LIPOCINE®

ENHANCING HEALTH

CORPORATE PRESENTATION
July 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 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 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.

Innovative Oral Candidates for Metabolic and CNS Disorders

Candidate *(Indication)*	PRE-CLINICAL / PHASE 1 / PHASE 2 / PHASE 3 / Approved	Commercial Partner
TLANDO® *(Testosterone Replacement Therapy)*	On Market in U.S.	***U.S.:*** *Halozyme* ***EX-US:*** *Available*
LPCN 1111 *(Once Daily Testosterone Replacement Therapy)*	Phase 2 Completed	
LPCN 1144 *(Non-Cirrhotic NASH)*	Phase 2 and OLE Studies Completed	
LPCN 1107 *(Prevention of PTB)*	Food Effect Study Completed	
LPCN 1148 (*Decompensated Liver Cirrhosis)*	P2 Study Ongoing	
LPCN 1154 *(Postpartum Depression)*	Food Effect Study Ongoing	
LPCN 2101 *(Women With Epilepsy)*	IND Cleared	

PTB = Preterm birth NASH = Non-alcoholic steatohepatitis

TLANDO® is a registered trademark assigned to Antares https://www.tlando.com

TLANDO®

The Convenient Oral TRT
without Titration Requirement

https://www.tlando.com/

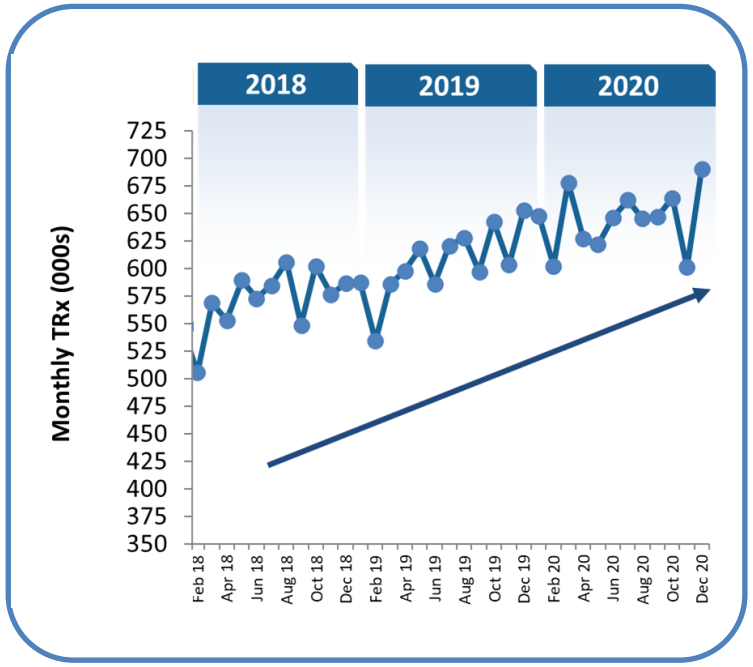
LPCN 1111

Once Daily Oral TRT

TLANDO® Market Potential

Attributes Particularly Attractive for Topical Switch, and Treatment Naive 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™

Source: Sources: IQVIA database., Antares Investor Presentation June 2021, and Lipocine Market Research

TLANDO® On Market in U.S.

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

LPCN 1111: Next Generation TRT Option

- 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:

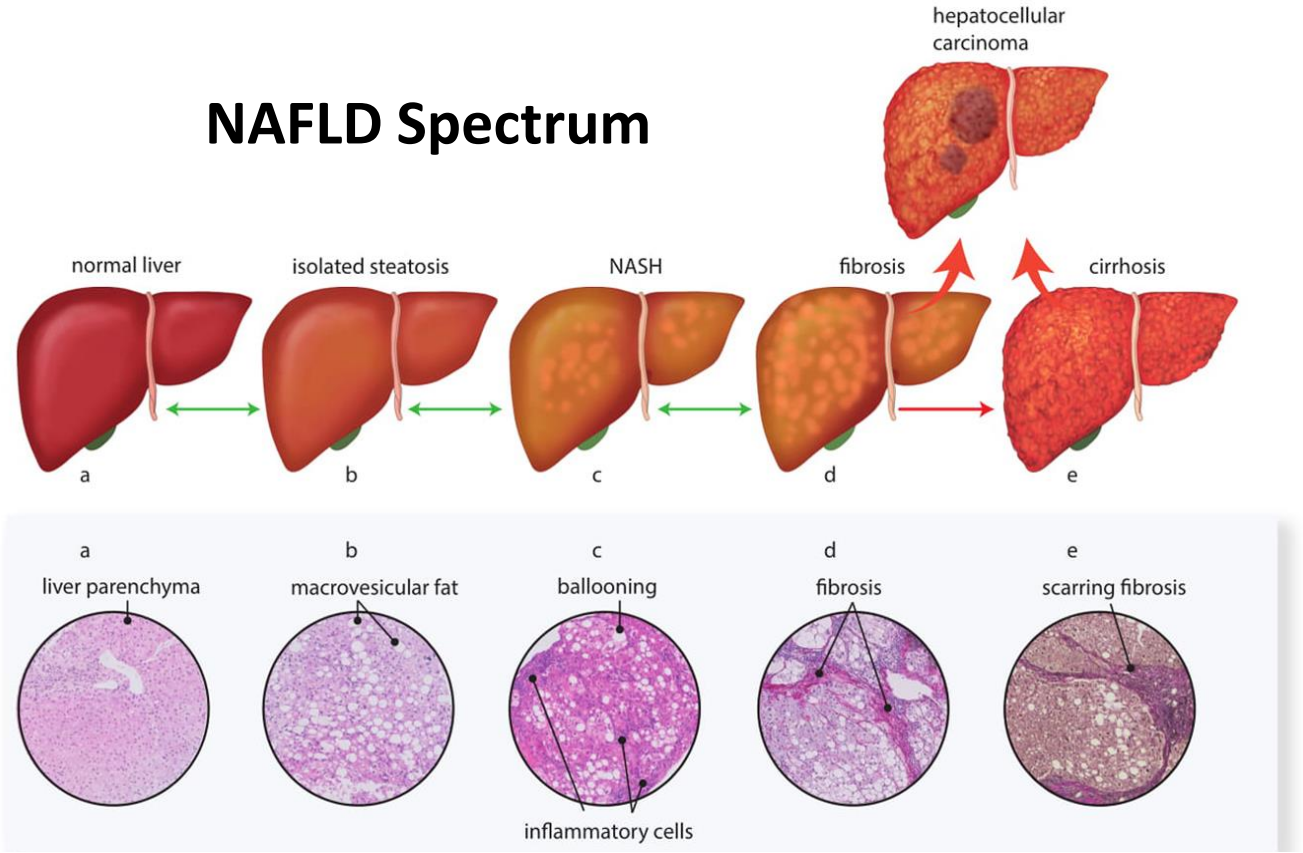
End of phase 2 meeting

Currently No Approved Treatment For NASH

LPCN 1144: Market Potential

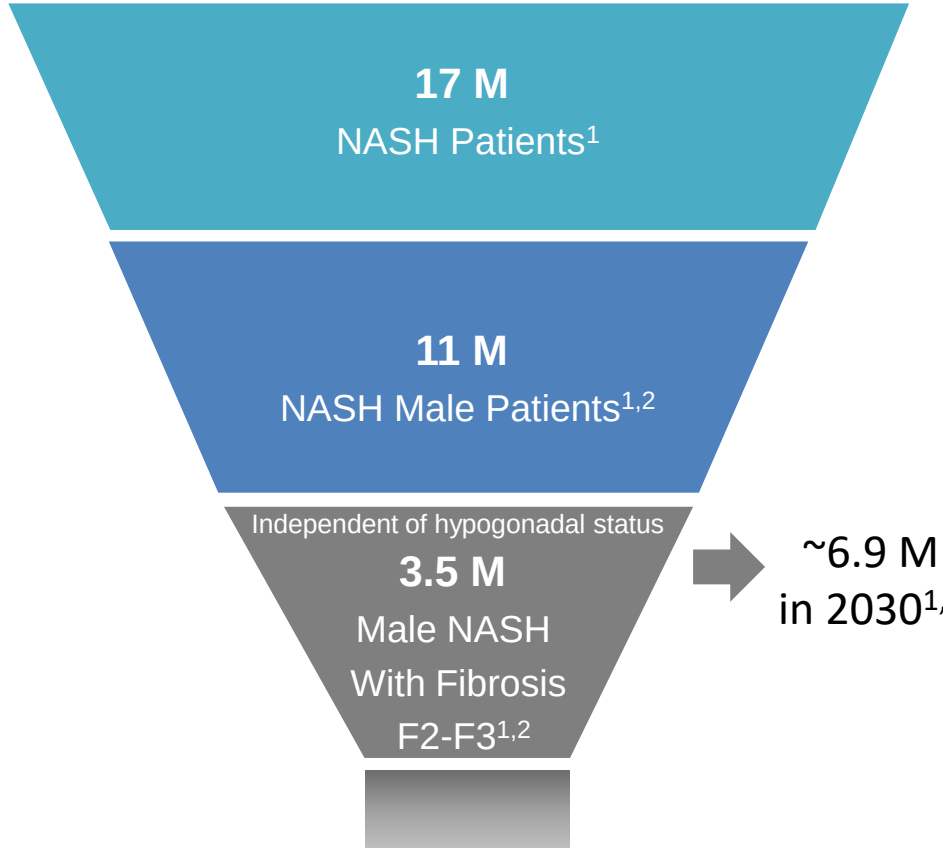
NASH, a Silent Liver Disease Epidemic

NAFLD Spectrum



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

Current Target Population



Multibillion Dollar Market Opportunity[3]

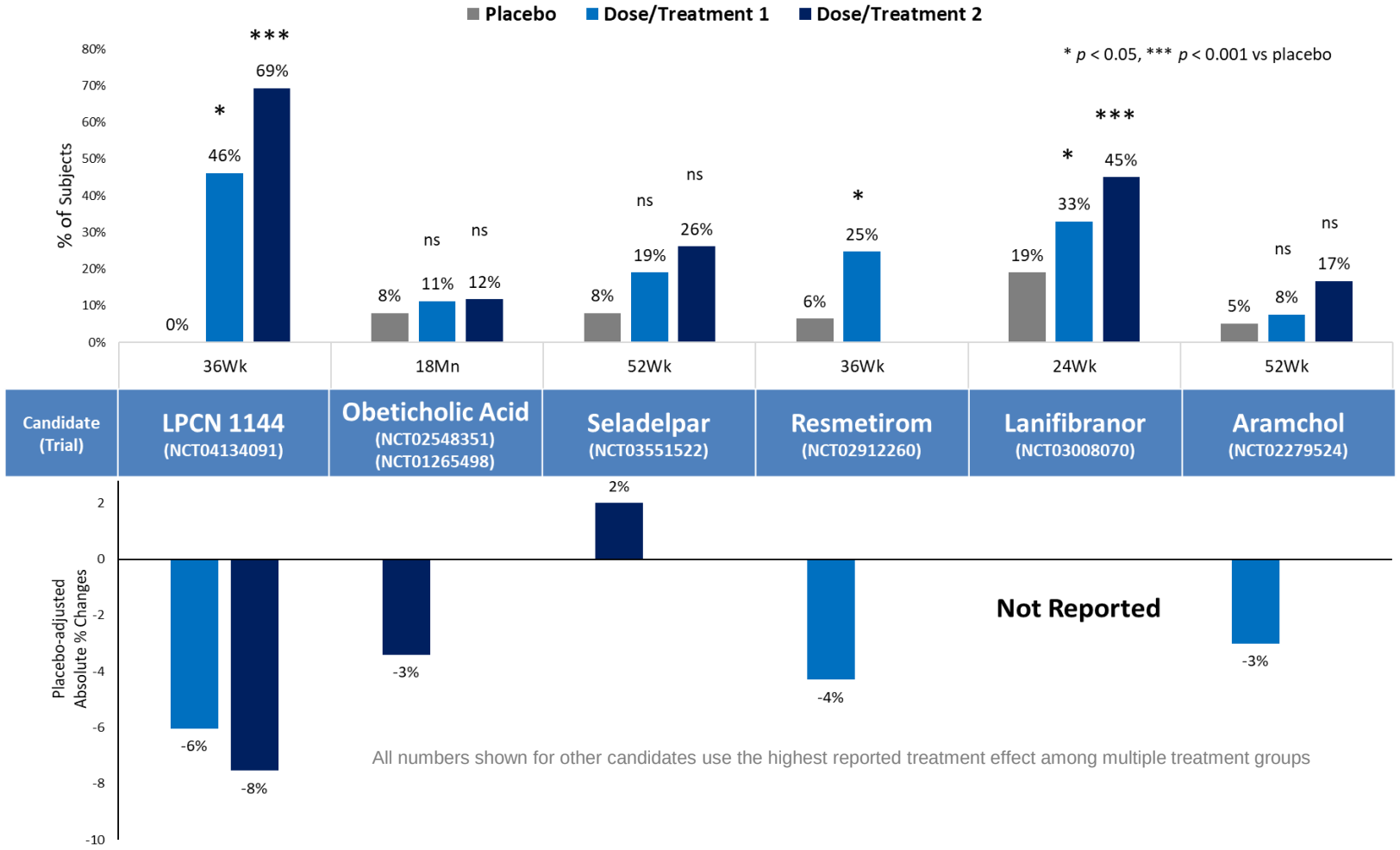
1. Estes et al., Hepatol 2018. 2. Williams et al., Gastroenterology 2011. 3. LifeSci Partner Analysis 2022

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



All numbers shown for other candidates use the highest reported treatment effect among multiple treatment groups

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)

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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†	1 (5.3%)	3 (17%)	0 (0%)
Pruritus	1 (5.3%)	1 (5.6%)	0 (0%)

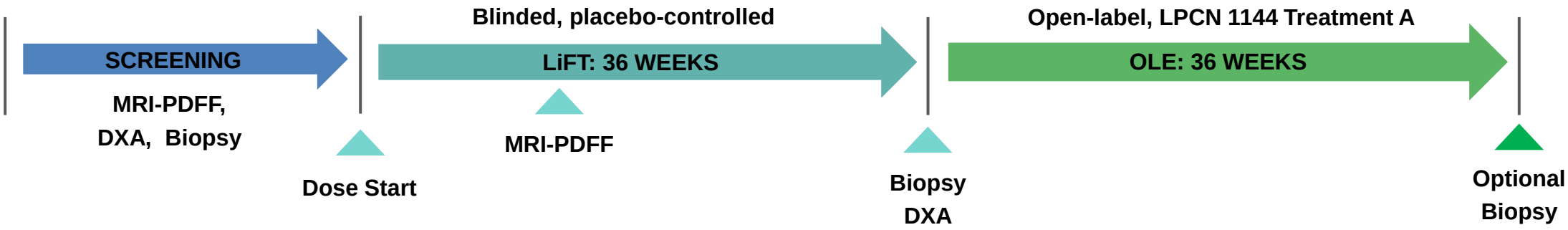
TEAE = Treatment Emergent Adverse Events, BPH = Benign Prostatic Hyperplasia; PSA = Prostate-Specific Antigen; † New or worsening hypertension

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



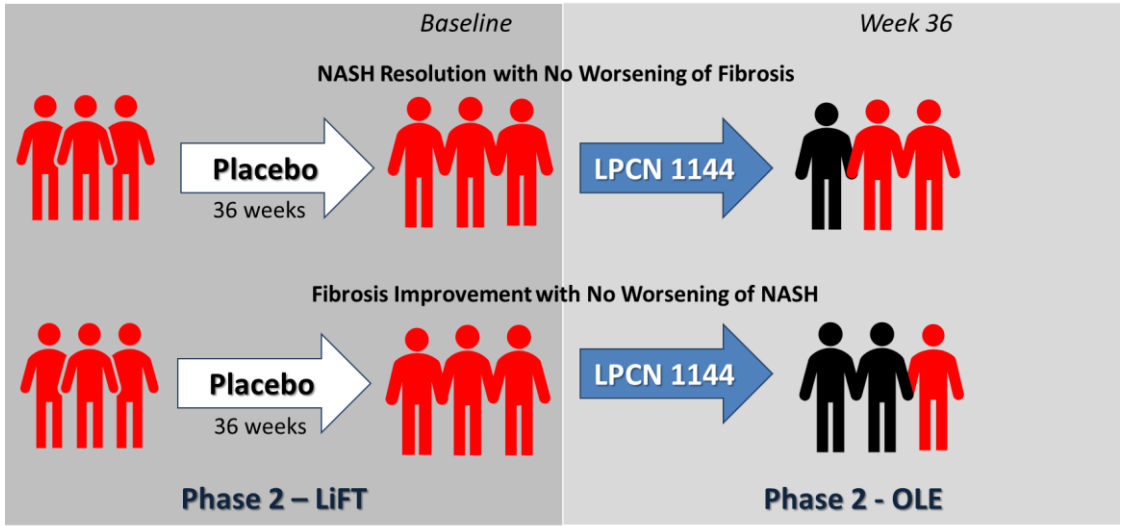
Safety Overview of LPCN 1144 in OLE

Well-Tolerated with No Observed Safety Signals

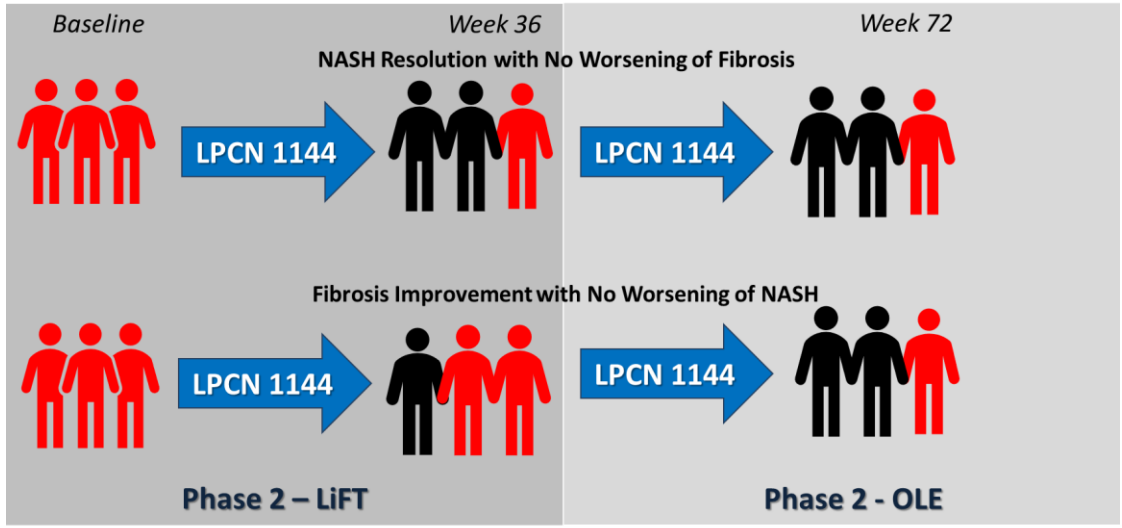
- In the OLE-Safety Set, the frequency and severity of TEAEs were comparable to those observed in the LiFT study
- There were no reported cases of cardiovascular events, thromboembolic events, hepatocellular carcinoma, or drug induced liver injury ("DILI")
- Weight change from baseline was minimal and 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

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

- Over 2 million cases[1] ; 500k+ living with decompensated cirrhosis[2]
- 62% of those on the liver transplant (LT) waitlist are male[3]
- High (~$812,500/transplant) economic burden[4]
- 40-70% of cirrhotic men have sarcopenia[5,6]

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

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

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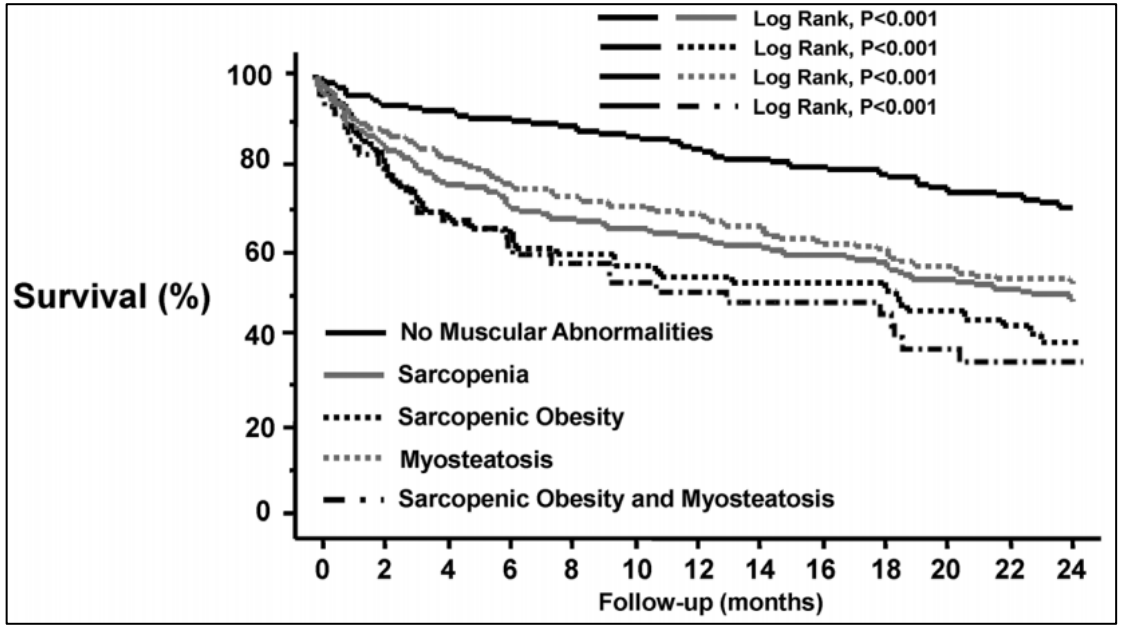
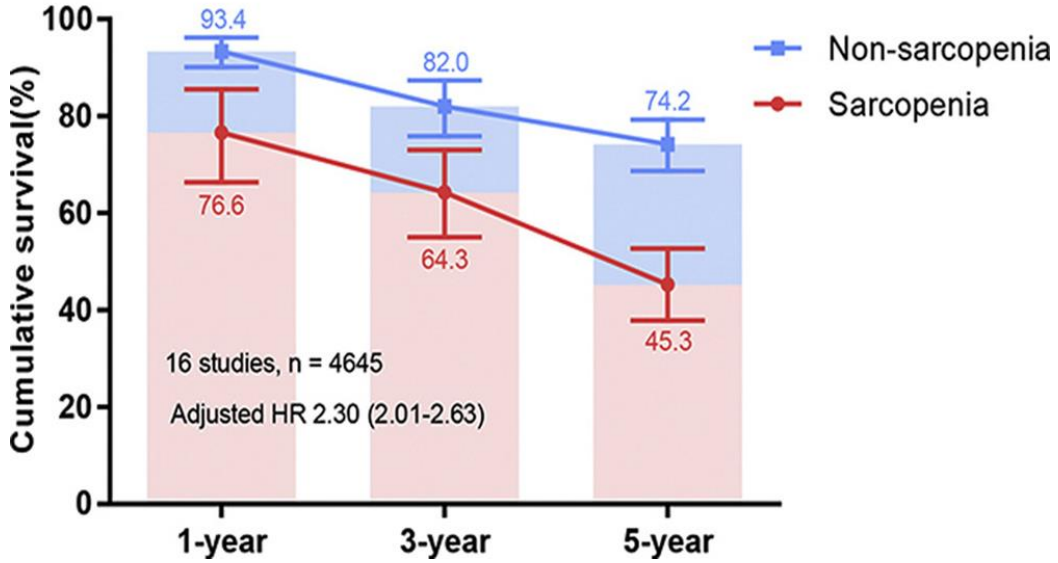
Survival in Cirrhotic Patients with Muscle Disorders

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

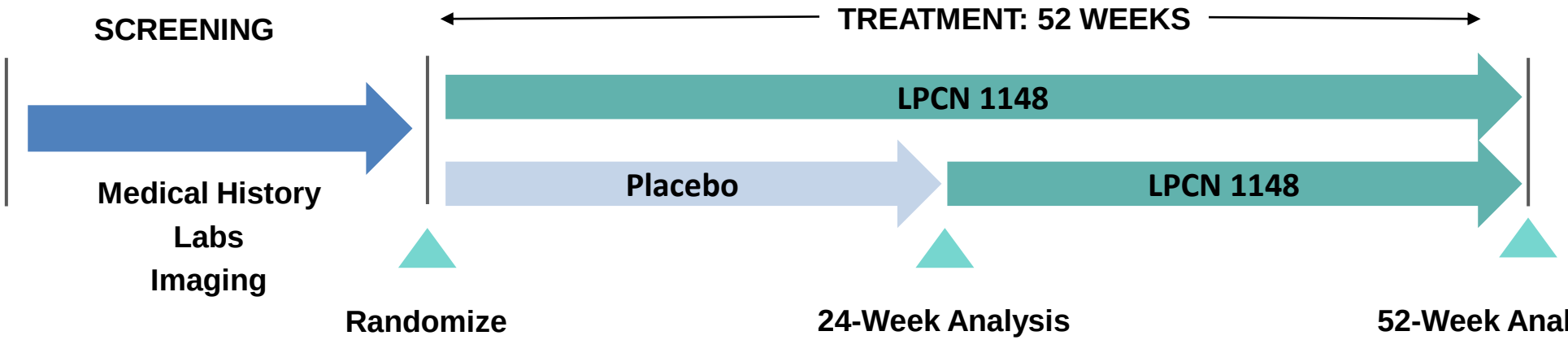
Phase 2, Multicenter, Double-Blinded, Placebo-Controlled Study*

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, myosteatosis
  - Patient Reported Outcomes (PRO's)



*NCT04874350

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

https://www.postpartumdepression.org/resources/statistics/
Evins GG et al. Am J Obstet Gynecol. 2000;182(5):1080-1082
Moore Simas et al. Curr Med Res and Opin. 2018; 35(3):383-393
Goodman J. J Adv Nurs. 2004;45(1):26-35.

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LPCN 2101

for Women With Epilepsy (WWE)

Next Step:

Phase 2 – PSE Study

No epilepsy drug specifically approved for WWE of childbearing age

Women with Epilepsy (WWE) of Childbearing Age

Balance Seizure Control with Specific Concerns

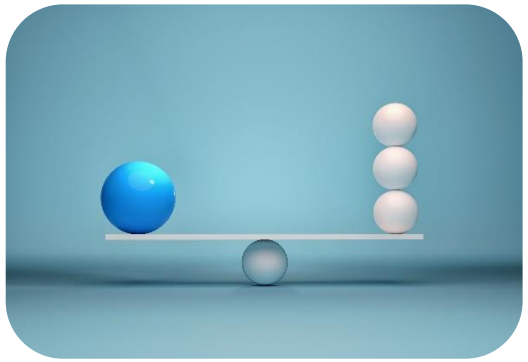
~ 900,000 of childbearing age women suffer from active epilepsy in US

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

AED = Antiepileptic Drug

S.Bangar et al. Functional Neurology 2016; 31(3): 127-134
Reimers et al. Seizure. 2015 May;28:66-70.

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	2Q 2022
LPCN 1107	FDA Meeting on Path Forward	2H 2022
LPCN 1154	Food Effect Study Results	2Q 2022
LPCN 2101	Phase 2 - Photosensitivity Epilepsy Study	2H 2022