



# CORPORATE PRESENTATION

## May 2022

Enabling Oral Drug Delivery to  
Improve Patient Compliance



# 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, FDA’s approval of TLANDO®, the expected timing of Phase 3 trials for LPCN 1111, LPCN 1144 and LPCN 1107 and Phase 2 studies for LPCN 1148 and LPCN 1154, and IND filing of LPCN 2101 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](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.

# Innovative Oral Candidates for Neuroendocrine and Metabolic Disorders

Candidate ( <i>Indication</i> )	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	Approved*	Commercial Partner
<b>TLANDO®</b> ( <i>Testosterone Replacement Therapy</i> )	Expected U.S. Launch Q2 2022					<b>U.S.:</b> Antares Pharma <b>EX-US:</b> Available
<b>LPCN 1111 (TLANDO XR)</b> ( <i>Once Daily Testosterone Replacement Therapy</i> )	Phase 2 Completed					
<b>LPCN 1144</b> ( <i>Non-Cirrhotic NASH</i> )	Phase 2 and OLE Studies Completed					
<b>LPCN 1107</b> ( <i>Prevention of PTB</i> )	Food Effect Study Completed					
<b>LPCN 1148</b> ( <i>Decompensated Liver Cirrhosis</i> )	P2 Study Ongoing					
<b>LPCN 1154</b> ( <i>Postpartum Depression</i> )	Food Effect Study Ongoing					
<b>LPCN 2101</b> ( <i>Women With Epilepsy</i> )	IND Filing					

# TLANDO®

The Convenient Oral TRT  
without Titration Requirement

## LPCN 1111

Once Daily Oral TRT

NDC 54436-112-20

Rx only

Recommended Dosage: See prescribing information.

 **TLANDO**<sup>TM</sup>  
(*testosterone undecanoate*)

Capsules 112.5 mg 

Dispense accompanying  
Medication Guide to each patient



**120 capsules**

**Active Ingredient:** Testosterone Undecanoate 112.5 mg

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature].

Do NOT flush unused product.



3 54436 11220 3  
GTIN 10354436112200

566209



S/N: 123456789012  
LOT: 1234ABCD  
EXP: YYYY MM

**Manufactured for:**

Antares Pharma, Inc  
Ewing, NJ 08628

Manufactured in the United Kingdom

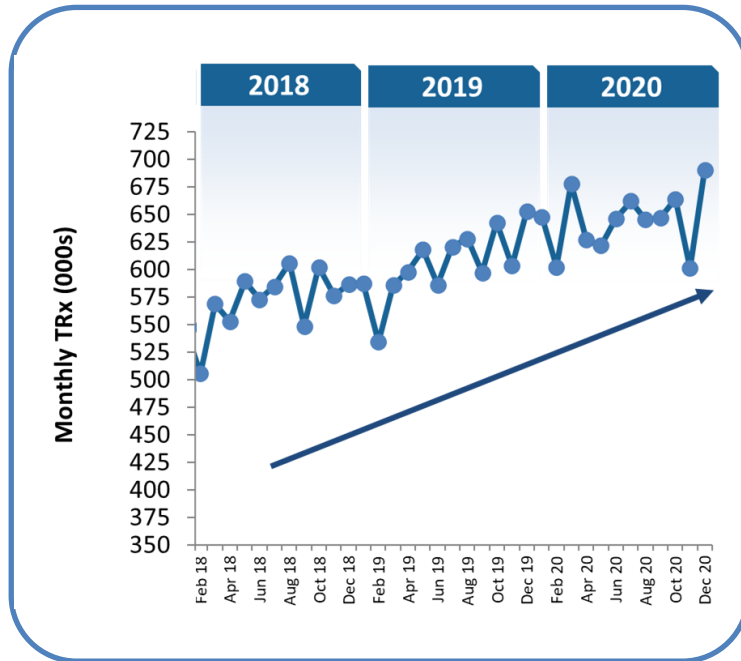
LB-0189 V02



# TLANDO® Market Potential

Attributes Particularly Attractive for Topical Switch, and Treatment Naïve Patients

## Overall TRT Market



~7.6M 2020 TRx

## Topical Segment

- ~24% of TRT market
- ~1.8M 2020 TRx

## Naïve Patient Segment

- 33% of ~2M patients
- ~660K new annually

**85%**  
of Physicians

Have a strong interest  
in an oral treatment

**94%**  
of TRT Patients

Likely to ask  
their Doctor about  
**TLANDO™**



# TLANDO®: Update

## Licensed U.S. Rights to Commercialization Partner - Antares Pharma



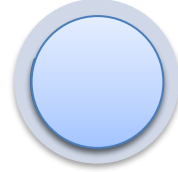
### Economic Interest

Up to \$21.0 million in licensing fees

Commercial sales milestone payments of up to \$160.0 million

Tiered royalties on net sales of TLANDO from mid-teens up to 20%

Licensee to undertake all commercialization, P4 studies, and sourcing



### Launch Potential

Targeting 7.6M annual TRx

Unique attributes:

Oral

No titration requirement

Licensee has largest detailing force in TRT space

Licensee has established relationship with payers, KOLs, and physicians



### Status

FDA Approved

Expected Launch Q2 2022

# LPCN 1111: Next Generation TRT Option

## Antares Pharma Has an Option to License



LPCN 1111 is positioned to be the first oral once a day product



LPCN 1111 is clinically differentiated



Patients and physicians prefer once a day oral testosterone



Positive Phase 2b study results

**Tech transfer/scale up  
activities on-going**

# LPCN 1144

for Non-Cirrhotic NASH

## FDA Fast Track Status

Next Step:

End of phase 2 meeting

Currently No Approved Treatment For NASH

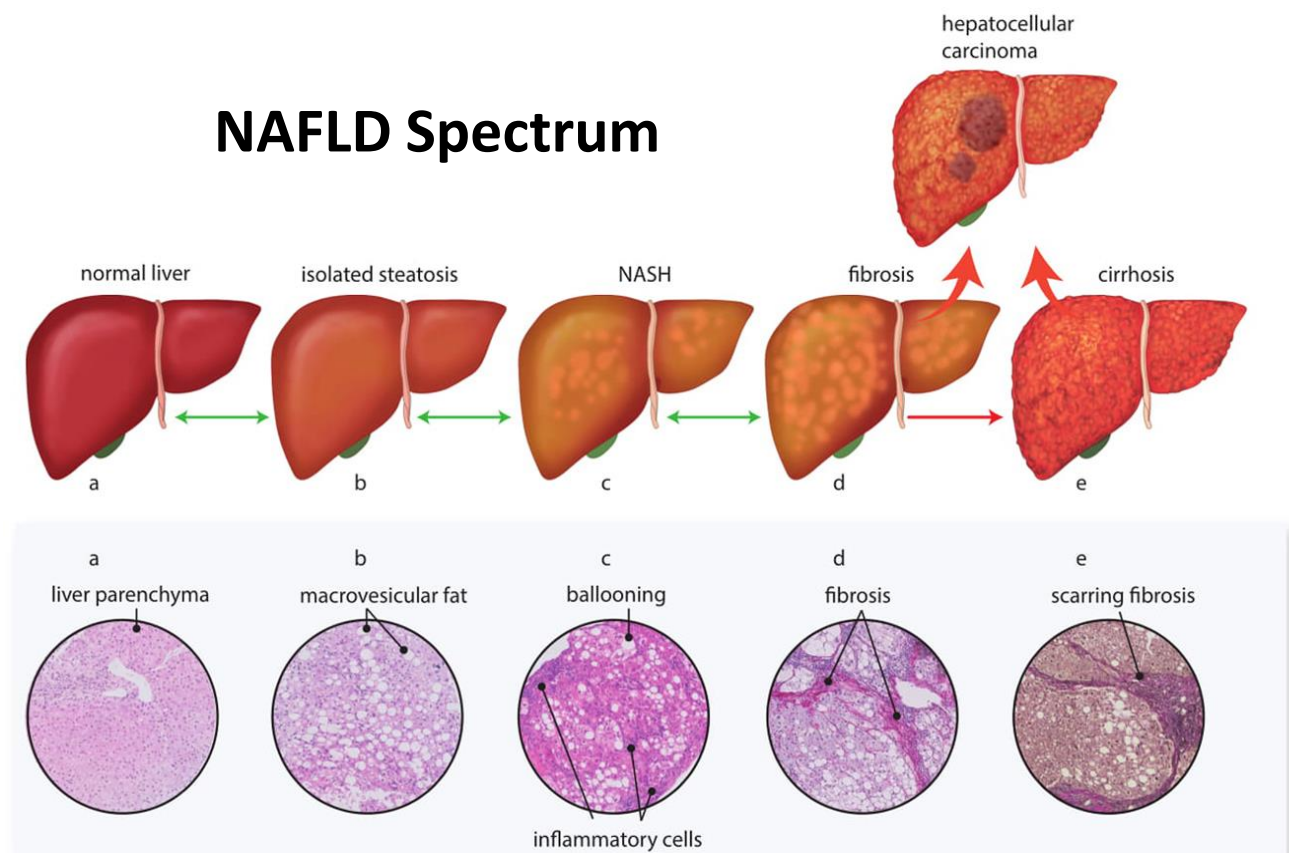




# LPCN 1144: Market Potential

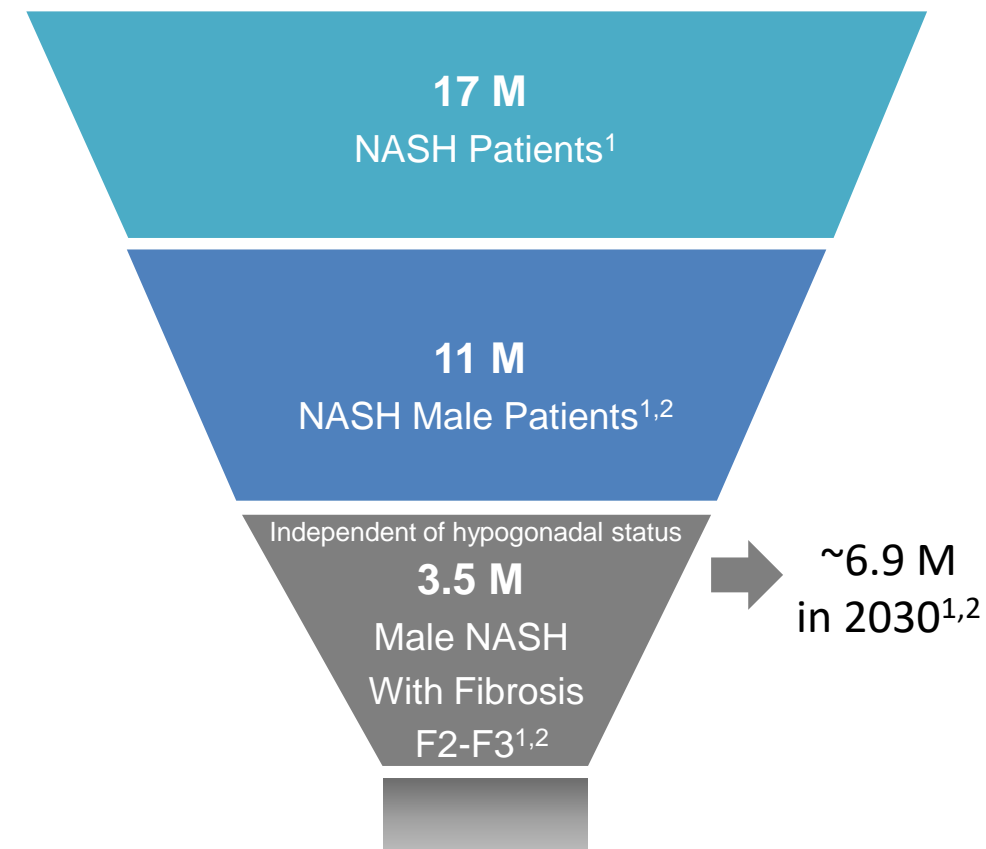
## NASH, a Silent Liver Disease Epidemic

### NAFLD Spectrum



European Journal of Endocrinology 183, 3; 10.1530/EJE-20-0065

### Current Target Population

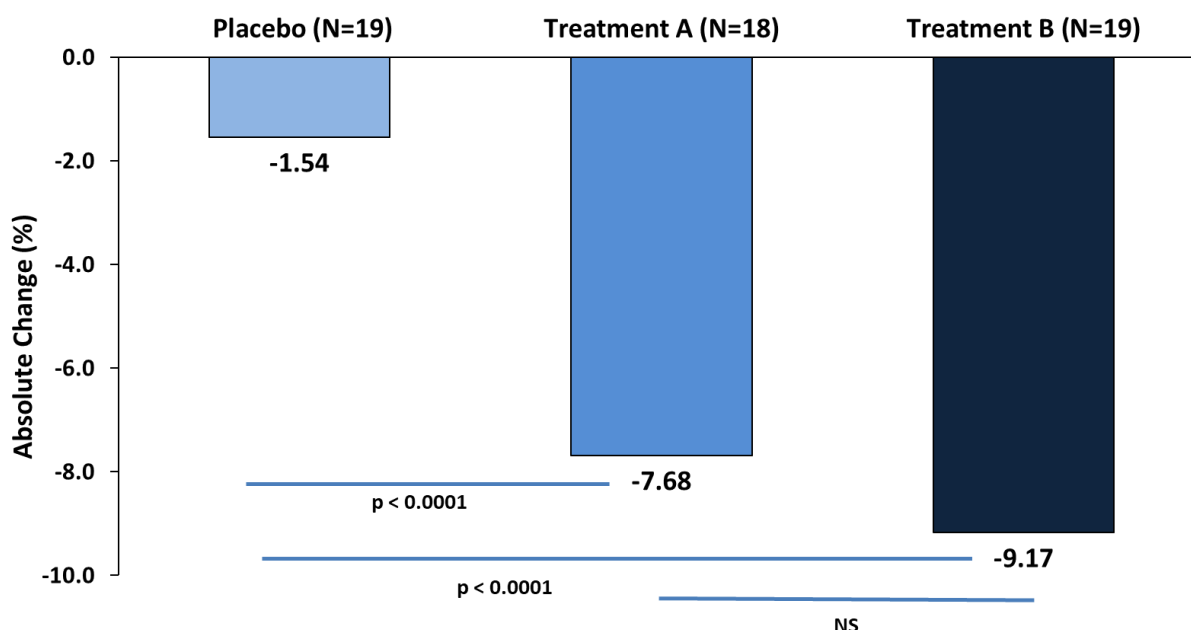


**Multibillion Dollar Market Opportunity<sup>3</sup>**

# Key Results from *LiFT* Study

## Met NASH Resolution Histology Endpoint and Fat Reductions

### Liver Fat Reduction at Week 12 (MRI-PDFF)



Treatment A: 142 mg eq. T twice daily

Treatment B: 142 mg eq. T + 238 mg d-alpha tocopherol twice daily

All Subjects: ITT Dataset, n = 56, missing data imputed using multiple imputation

NS = Not Statistically Significant

### NASH Resolution with No Worsening of Fibrosis<sup>1</sup>

#### Responders<sup>1</sup>, n (%)

	NASH Resolution Set <sup>2</sup>	Safety Set <sup>3</sup>
Placebo	0 (0%)	0 (0%)
Treatment A	6 (46%)*	6 (33%)**
Treatment B	9 (69%***)	9 (47%***)

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

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

2 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

3 All randomized subjects (ITT); subjects who were not eligible for NASH resolution evaluation or who were missing EOS biopsies were treated as non-responders

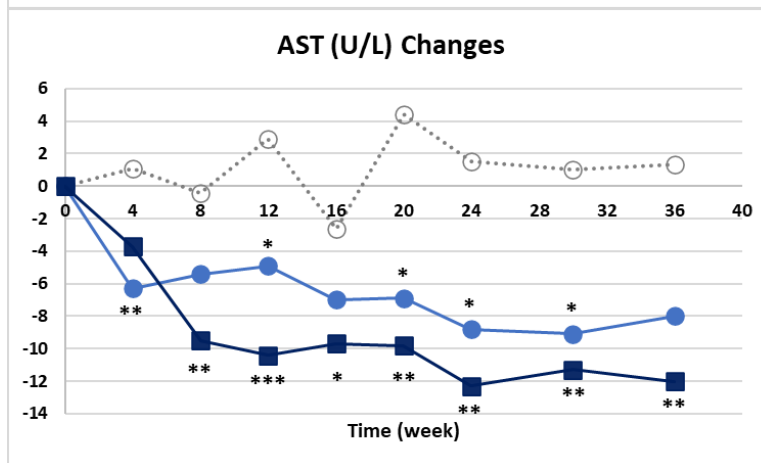
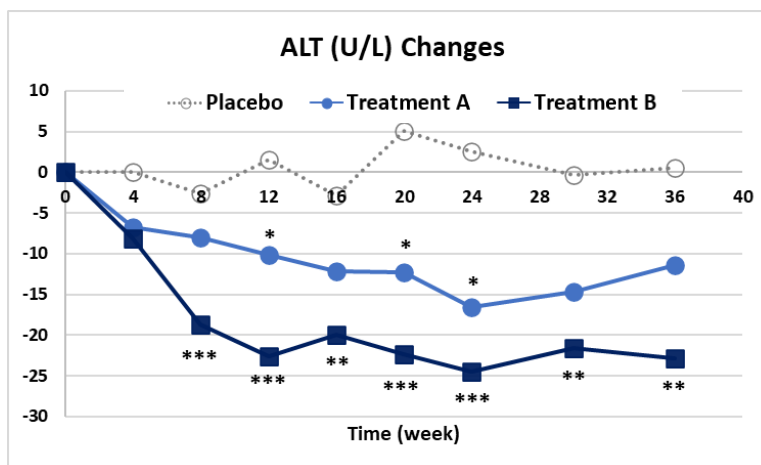
# Key Non-Histology Marker Results from *LiFT* Study

## Liver Enzyme<sup>#</sup> Reductions and Body Composition Changes

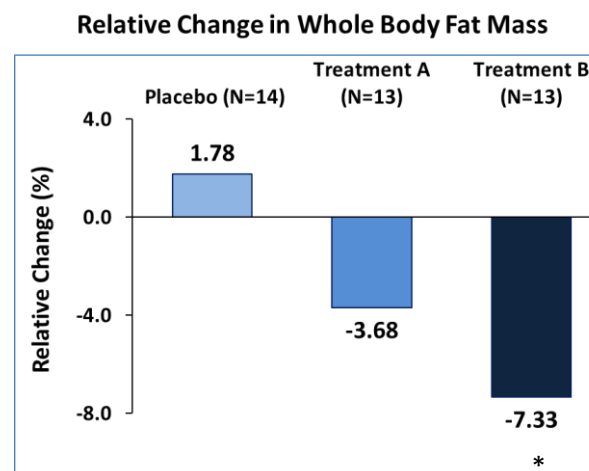
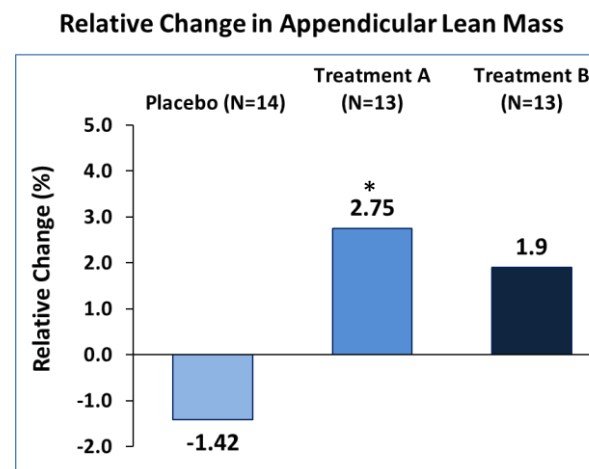
### Liver Injury Marker Reduction

#### Mean Baseline

	ALT (U/L)	AST (U/L)
Placebo (N=19)	49.0	35.4
Treatment A (N=18)	53.9	32.4
Treatment B (N=19)	51.5	31.9



### Positive Effects on Body Composition<sup>†</sup>



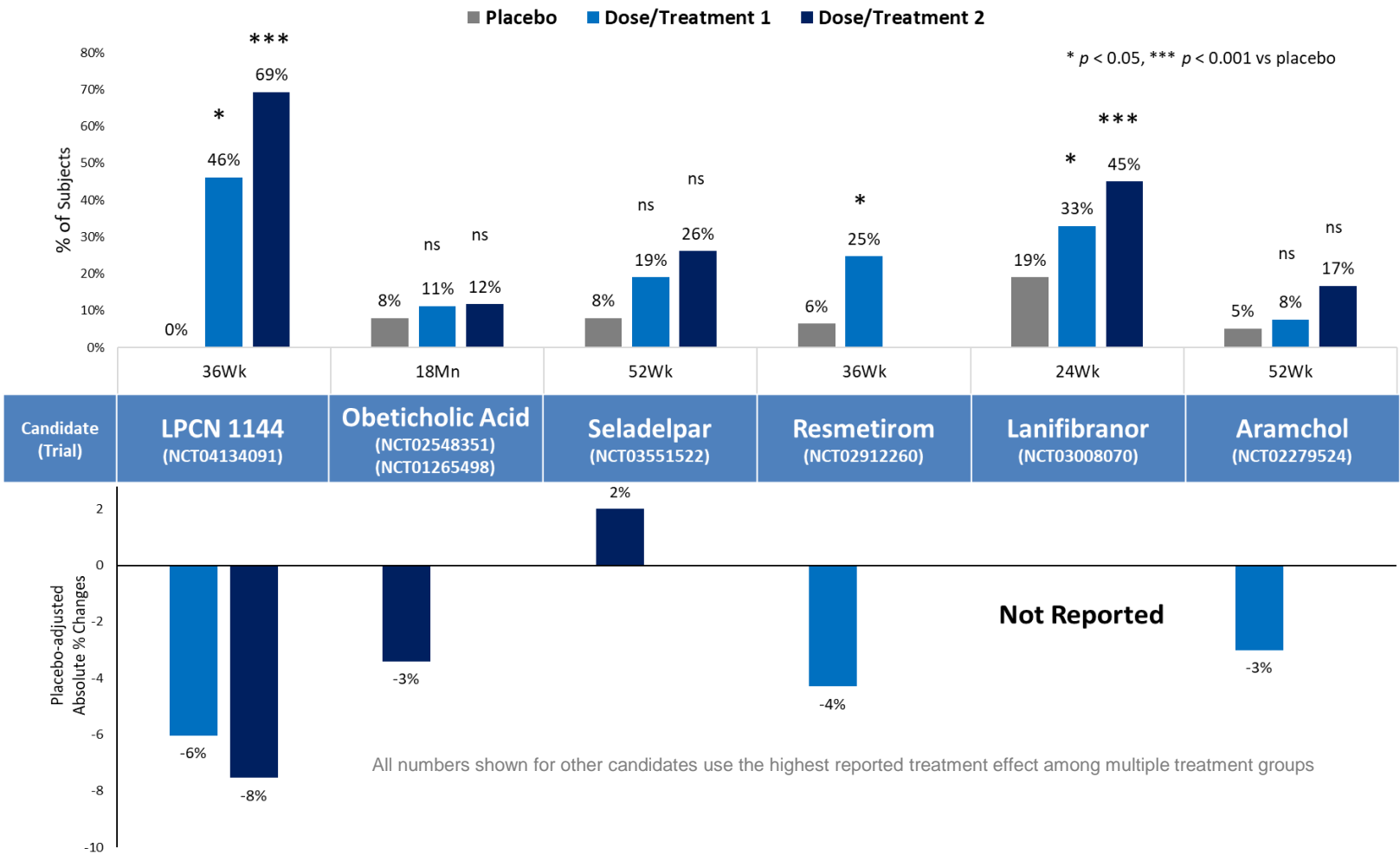
<sup>†</sup> All available data at Week 36 (Last Observation Carry Forward ("LOCF"))  
\* p < 0.05 vs placebo

# Comparison with Other Oral Drug Candidates

## Best in Class in NASH Resolution and Liver Fat Reduction

NASH Resolution with  
No Worsening of Fibrosis

Absolute Changes of Liver  
Fat from Baseline



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. For Resmetirom, reduction 2-point on NAS or resolution of NASH without worsening of fibrosis with at least a 2-pt reduction in NAS.

Reference: Obeticholic acid (Younossi et al, Lancet 2019), Seladelpar (Cymabay, Apr 2021 Corp deck), Resmetirom (Harrison et al, Lancet 2019; Madrigal, June 2019 Corp deck), Lanifibranor (Inventiva, Jul 2021 Corp deck); Aramchol (Raymond James Life Sciences and MedTech Conference 2019)

# 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
- Discontinuance of study drug due to TEAEs: 4 subjects in placebo and 1 subject in treatment arms
- Cardiovascular events were balanced among groups
- No reported cases of hepatocellular carcinoma or Drug Induced Liver Injury (“DILI”)
- Weight change from baseline was comparable among groups
- Changes in lipids comparable to placebo

AEs of Interest, n (%)	Placebo	Treatment A	Treatment B
Diarrhea	2 (10.5%)	1 (5.6%)	0 (0%)
Nausea	1 (5.3%)	1 (5.6%)	0 (0%)
Vomiting	none	none	none
Peripheral Edema	2 (10.5%)	1 (5.6%)	1 (5.3%)
BPH	1 (5.3%)	0 (0%)	0 (0%)
PSA Increased	0 (0%)	1 (5.6%)	0 (0%)
Hypertension <sup>†</sup>	1 (5.3%)	3 (17%)	0 (0%)
Pruritus	1 (5.3%)	1 (5.6%)	0 (0%)

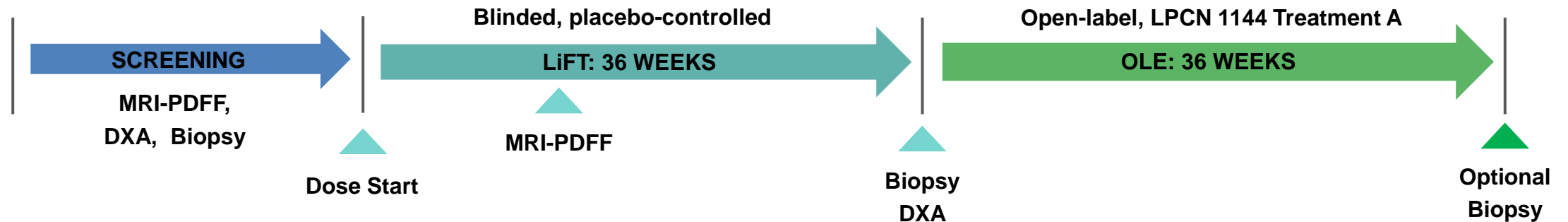


# LPCN 1144: NASH Open Label Extension Study

## Objective & Design

Objective: To evaluate the safety and tolerability of extended (up to 72 weeks) treatment with LPCN 1144 in subjects with biopsy confirmed Nonalcoholic Steatohepatitis (NASH)

- ❑ A multicenter study (NCT04685993) to provide LPCN 1144 treatment to subjects from the LiFT study (NCT04134019) who chose to participate



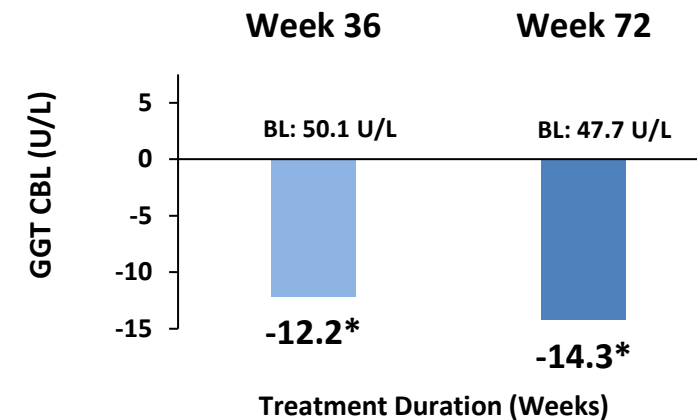
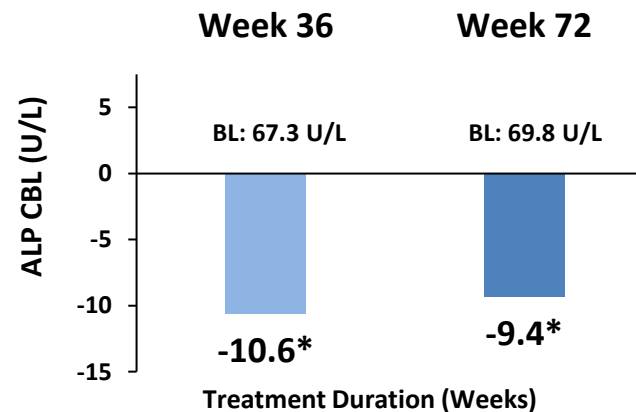
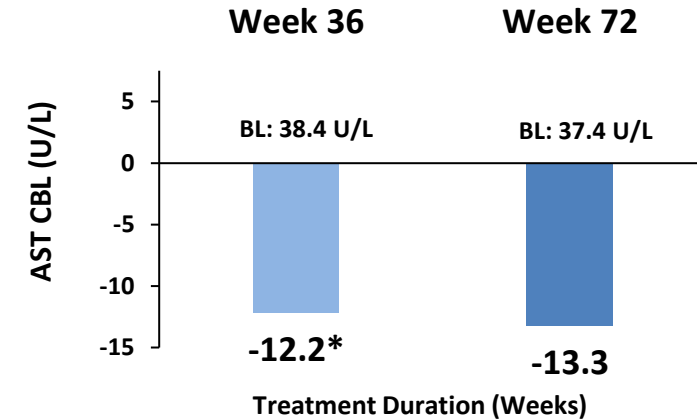
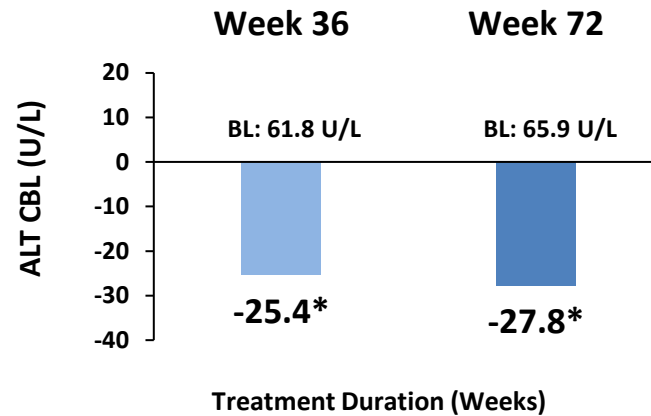
# Safety Overview of LPCN 1144 in OLE

## Well-Tolerated with No Observed Safety Signals

- ❑ In the OLE-Safety Set, the frequency and severity of TEAEs were comparable to those observed in the LiFT study
- ❑ There were no reported cases of cardiovascular events, thromboembolic events, hepatocellular carcinoma, or drug induced liver injury ("DILI")
- ❑ Weight change from baseline was minimal and comparable to the LiFT results
- ❑ A GI adverse event was reported in one subject, and pedal edema was also reported in one subject, neither of which were considered related to study drug
- ❑ Additionally, no clinically meaningful changes in lipids were observed

# Observed Key Liver Injury Markers Change from Baseline

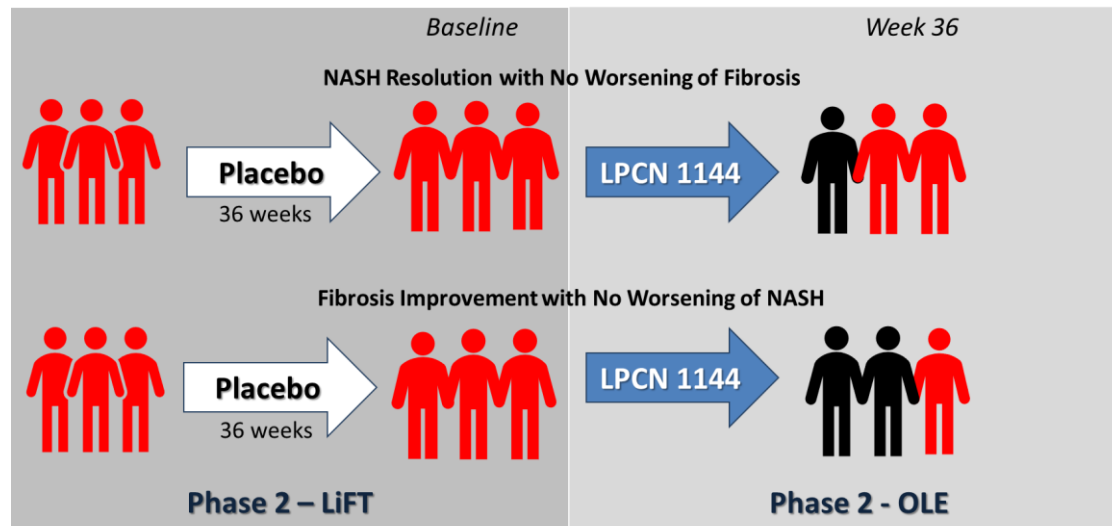
Liver Injury Markers were Reduced Significantly and Maintained with Extended LPCN 1144 Treatment



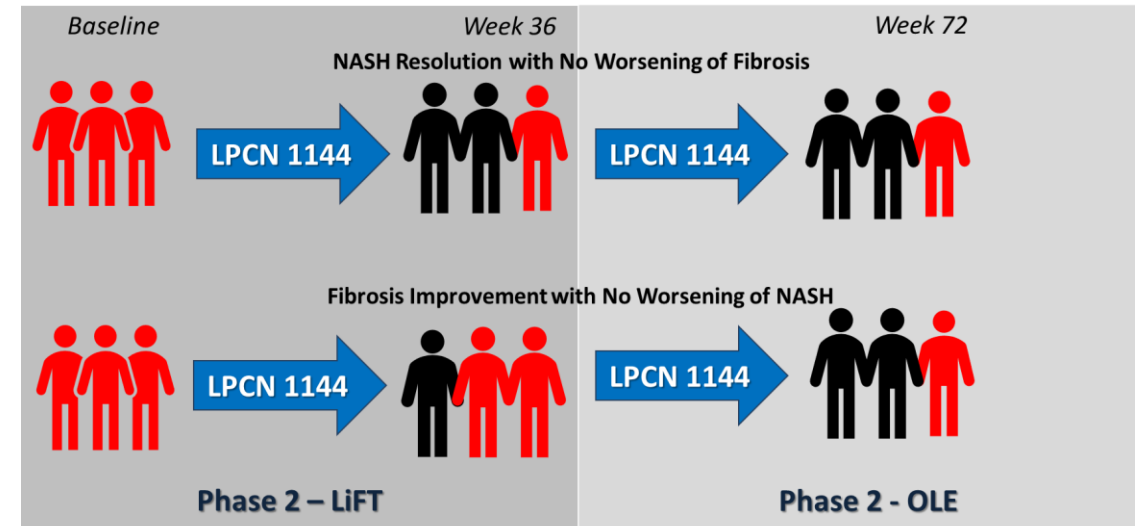
CBL= Change from Baseline; Baseline was measured at LPCN 1144 pretreatment; \* p<0.05; N = 25 for week 36 data and 16 for week 72 data

# Histological Changes\* in OLE Subjects with EOS Biopsy

## Subjects Initiated LPCN 1144 Treatment after Placebo Run-In



## Extended LPCN 1144 treatment subjects



Black = Improved individual subject; Red = Individual subject without improvement

Baseline was measured prior to LPCN 1144 treatment initiation

\*Biopsy changes in the subjects assessed utilizing NASH CRN (Clinical Research Network) scoring

# LPCN 1148

for the Management of  
Liver Cirrhosis

Next Step:

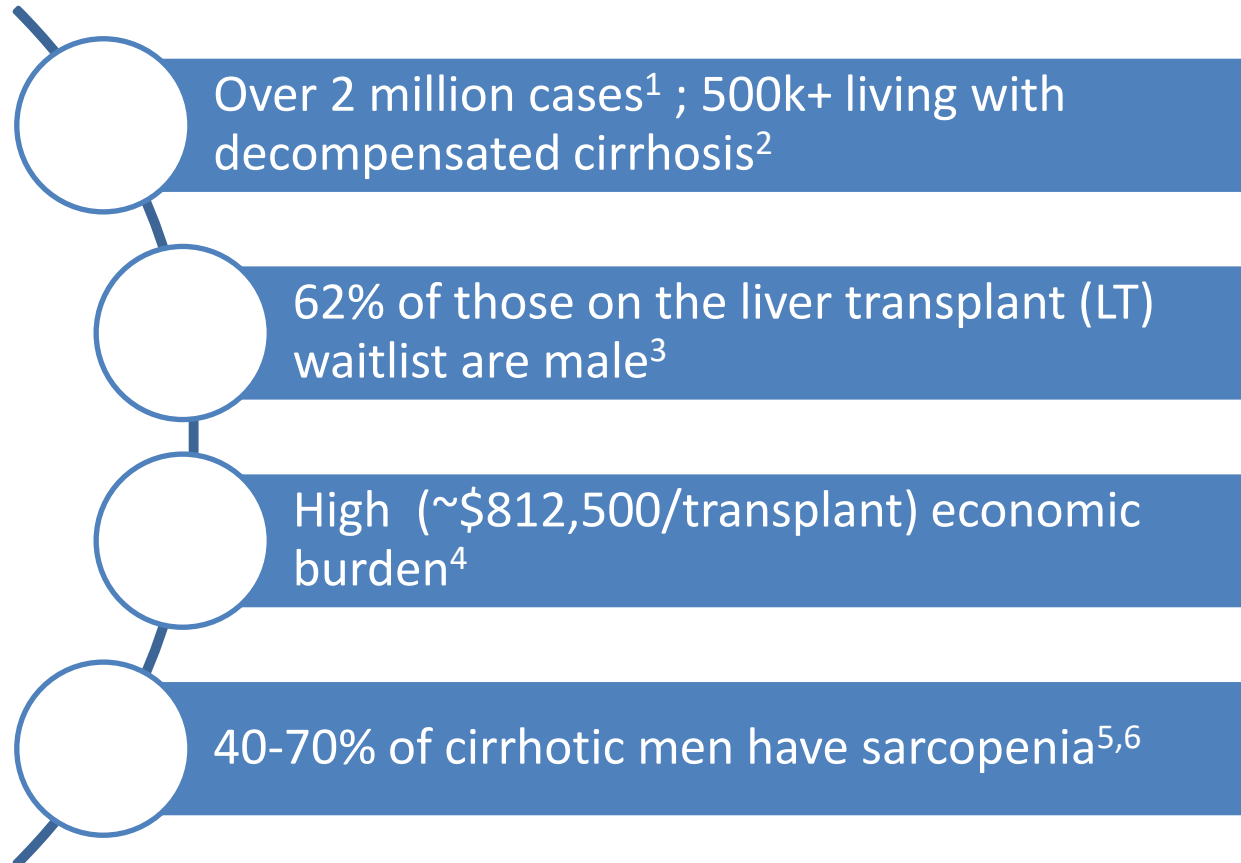
Complete enrollment P2 study

Potential for Orphan Drug Designation





## Liver Cirrhosis in US



1. Moon, Clin Gas and Hep, 2019

2. GBD 2017 Cirrhosis Collaboration, Lancet, 2021

3. Sarkar et al. J Hepatol. 2015

4. Bentley & Phillips, Milliman Research Report 2017

5. Sinclair, Ailment Pharmacol Ther, 2016

6. Lai, Am J Transplant, 2014

## Targeting Unmet Need in Cirrhosis

Event free survival/improve quality of life for patients on transplant list

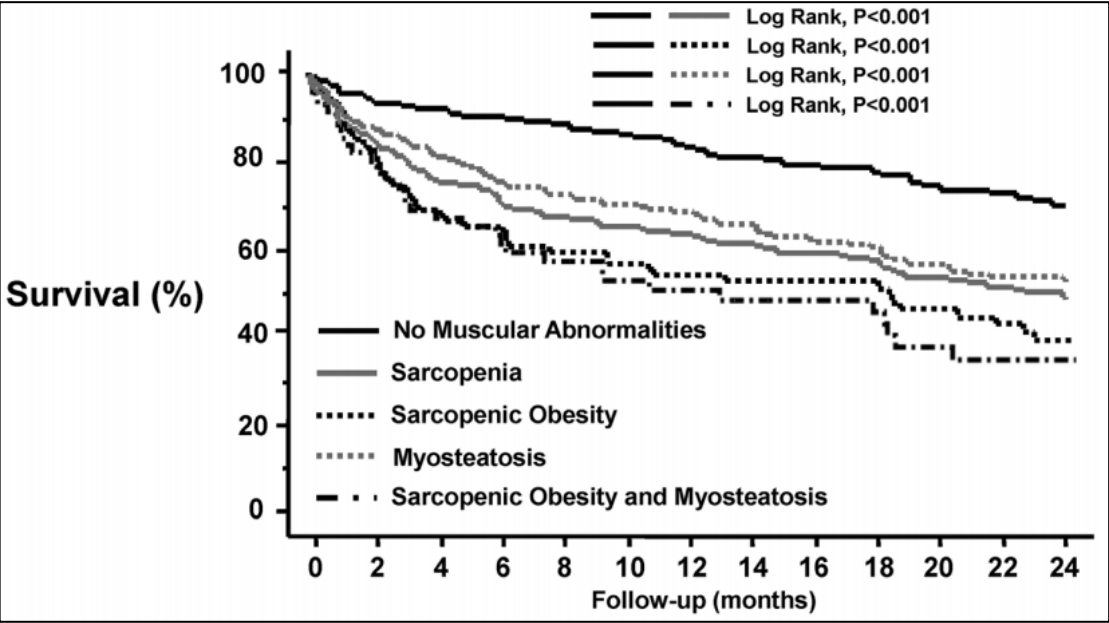
- Pre-listed, listed, and the others who have opted out or are denied for the waitlist

Improvement of post transplant outcomes/costs

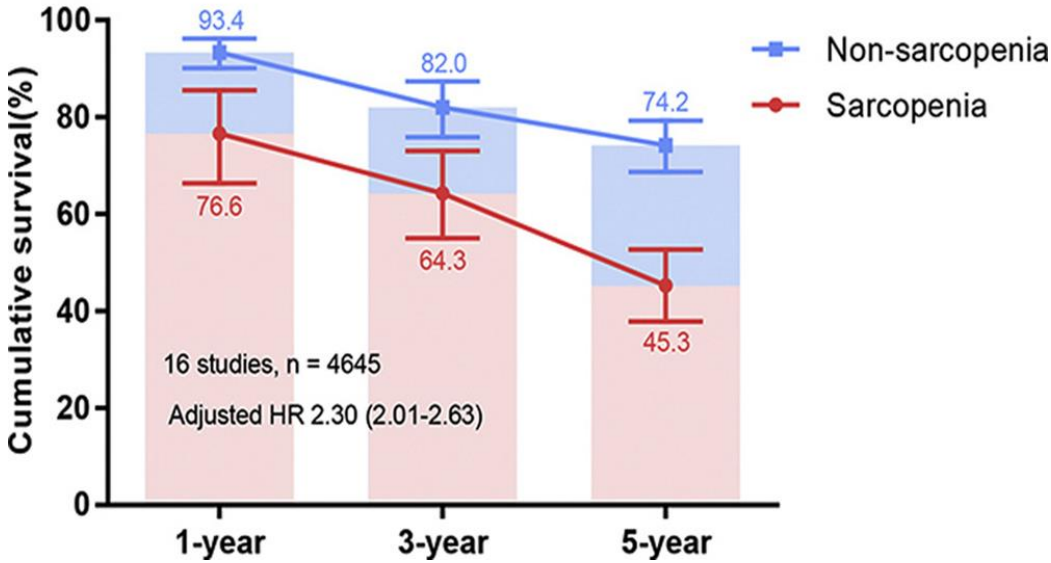
- Decreased hospital readmissions
- Shorter length of hospitalization

# Survival in Cirrhotic Patients with Muscle Disorders

Patients with Either Sarcopenia and/or Myosteatosis Had Significantly Worse Survival Rates



Montano-Loza, J Cachexia Sarcopenia Muscle. 2016 May; 7(2): 126–135



Tantai et al. J. Hepatol. 2022, 76, 588–599

# LPCN 1148: Proof of Concept Study

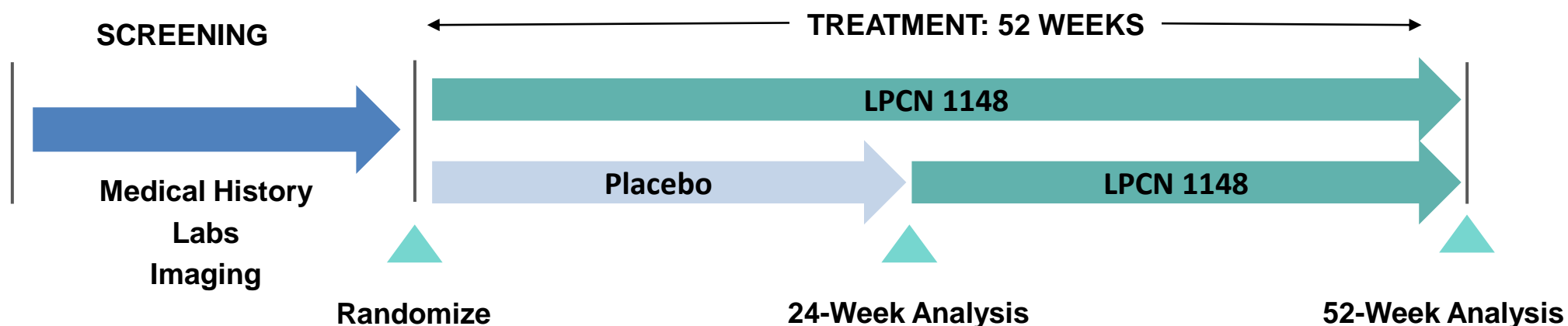
## Phase 2, Multicenter, Double-Blinded, Placebo-Controlled Study\*

### Study Design

- Male subjects with cirrhosis of the liver and sarcopenia
- Stage 1, Weeks 1-24
  - Two-arm (1:1 randomization)
    - Oral LPCN 1148 or Placebo
- Stage 2, Weeks 25-52
  - Single arm – LPCN 1148

### Endpoints:

- **Primary:** Change in Skeletal Muscle Index at Week 24
- **Key Secondary:**
  - Overall survival, hospitalization rates
  - Change in number of waitlist events
  - Rates of breakthrough hepatic encephalopathy/ascites
  - Change from baseline in Liver Frailty Index, myosteatorsis
  - Patient Reported Outcomes (PRO's)



# LPCN 1107

Prevention of Preterm Birth  
(PTB)

PTB, a leading cause of neonatal  
mortality/morbidity



# LPCN 1107: Potential To Be The Standard of Care for Prevention of PTB

## Oral Hydroxyprogesterone Caproate (HPC)

Convenient dosing

No injection site reactions

First and only oral enabling technology

Extensive IP coverage

Orphan drug designated





# LPCN 1154

Oral Neuroactive  
steroid (NAS) for  
Postpartum Depression

Next Step:

Food Effect Study

Received IND clearance for Phase 2 study



# Postpartum Depression (PPD)

A Major Depressive Episode Within Weeks of Delivery



~ 1 in 9 women in US  
suffer from PPD after  
giving birth



Only 50% (~500,000) of  
patients are currently  
diagnosed and treated  
in US



Negative impact on  
maternal and infant  
outcomes



Negative impact on  
family

# LPCN 1154 – Potential Oral Alternative for Post Partum Depression

## Addresses Limitations of the Current Treatment and Unmet Medical Needs

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No hospitalization requirement

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No facility REMS requirements

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Provide options for all women: easier access and no hospital logistics issues

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Provide privacy for the mother

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No bonding/breast feeding interruptions due to hospitalization required for infusion

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Faster acting than antidepressants (SSRIs)

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# LPCN 2101

for Women With Epilepsy  
(WWE)

Next Step:  
IND filing

No epilepsy drug specifically approved for  
WWE of childbearing age





# Women with Epilepsy (WWE) of Childbearing Age

## Balance Seizure Control with Specific Concerns

~ 900,000 of childbearing age women suffer from active epilepsy in US



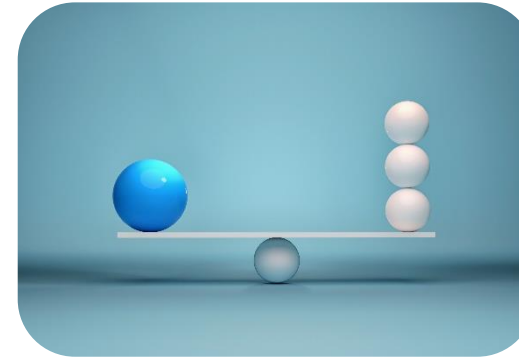
### Fetal/neonatal toxicity

- Adherence to AEDs
- Lowest dose of monotherapy AED is preferred



### Pregnancy

- Planned pregnancy
  - AED selection
- Unplanned pregnancy
  - Contraception failure



### Seizure Control

- Drug-drug interaction
- Freedom to drive



### Comorbidities

- Anxiety
- Depression
- Sleep impairment



# Upcoming Milestones

## Near Term Value Drivers

	Event	Expected Timing
LPCN 1148	Complete Enrollment Topline Primary Endpoint Results	3Q 2022 1Q 2023
LPCN 1144	End of Phase 2 Meeting	3Q 2022
TLANDO®	Partner Launch Targeted	2Q 2022
TLANDO® XR	License Option Exercise	by June 30, 2022
LPCN 1107	FDA Meeting on Path Forward	2H 2022
LPCN 1154	Food Effect Study Results	2Q 2022
LPCN 2101	IND Filing	2Q 2022