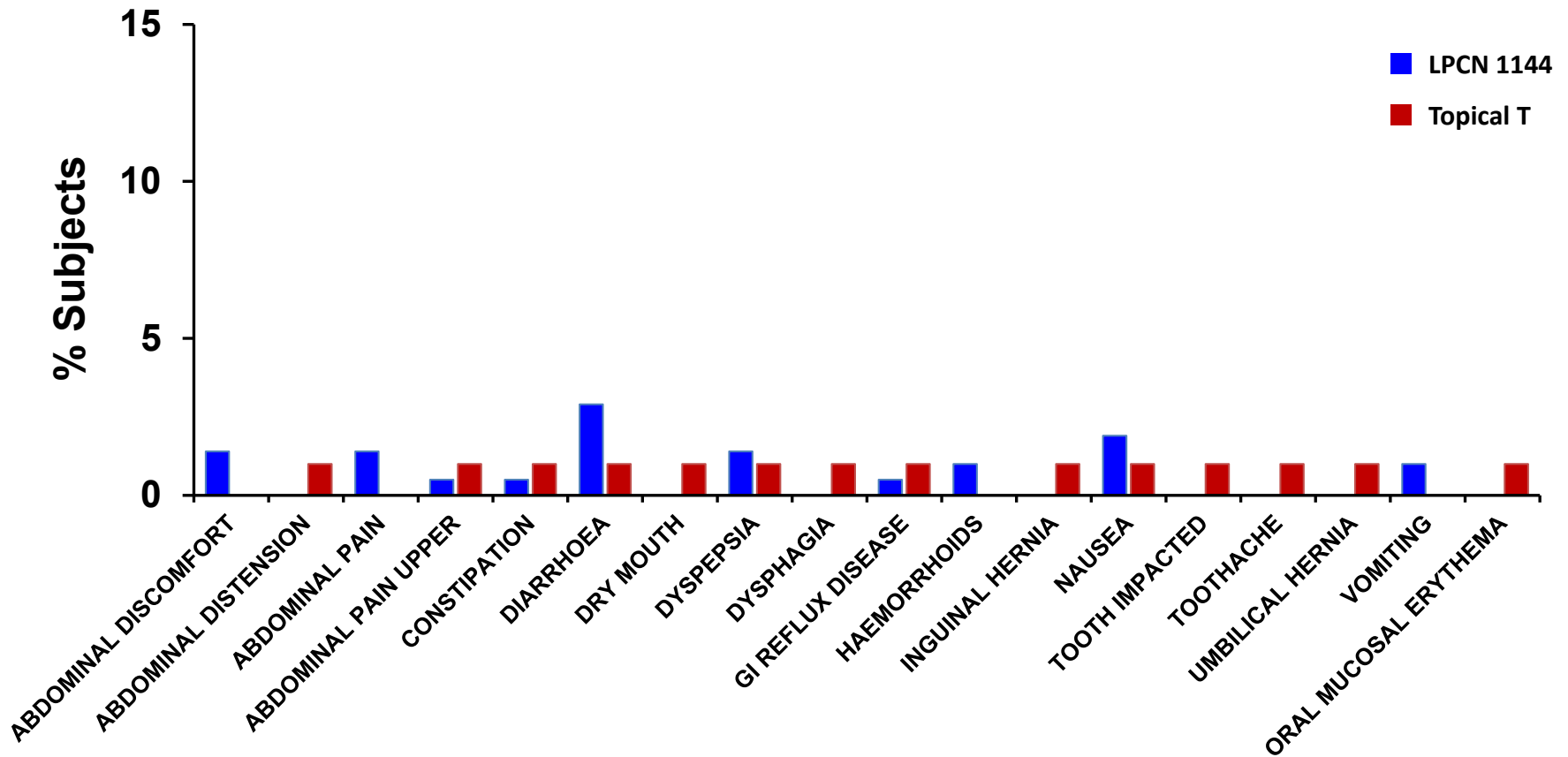
Well Tolerated

- **Extensive clinical safety database with LPCN 1144**

- 700+ subjects in 14 studies with up to 52 week exposure
- No drug related SAEs
- Safety profile well-characterized and demonstrated no unexpected risks
- Good gastrointestinal tolerability with no signs of skeletal fragility or nephrotoxicity
- No signs of drug induced liver enzyme toxicity, no deaths or MACE events

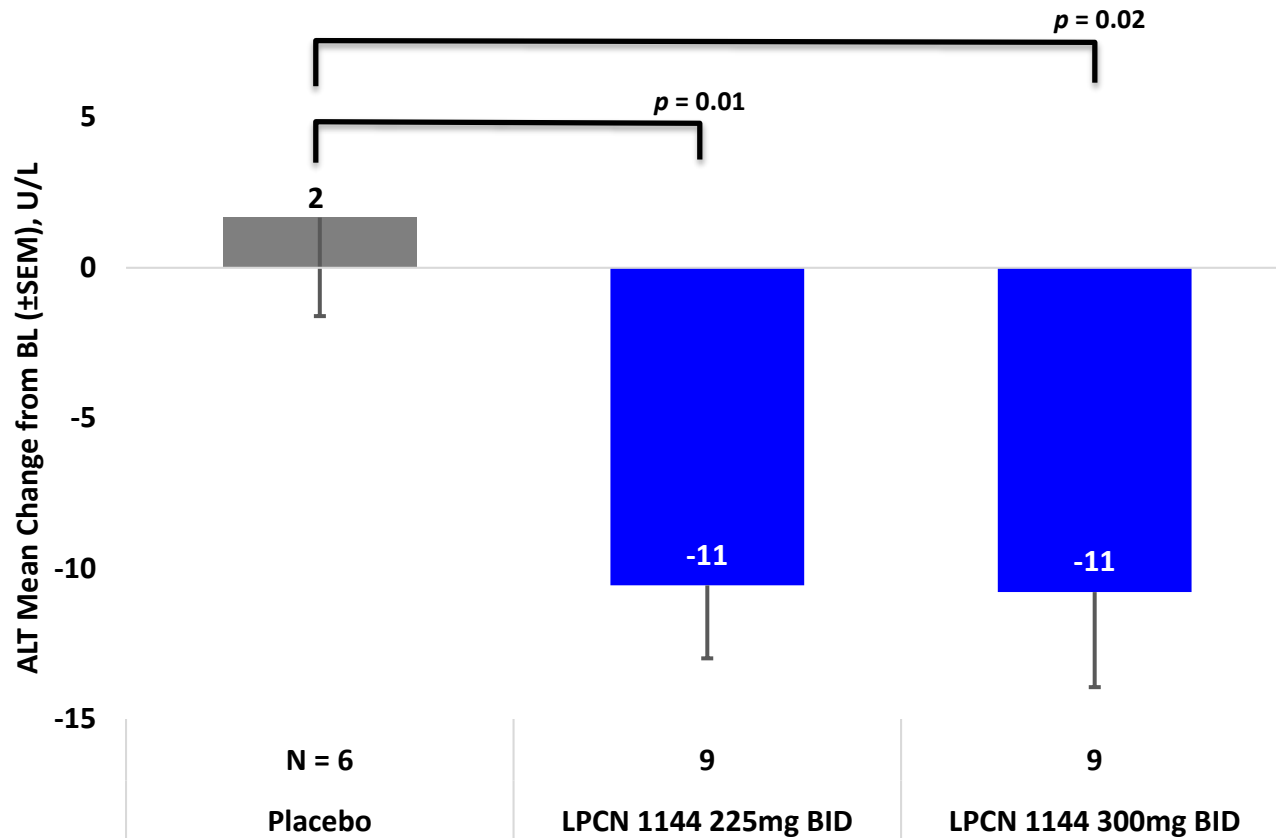
LPCN 1144: Gastrointestinal Safety

Gastrointestinal Disorders $\geq 1\%$ in SOAR Trial (52 Weeks)



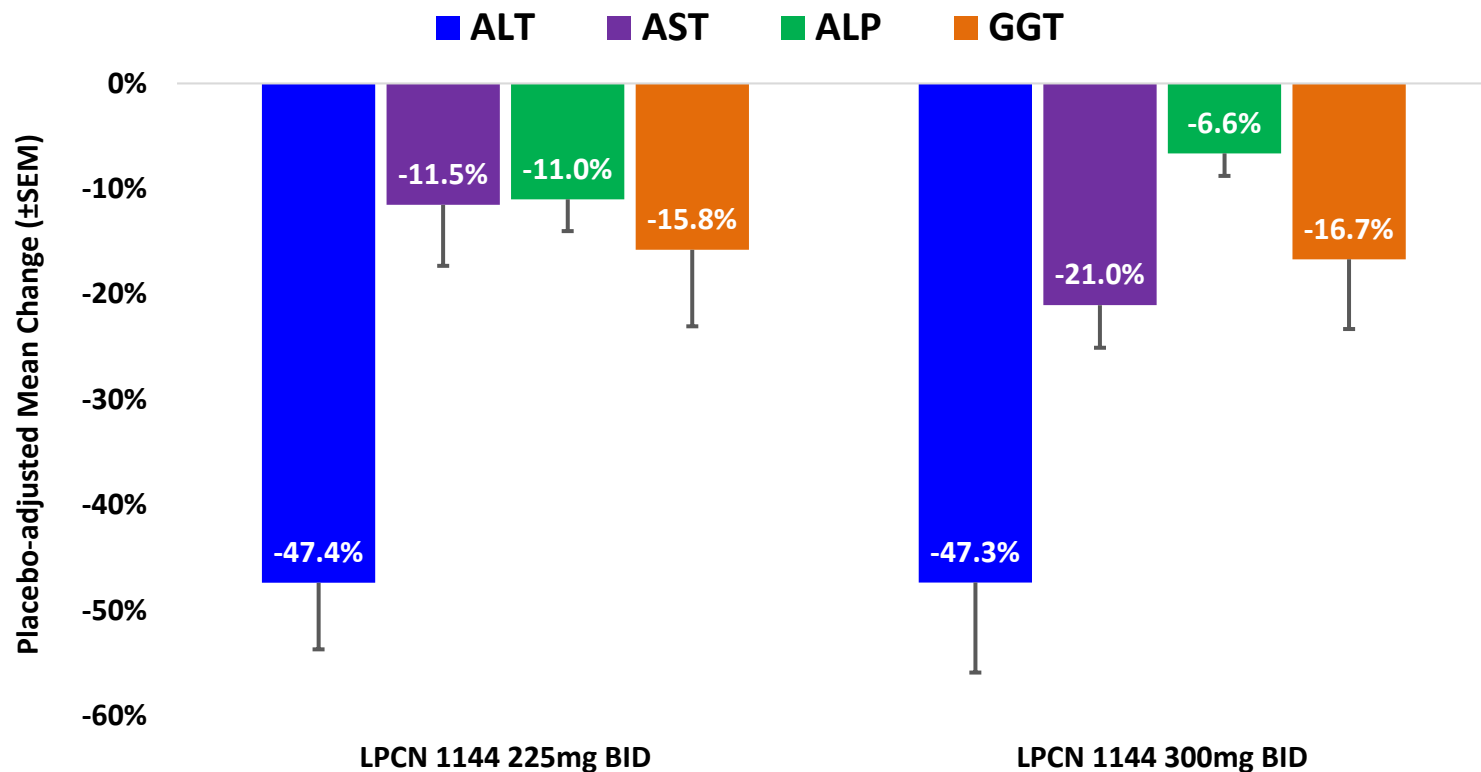
LPCN 1144: Significant Reduction in ALT Levels

- Placebo Controlled 4 Week Study (M12-778)



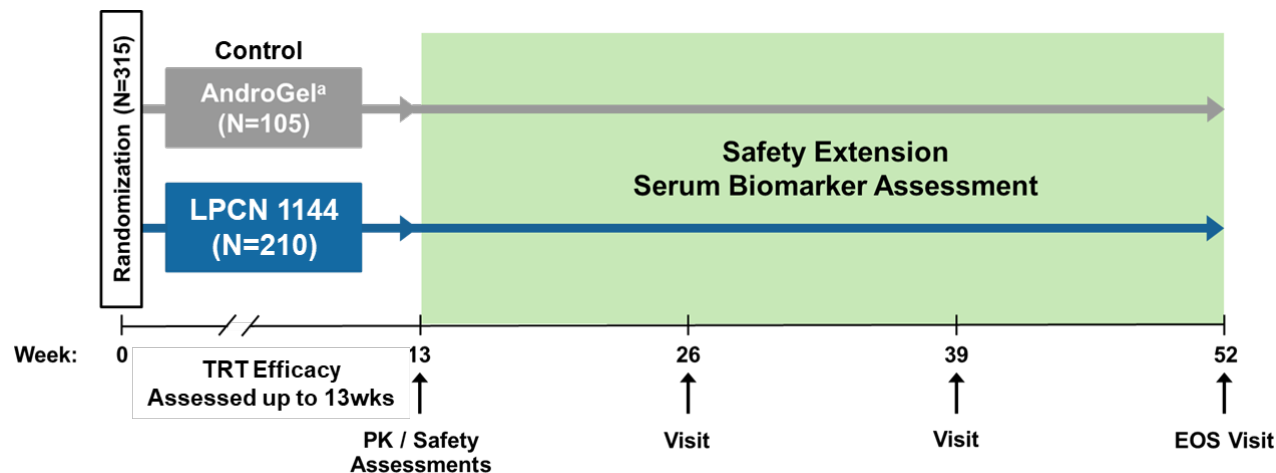
LPCN 1144: Reduction in Liver Enzyme Levels

- Placebo Controlled 4 Week Study (M12-778)



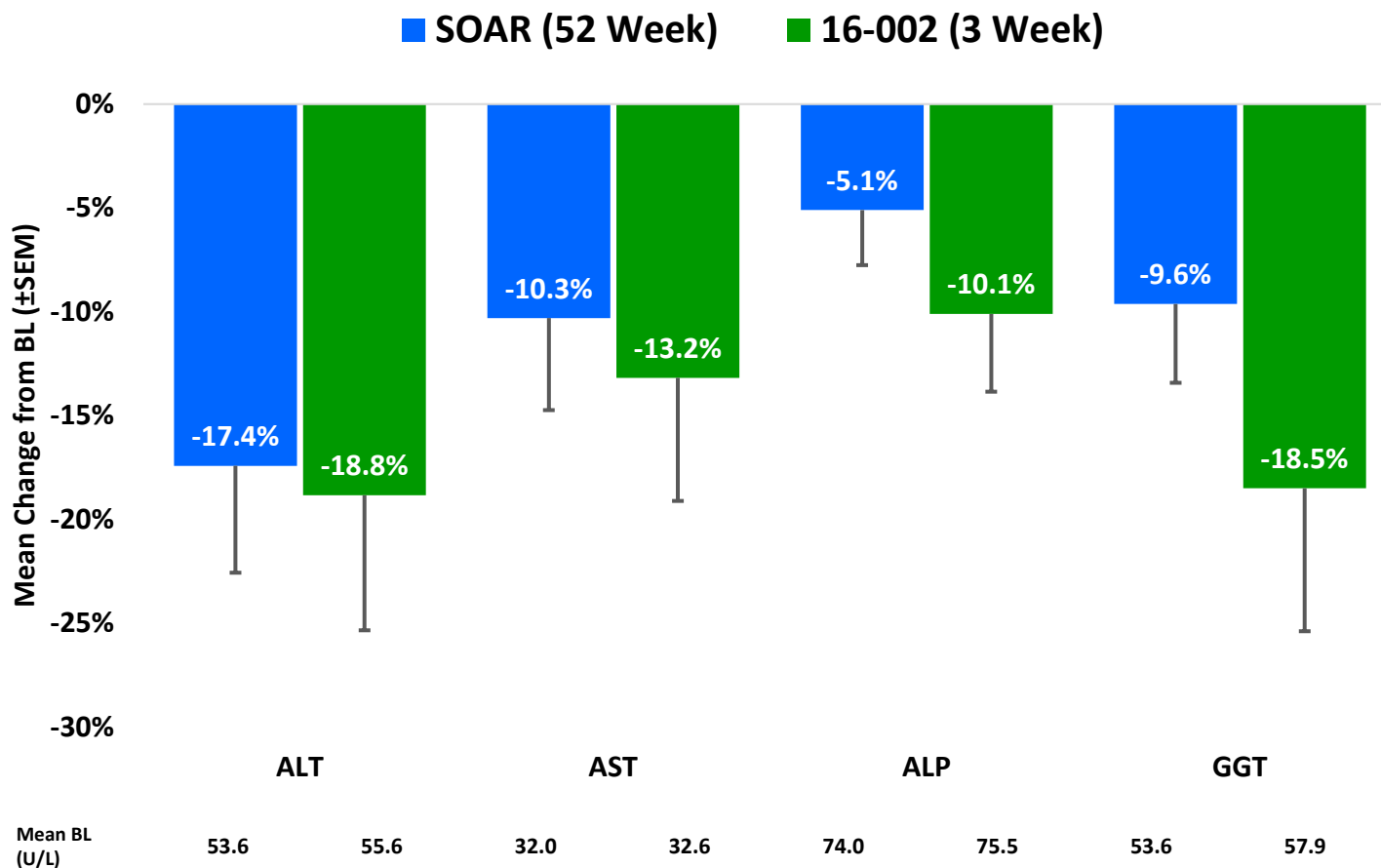
LPCN 1144: Post-hoc Analysis Methods

- Analyses were performed involving hypogonadal male cohorts with baseline liver enzymes* and lipids**
 - Active-controlled, randomized, open label study (SOAR) NCT02081300, (N=210) with 52 week treatment - 225mg \pm 75mg BID
 - Treatment arm: LPCN 1144
 - Control arm: Topical T Gel



LPCN 1144: Consistent Liver Function Improvement Across Studies*

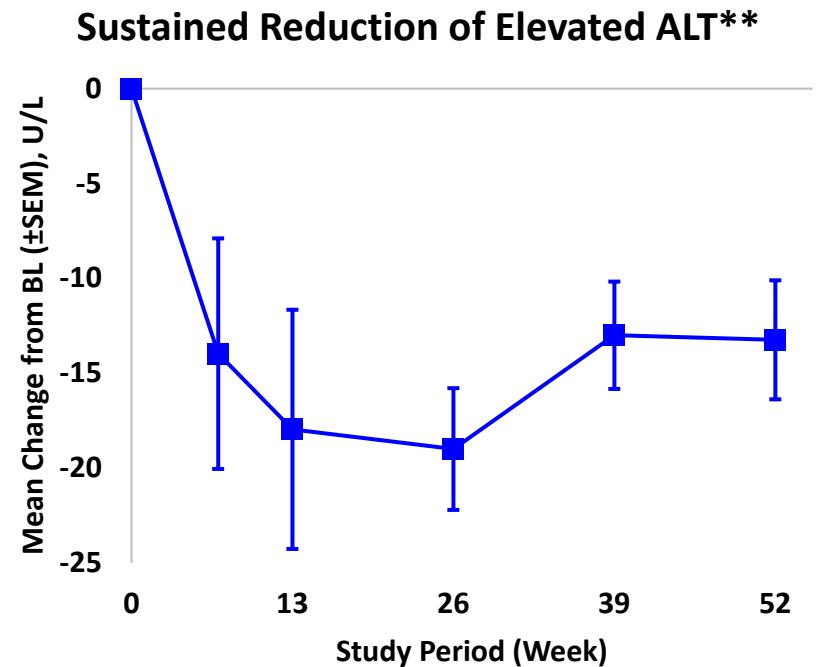
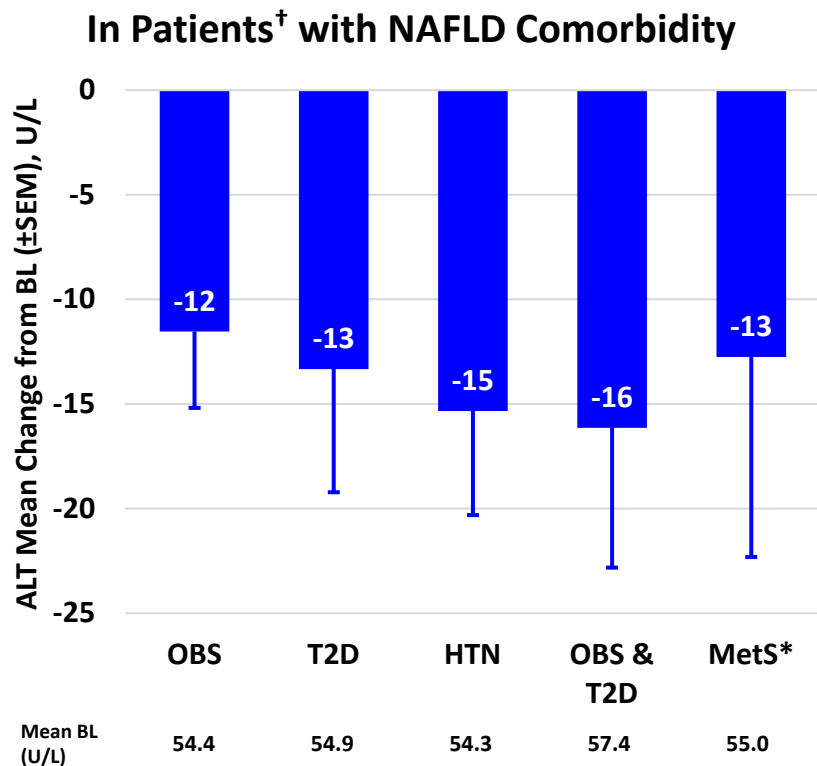
Effect Observed as Early as 3 Weeks



• LPCN 1144 Patients for ALT > 40 U/L at BL; SOAR (NCT02081300), N=42, 16-002 (NCT03242590), N=13;

LPCN 1144: Reductions of Elevated ALT in Patients at Risk of NAFLD

■ Active Controlled 52 Week Study (SOAR)



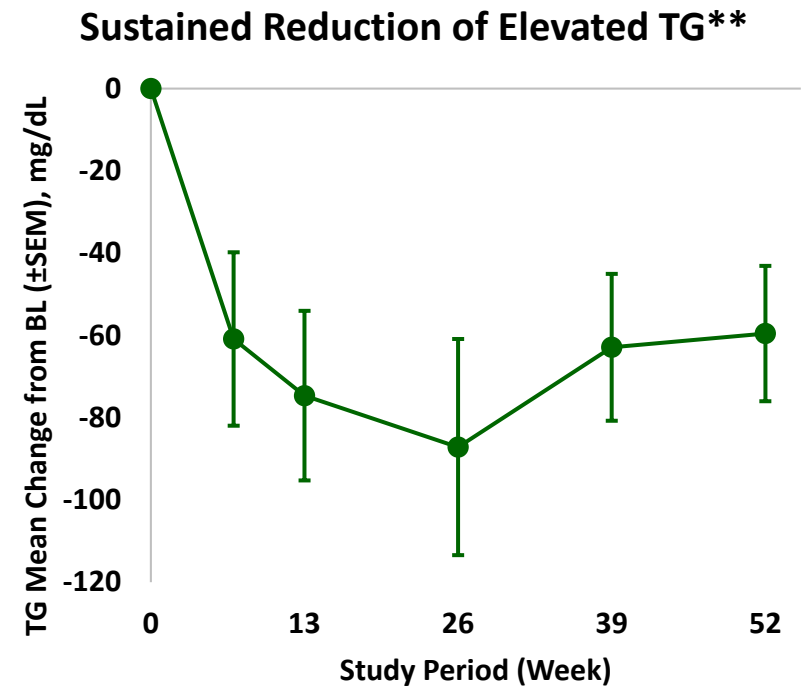
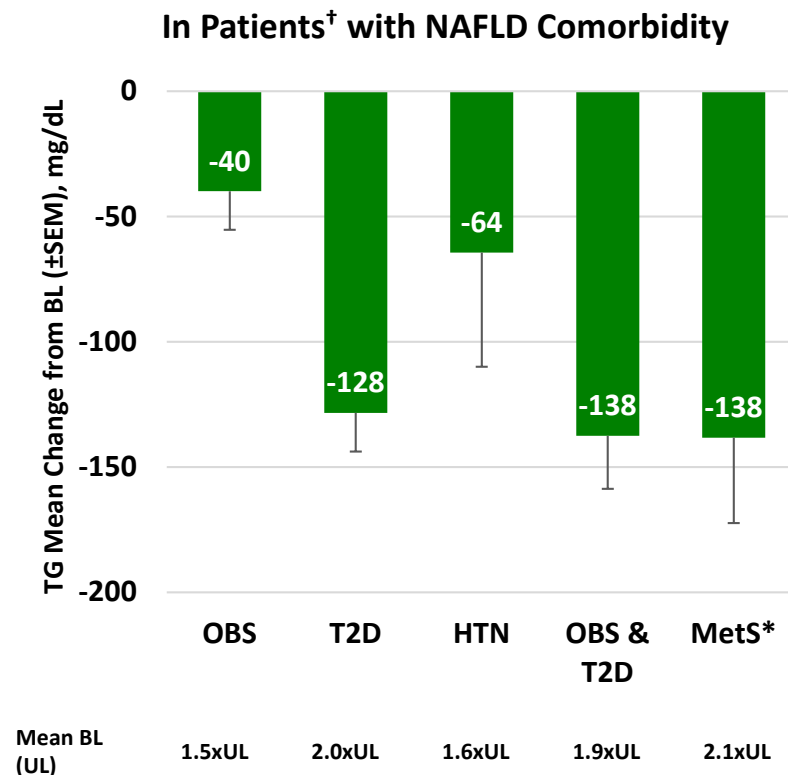
** Patients[†] with ALT > 40 U/L at BL (N=42); ALT mean BL = 53.6 U/L

† Patients with ALT > 40 U/L at BL in SOAR Trial

* Metabolic syndrome: obesity + diabetes + hypertension

LPCN 1144: Reductions of Elevated TG in Patients at Risk of NAFLD

■ Active Controlled 52 Week Study (SOAR)



** Patients[†] for TG > 200 mg/dL at BL (N=73); TG mean BL = 320 mg/dL

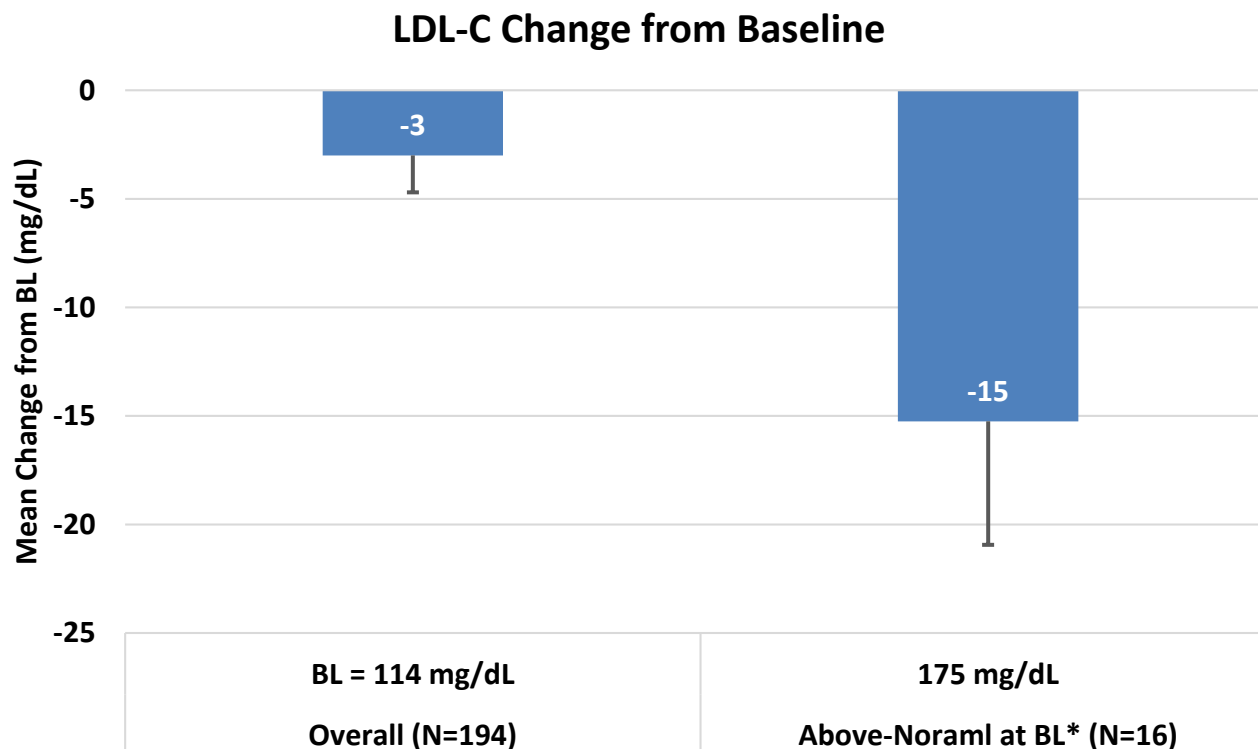
[†] Patients with TG > 200 mg/dL at BL in SOAR Trial

* Metabolic syndrome: obesity + diabetes + hypertension

LPCN 1144: Oral T

Mean LDL Reduction for Patients with Elevated LDL at Baseline

- 52 Week SOAR Trial

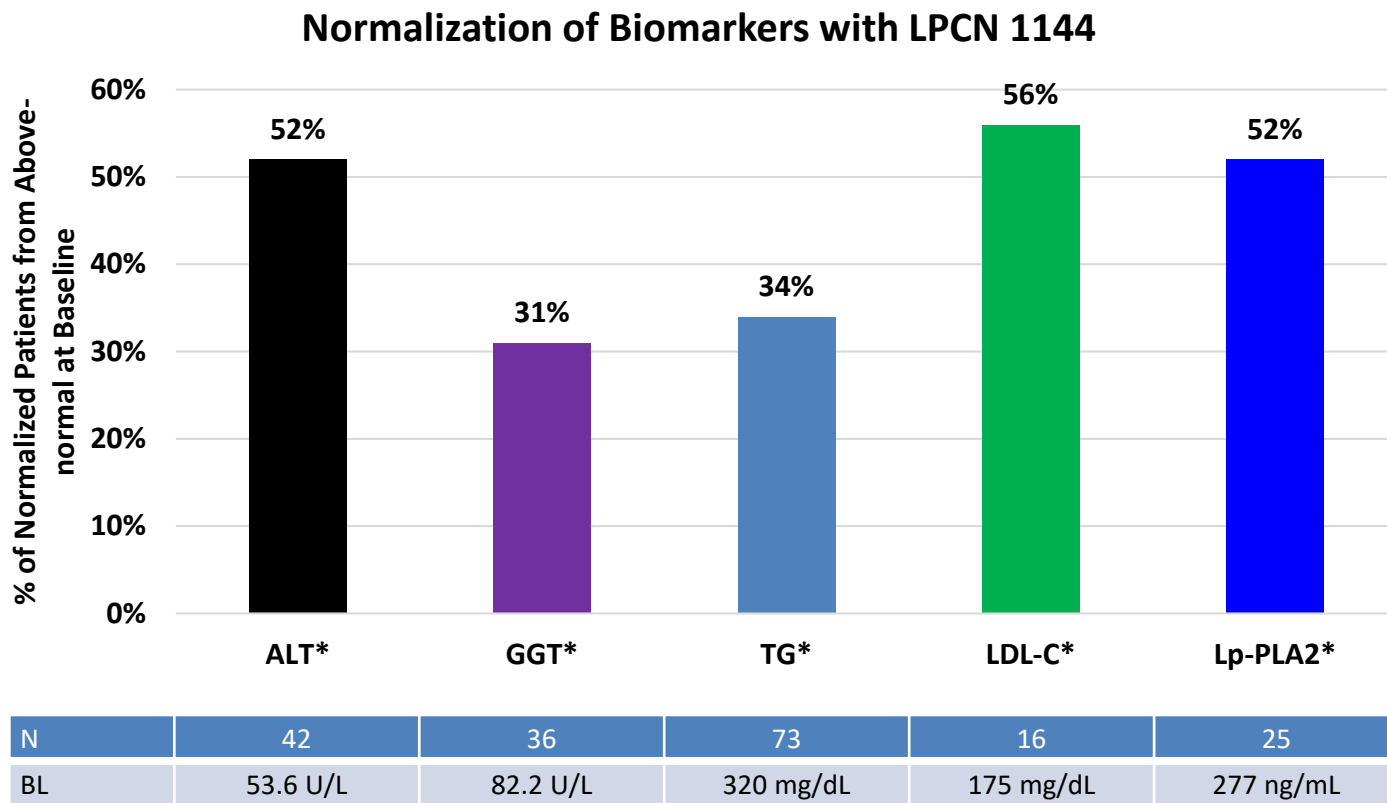


* LDL-C upper normal limit is 160 mg/dL.

LPCN 1144: Oral T

Appreciable % of Patients Experienced Normalization of ALT, GGT, TG, LDL-C, and Lp-PLA2

- 52 Week SOAR Trial



* ALT, GGT, TG, LDL-C, and Lp-PLA2 normal range upper limit is 40 U/L, 49 U/L, 200 mg/dL, 160 mg/dL, and 235 ng/mL, respectively

LPCN 1144: Robust ALT Response

Good Potential for Histological Improvement¹

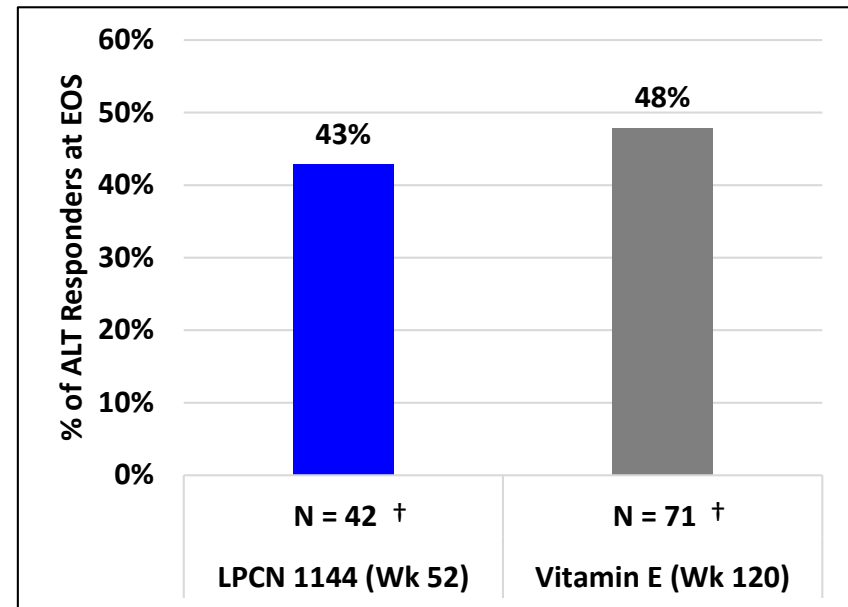
- Comparable LPCN1144 ALT response to Vitamin E in PIVENS Trial²

Histological feature	Vitamin E		P value
	ALT R* (n = 34)	ALT NR* (n = 37)	
Mean change in steatosis score	-1.1	-0.4	<0.001
Mean change in inflammation score	-1.1	-0.3	<0.001
Mean change in Ballooning score	-0.8	-0.2	0.01
Mean change in NAS [†] score	-3.0	-0.8	<0.001
Mean change in Fibrosis score	-0.5	-0.2	0.34
Decrease in NAS by ≥2 points	82%	32%	<0.001
Resolution of NASH [‡]	44%	22%	0.07
Mean change in Weight (kg)	-0.9	1.8	0.03

* ALT Responders: Patients with ALT > 40 U/L at baseline, ending with ≤ 40 U/L and more than 30% reduction at end of study post therapy

† Total non-alcoholic fatty liver activity score (NAS), comprising the sum of scores for steatosis, inflammation, and ballooning cell injury

‡ Resolution of histological features that fulfil the criteria for diagnosis of NASH



† Total N is for patients with ALT > 40 U/L at baseline (ALT normal range is ≤ 40 U/L)

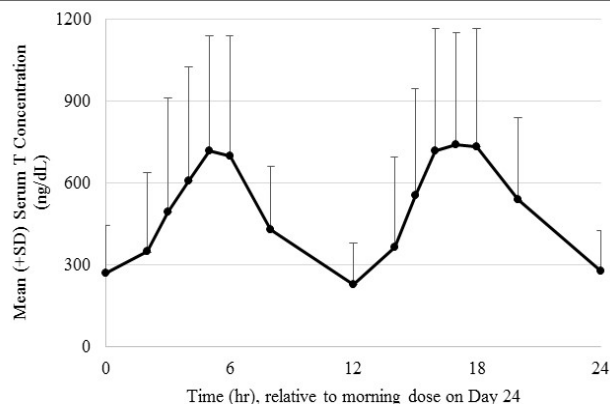
LPCN 1144

**Comparison with Topical
Testosterone**

LPCN 1144: Comparison of PK Profile with Topical T and Injectable T

Fluctuating levels during the day

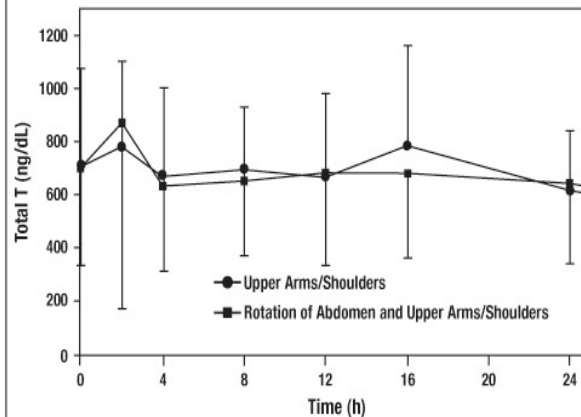
Oral (LPCN 1144)



Mean (+SD) Serum Total Testosterone Concentrations on Day 24, LPCN 1021-16-002 study results (PK Set, N=90)

Sustained high levels during the day

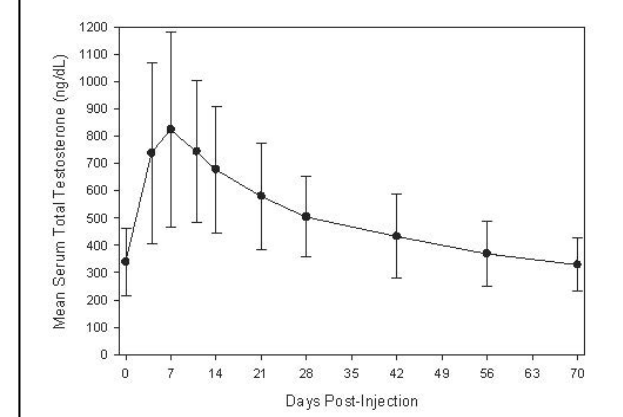
Topical (AndroGel*)



Mean (±SD) Serum Total Testosterone Concentrations on Day 7 in Patients Following AndroGel 1.62% Once-Daily Application of 81 mg of Testosterone (N=33) for 7 Days

Sustained high levels for weeks

Injectable (Aveed**)



Mean (SD) Serum Total Testosterone Concentrations (ng/dL) at 14-24 Weeks

* AndroGel 1.62% label

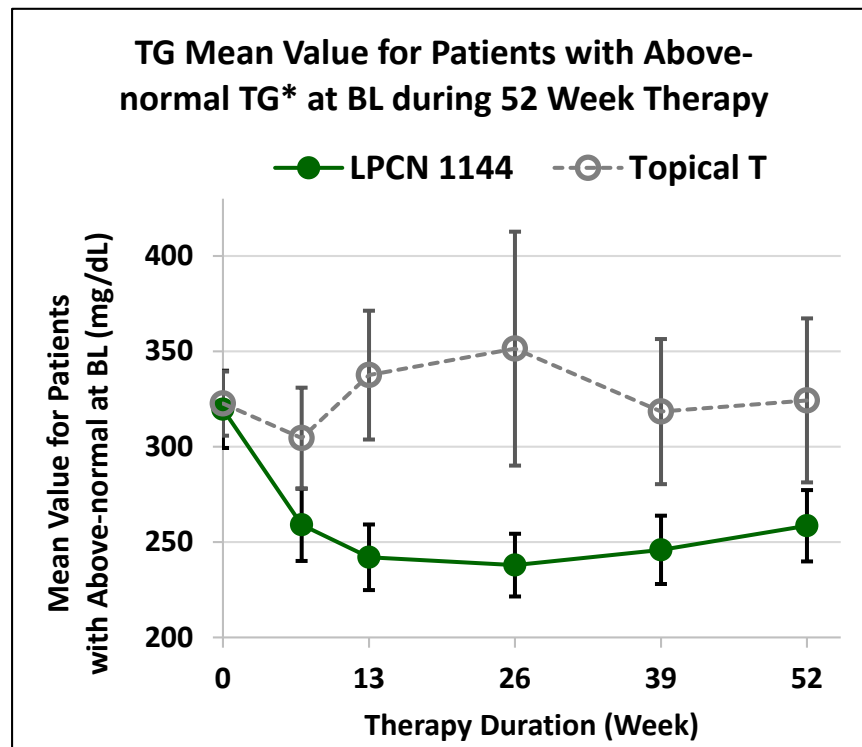
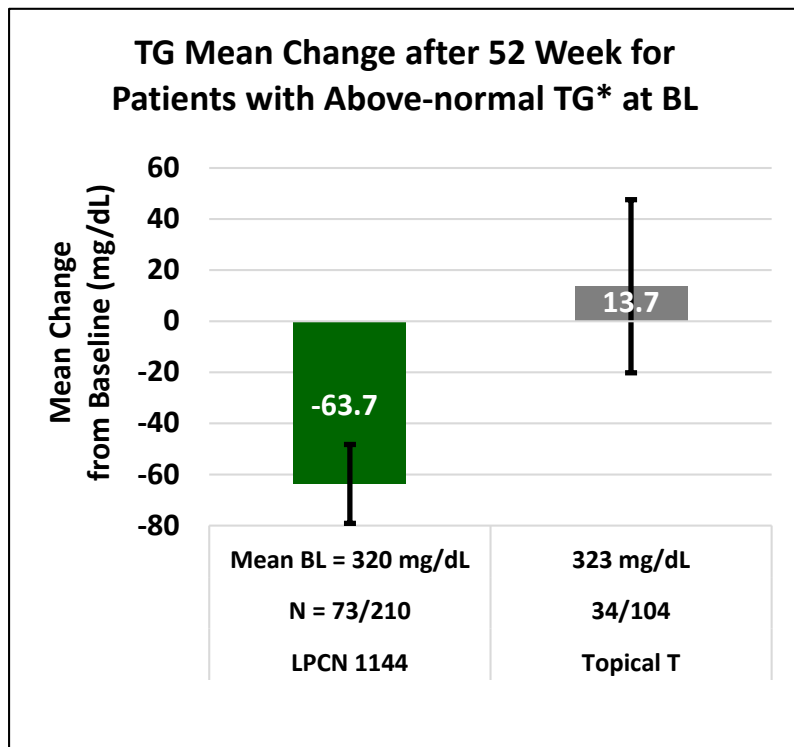
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LPCN 1144: Oral T

Unique TG Reduction Compared to Topical Gel

- 52 Week SOAR Trial

TG mean change post therapy in patients on oral T vs non-oral T therapy

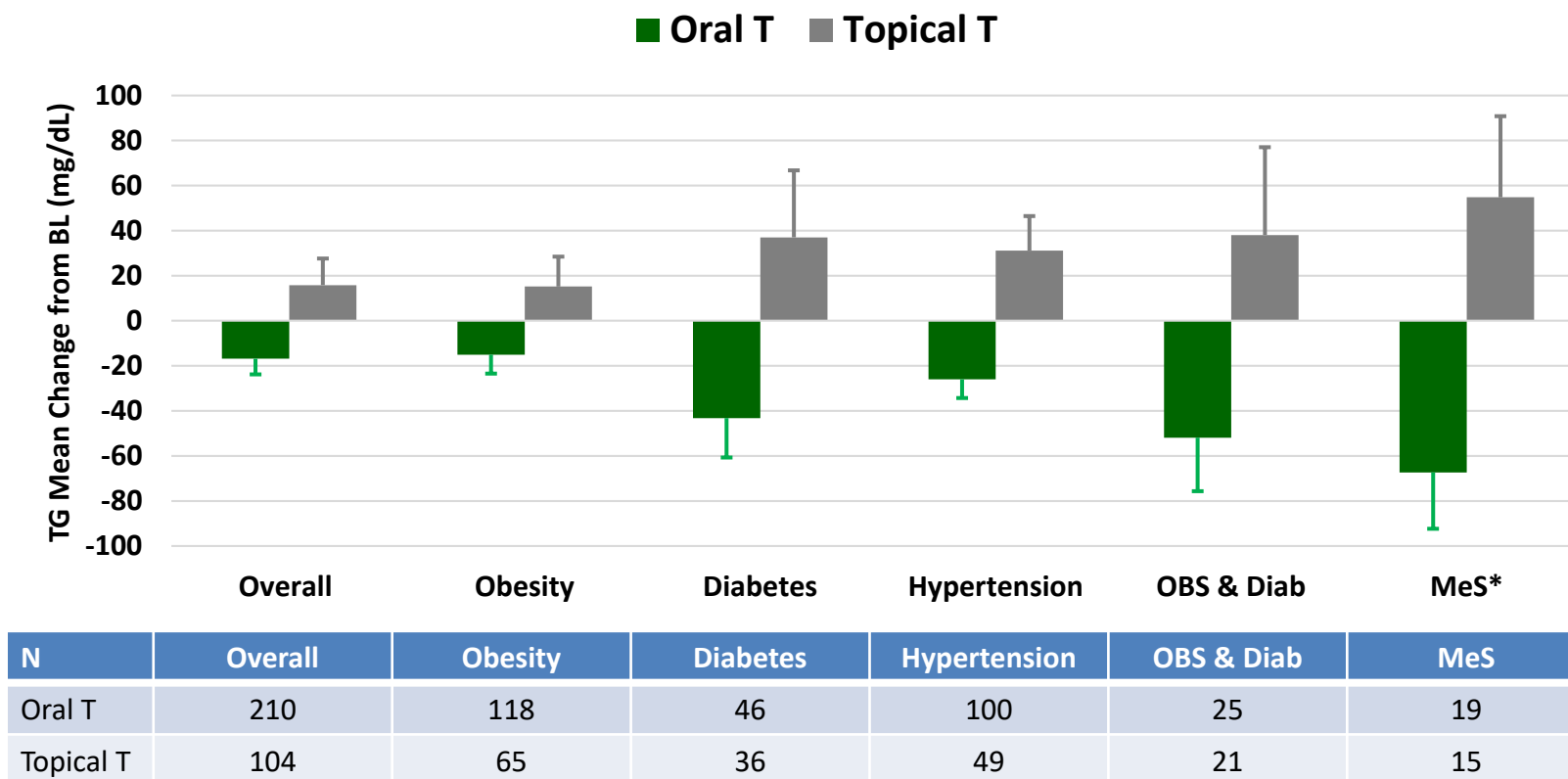


LPCN 1144: Oral T

TG Reduction Comparison with Topical T Across Various Comorbidities

■ 52 Week SOAR Trial

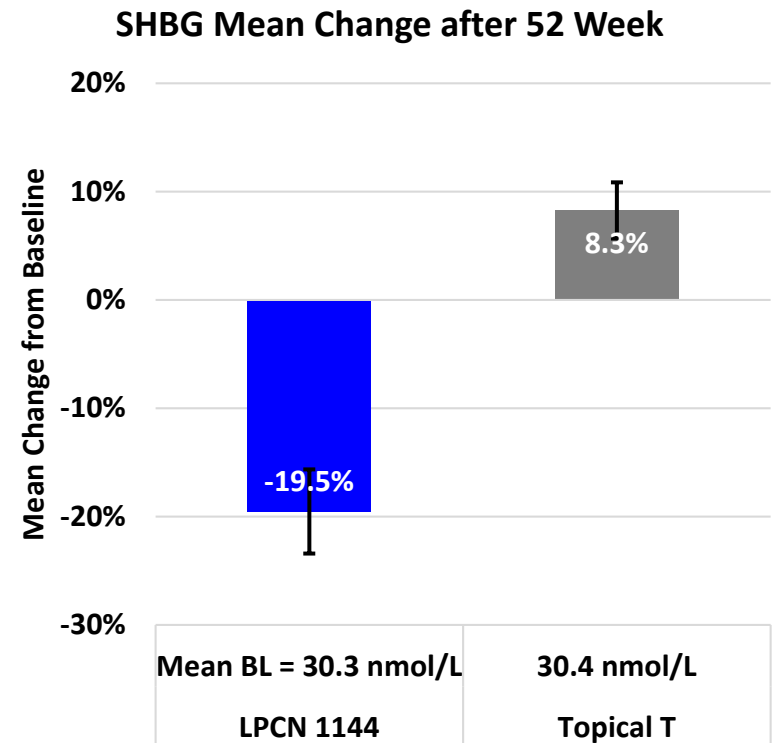
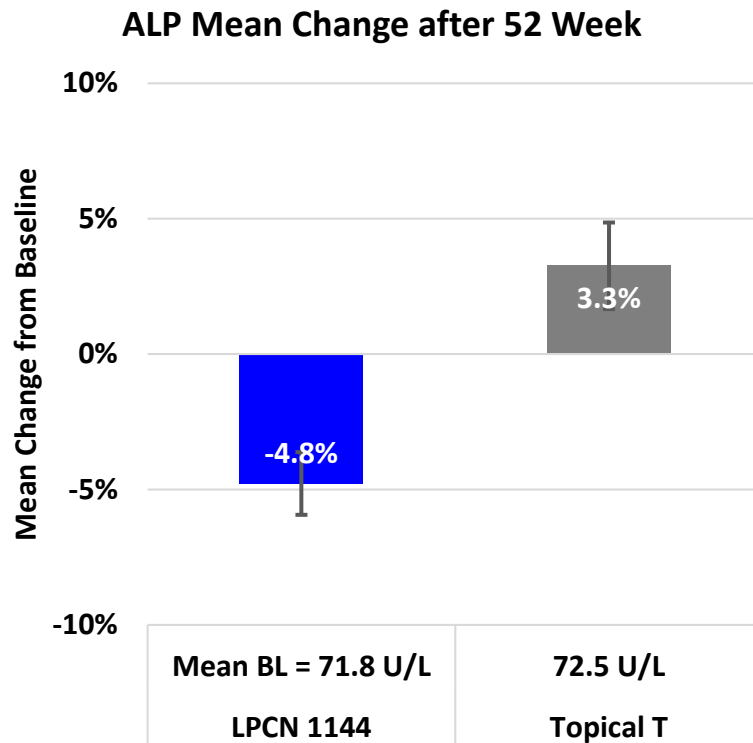
Unique Oral T Therapy in TG Reduction Post 52 Week Therapy in Patients with Comorbidities



LPCN 1144: Oral T

Unique Effects on Liver Compared to Topical gel

- 52 Week SOAR Trial



LPCN 1144: Next Step

Advancing Forward

- Initiate Phase 2 clinical study in biopsy confirmed NASH subjects
 - Study Design
 - Three-arm, placebo controlled
 - Biopsy confirmed F2/F3 NASH male hypogonadal subjects with NAS ≥ 4
 - Paired biopsy at baseline and EOS
 - 36-weeks duration
 - IND cleared by FDA