



Forward-Looking Statements

This presentation contains "forward-looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding our product development efforts, our strategic plans for developing product candidates to treat CNS disorders, our ability to monetize non-core product candidates, including through entering into partnering arrangements, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the achievement of milestones within and completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates to treat CNS disorders, we may not have sufficient capital to complete the development processes for our product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals and our ability to utilize a streamlined approval pathway for LPCN 1154, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this presentation, except as required by law.



Investment Highlights

Validated Proprietary Lip'ral Technology Platform

Enabling Effective Oral Delivery

Curated Clinical Development Focus

LPCN 1154: Fast Acting Oral Antidepressant

LPCN 1148: Unique MOA for Hepatic Encephalopathy

LPCN 2101: Novel MOA for Treating Women with Active Epilepsy

LPCN 2203: Oral NAS for Essential Tremor

Value Through Partnering of Non-Core Assets

Testosterone Replacement Therapy: TLANDO® and LPCN 1111 (TLANDO XR)

Prevention of Preterm Birth: LPCN 1107

Chronic Liver Disease: LPCN 1144, LPCN 1148

Near-Term Value Events

Q1 2024

LPCN 1148: Topline P2 OLE Results



Q2 2024

LPCN 1154: Topline Pivotal Study Results

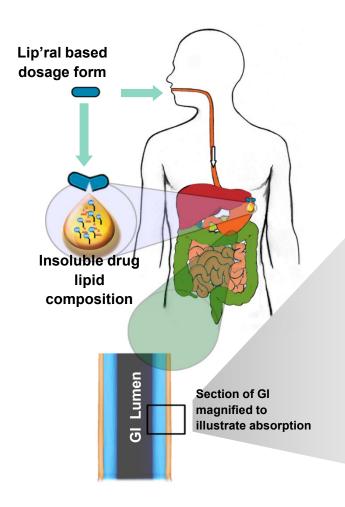


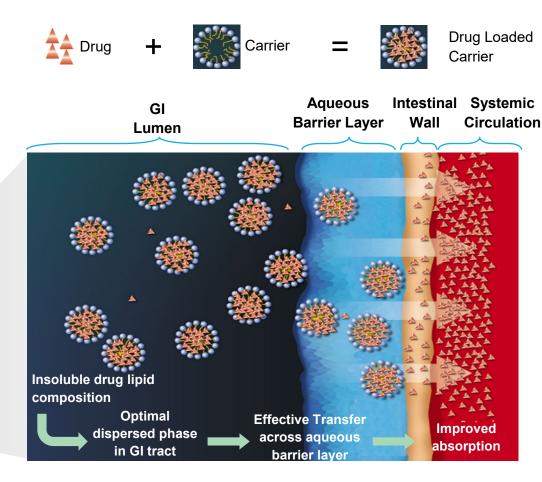
Q4 2024

LPCN 1154: Target NDA Filing



Validated Proprietary Lip'ral Technology Platform





Superior Oral Bioavailability

e.g., TLANDO®

Enable Effective Oral Delivery

e.g., neuroactive steroids, 17-hydroxyprogesterone caproate

Lipocine Clinical Development Pipeline





LPCN 1154

Oral Brexanolone for Postpartum Depression (PPD)

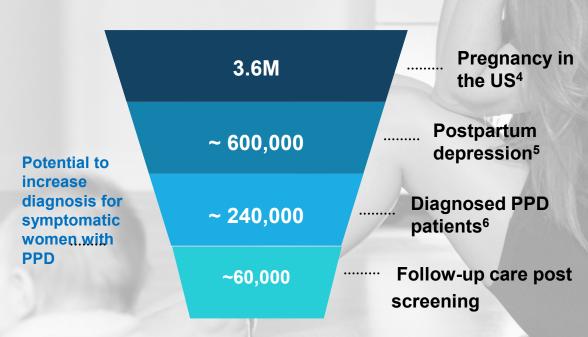


Postpartum Depression (PPD) and Market Potential

Dynamic PPD market offers significant opportunity for differentiated LPCN1154

- Well defined population
- Suicide is a leading cause of maternal death in the first year following childbirth¹
 - Up to 30% of women with PPD experience suicidal ideations²
- Critical to prevent harm to mother and infant
- Negative impact on family/society
- High economic burden

Estimated patients in the U.S. with PPD³



Zurzuvae Rx price: \$15,900

Projected peak Zurzuvae sales of \$1.2B in 2033*



et al. Curr Psychiatry Rep, 2022; 24(4):239-275

Lipocine, March 2024

LPCN 1154 - A New Paradigm with Oral Bioidentical NAS for PPD

Patients in need of a highly efficacious, fast-acting, and convenient antidepressant

Zuranolone (Zurzuvae®)

Synthetic NAS derivative

14-day treatment duration

Long terminal half-life (20-25 hr)

Impaired ability to drive, CNS depressant effect¹

Embryo-fetal toxicity¹

Remission of 19% at day 3 and 45% remission post **2 weeks** treatment²

Dosage modifications needed for concomitant use with CYP3A4 modulators¹

Tolerability¹

LPCN 1154 Advantage

Robust rapid relief with 48-hour treatment duration

Symptom relief as early as 24h³

Up to 75% remission post treatment (60 hours)⁴

Up to 84% response post treatment (60 hours)⁴

Brexanolone dosing is based on returning women to pre-delivery levels of allopregnanolone⁵

Remission defined as (HAMD-17 score ≤7) Treatment response as > 50% change from baseline in the HAM-D total score



^{1.} Zurzuvae label

^{2.} Kristina M. Deligiannidis et al., JAMA Psychiatry. 2021 Sep; 78(9): 1–9

LPCN 1154: Multidose Dosing Regimen Results

Positive results confirm 48-hour dosing regimen for the pivotal PK study

Comparative Exposure

PK	Ratios (%) of geometric mean LPCN 1154 vs IV brexanolone		
Parameter	DR 1 vs IV 60 μg*	DR 2 vs IV 90 μg	
AUC∞	98%	83%	
C_max	114%	79%	

Showed comparable PK exposure to both efficacious doses of IV Brexanolone

Adverse Reactions of Interest

	DR 1 (n=12)	DR 2 (n=12)	DR 3** (n=8)	Total (n=32)***
Loss of consciousness	0	0	0	0
Sedation, somnolence	0	0	0	0
Dizziness, presyncope, vertigo	0	0	0	0
Flushing, hot flush	0	0	0	0
Dry mouth	0	0	0	0
Decreased oxygen saturation	0	0	1	1
Нурохіа	0	0	0	0

The exposure PK parameters observed with DR 3 are comparable to those of IV infusion brexanolone administered per label instructions

LPCN 1154 Status

Streamlined pathway to NDA submission goal in 2024







Pilot PK Bridge Study

Positive Topline Results

Established feasibility of multidose oral administration of LPCN 1154

Pivotal PK Study

Confirmatory trial to enable NDA submission*

NDA Filing

Expected to be the first oral brexanolone

Completed

Q2 2024 Topline Results

Q4 2024 Target

- Following positive results from the pilot PK bridge study, Lipocine completed a successful meeting with the FDA
- FDA agreed on the acceptance criteria for the pivotal study

LPCN 1148

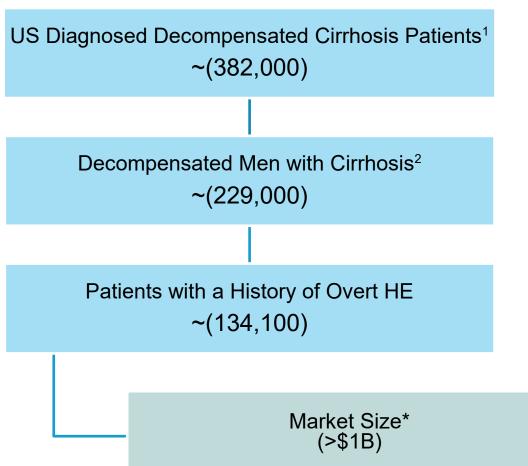
Management of Liver Cirrhosis

- Overt Hepatic Encephalopathy (OHE)
- Secondary Sarcopenia (SS)



Overt HE Market Considerations

Blockbuster potential



Rifaximin for Reduction in Risk of OHE Recurrence

- Rifaximin (Xifaxan[™]) is used to prevent episodes of HE by stopping the growth of bacteria that produce toxins that may worsen liver disease
- Approval based on subjects with reduction in breakthrough HE events: 22.1% of patients with breakthrough HE events in rifaximin group, vs 45.9% in placebo group (p<0.001)³
- Xifaxan (550 mg tablet) sales > \$1B in 2021
- LPCN 1148 is positioned for development to be used either mono or adjunct therapy with current SOC for a greater effect on the prevention of overt HF

Current Standard of Care & Unmet Needs in OHE

Limited options - significant enduring medical need

Current Standard of Care

Reduction of OHE Recurrence Risk¹

- First Line: Lactulose or Lactitol
- Add On to 1st Line: Rifaxamin
- Transplantation

Key Unmet Needs

Significant Mortality

High Recurrence Rate

Low Tolerability

Overt HE patients have significant near-term morbidity and mortality²

Lactulose/lactitol and rifaximin are used in reducing the risk of overt HE, however many patients have recurrent episodes on these therapies³

Adherence to lactulose / lactitol is hindered by its tolerability profile, which can include nausea, vomiting, and gastrointestinal adverse events 4,5

son, Eur J Gastroenterol Hepatol, 2019

Lactulose Package Insert. Lactitol Package Insert

LPCN 1148: A Blockbuster Opportunity

Product Candidate **Attributes**

Oral androgen receptor agonist

Dosage form comprising testosterone dodecanoate, a unique prodrug of an endogenous hormone

Targeted Mechanism of Action

Anabolic¹

Increase muscle mass and strength²; Reduce fat mass³; Increase bone density⁴; Inhibit myostatin⁵; Improve appetite and nutritional status*

Ammonia Lowering

Via improved liver health⁶ and improved muscle health⁷; Antibacterial⁸

Androgenic

Induce hematopoiesis⁹; Improve endocrine/sexual dysfunction¹⁰



^{3.} Bhasin, Clin Infect Dis 2003 4. Snyder et al., JAMA Intern Med 2017

Primary Endpoint Met

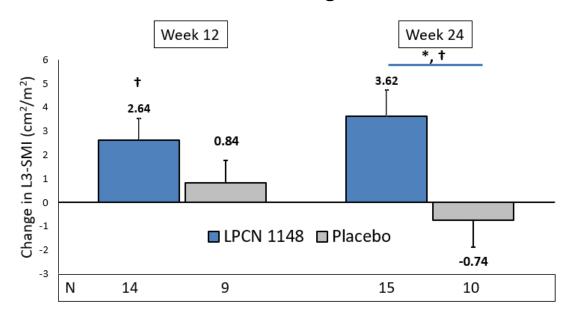
LPCN 1148 therapy resulted in a significant increase in L3-SMI at week 24

L3-SMI Change from Baseline

			P-v	alue	
Timepoint	LPCN 1148 (N=15)	Placebo (N=10)	1148 CFB	1148 vs. Placebo	
Baseline (cm²/m²)	47.8 (1.8)	45.8 (2.3)	N/A	NS	
Week 24 CFB (cm ² /m ²)	+3.62 (0.93)	- 0.74 (1.14)	<0.001	0.007	

LS mean (SE). CFB - Change from baseline

L3-SMI Absolute Change from Baseline



LS mean (SE), †P<0.05 for change from baseline; * P=0.007 vs. placebo

LPCN 1148 Efficacy

Recurrence of Overt HE was decreased with LPCN 1148

Parameter	LPCN 1148 (N=15)	Placebo (N=14)
Total decompensation events	7	10
Total decompensation events > Grade 1	6	10
Hepatic Encephalopathy events	3	6
HE > Grade 1*	2	6
Recurrence of HE > Grade 1*	1	6
Time to first recurrence of HE > Grade 1 (days)	115	36**

LPCN 1148 Efficacy

LPCN 1148 therapy produced trends in improvement in other secondary endpoints

Parameter	LPCN 1148	Placebo
Deaths (n)	0	1
Days in hospital (total)	54	117
Length of hospital stay (median, days)	3	5
6 min walk test (feet)*	270	-16
EncephalApp Stroop Test (total time, seconds)*	-4.8	13.8

^{*}mean change from baseline, LOCF



LPCN 1148 Safety

Overall LPCN 1148 was well tolerated

Parameter		N 1148 =15)	Placebo (N=14)		
	#	n	#	n	
Total AE events	33	8	36	10	
Serious AE events	15	5	16	5	
Severe AE events	6	4	10	4	

- Administration of LPCN 1148 was well tolerated in this end-stage population, with rates and severities of adverse events (AEs) similar to those within the placebo group
- Fewer days in the hospital with 1148 therapy
- No cases of drug-induced liver injury

LPCN1148: A Novel Approach for the Prevention of Overt Hepatic Encephalopathy and Reversal of Muscle Loss

Key takeaways

- **Blockbuster** opportunity that addresses a significant unmet medical need with a strong pharmacoeconomic rationale
- Targeted to be a "First in Class" product candidate with a novel MOA
- Met primary and relevant clinical endpoints including HE in P2 study with no background therapy restriction
- Potential **mono or add-on therapy** for a greater effect on the prevention of recurrence of overt HE
- Established development regulatory path with a commercially validated standard of care product
- Potential for **Orphan Drug Designation**/protected by robust patent portfolio
- **Expanded indication potential**



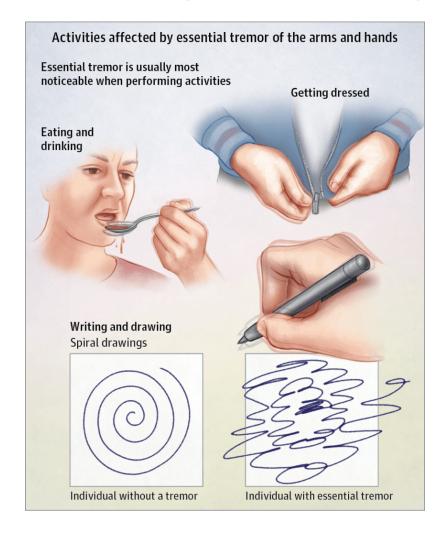
LPCN 2203

Oral NAS for Essential Tremor



Essential Tremor (ET)

No new drug approved in 50+ years



- Tremor highly disabling and stigmatizing
- Stress can aggravate tremor in social setting
- Major impact on activities of daily living leading to unemployment, anxiety and depression¹
 - Most common impacts on activities of daily living are pouring liquids and writing/typing (100%) and grooming/hygiene, drinking, dressing, eating, and reading (80-85%)
 - 90% of participants indicated the emotional impact of ET
 - 75% reported tremor-related worry or anxiety
- Majority of patients require caregiving¹

Essential Tremor Management – Opportunity

Daytime efficacy and improved tolerability remains an unmet need



Prevalence

- ~7 million patients in US1
- Estimated that only ~40% of patients are diagnosed
- Propranolol is the first line therapy
- 65% in need of 2nd line treatment
- ~44% of diagnosed patients treated with propranolol or primidone²



Standard of Care Limitations

Unfavorable benefit to risk profile³

- Most of patients are intolerant or have an inadequate response to first line propranolol or primidone
- 33% experienced no benefit from propranolol and 35% discontinued due to side effects
- 17% reported no benefit from primidone and 23% discontinued due to side effects



Unmet Need

Superior benefit to risk profile

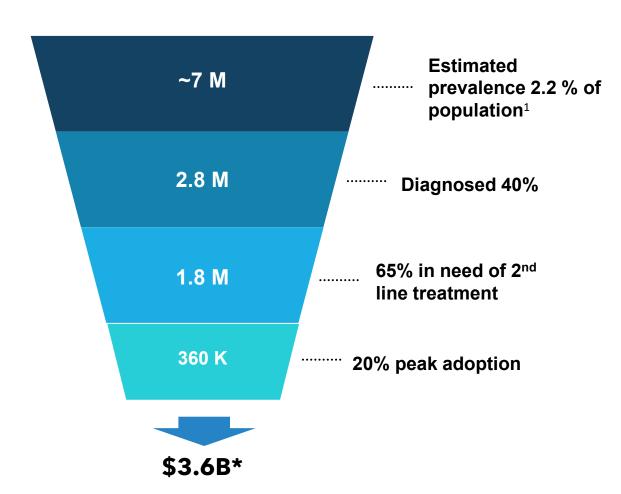
- Improve efficacy
- Fewer side effects
 - somnolence
 - dizziness
- Address anxiety/depression comorbidity
- Disease-modifying effects



Vetterick et al. Adv Ther. 2022; 39(12): 5546-5567

Market Potential and Competitive Development Landscape

\$3B+ blockbuster opportunity as 2nd line with 20% peak adoption



Products in Development*

SAGE-324: Adverse events - somnolence 68%, dizziness 38%, balance disorder 15%, diplopia 12%, dysarthria 12%, and gait disturbance 12%

38% discontinuation due to at least 1 AE

PRAX-944: Dizziness 14%, constipation 10%, headache 9%, fatigue 9%, anxiety 7%, feel abnormal 7%, paraesthesia 7%

JZP-385: Adverse events included dizziness (21% vs 6% in placebo), somnolence 2%

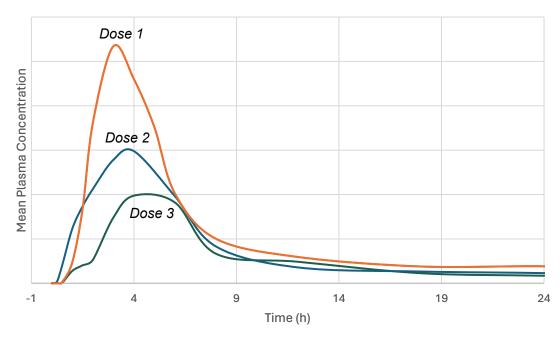
17% vs 4% discontinuation due to at least 1 AE



LPCN 2203: Oral GABA Positive Allosteric Modulator

Achieved relevant target levels with good tolerability in Phase 1 studies





- 84 doses administered across 4 single dose studies to 36 participants
 - No somnolence, sedation, and dizziness AE reported

Value Through Partnering of Non-Core Assets

Unlocking Value Through Partnering

Why Partnering?

Assets for Partnering

- Enables focus on CNS opportunities
- Candidate advancement
- Risk diversification
- Potential for non-dilutive financing
- Improved resource management





TRT Verity Alliance

TRT market is a large and growing with a significant untapped market potential

- ~8M annual prescriptions in the U.S.
- ~650,000 annual prescriptions in Canada

Verity Transaction

- Lipocine to receive \$11 million license fee
- Up to \$259 million in development and commercial sales milestones
- Tiered royalties on net sales of licensed products up to 18%
- Lipocine retains all rights for territories outside the United States and Canada, and all non-TRT rights globally
- Verity Pharma is responsible for regulatory and marketing obligations in the U.S. and Canada and all further development



Appendix

Zulresso® (Brexanolone) Post-marketing Safety#

Continuous IV Brexanolone Infusion

Post-market Experience (as of December 31, 2023)

FAERS Database* (n= 222)

0 % LOC

 IV infusion administration related AEs ~37%

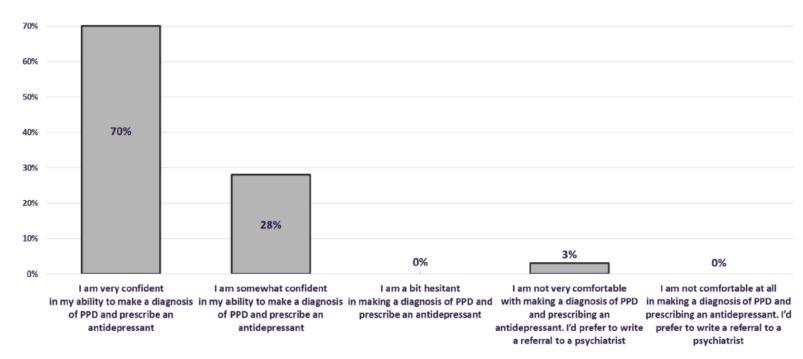
 Somnolence, sedation ~8%

 Dizziness, presyncope, vertigo ~6%

Obstetricians Awareness of PPD is High

A large majority of OB's are comfortable making a diagnosis of PPD and prescribing an antidepressant

How comfortable are you in making a diagnosis of PPD and prescribing an antidepressant?

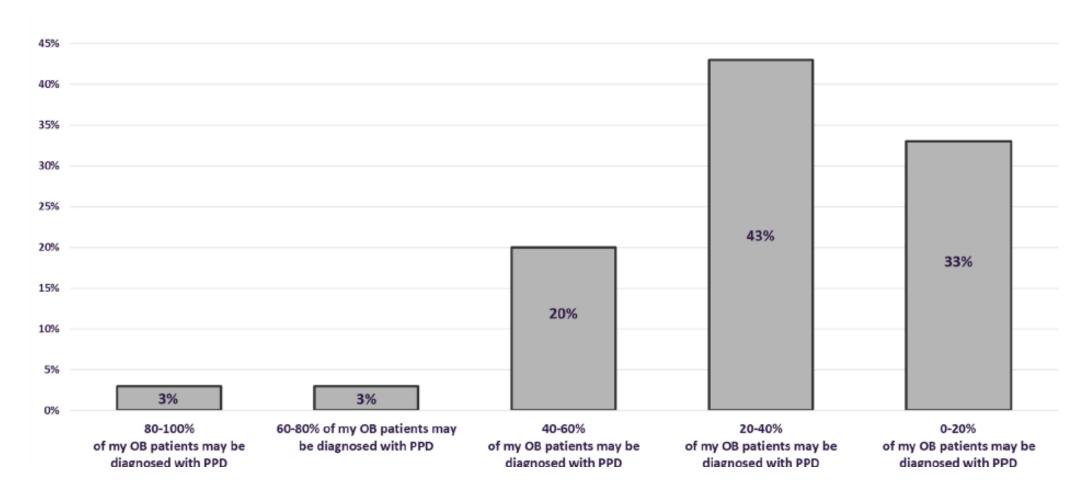


Source: Truist Securities Research

Truist conducted a survey of Zurzuvae with a group of 40 obstetricians



Obstetricians Estimate The Prevalence of PPD To Be >20% Which Is **Much Higher Than Previously Estimated***



*Source: Truist Securities Research, January 2024



Cirrhosis: Complications and Recent Trends

Complications

- Decompensation events hepatic encephalopathy, variceal bleeding, ascites, etc.
- Compromised liver function, immunity, and protein synthesis
- Muscle & bone disorders including sarcopenia
- Cachexia, malnutrition, and weight loss
- Symptoms of hypogonadism
- Increased inflammation

Recent Trends

- Occurrence of cirrhosis and related deaths are on the rise
- In the US between 1999 and 2019, greater than three-fold increase in deaths from alcoholic cirrhosis was observed¹
- Hepatitis C virus (HCV) infection remains the leading cause of global deaths related to cirrhosis, followed by alcohol-associated liver disease 2
- In the Americas, the dominant cause of cirrhosis is shifting from viral hepatitis to NAFLD and alcohol-associated liver disease²
- The global burden of cirrhosis associated with non-alcoholic fatty liver disease (NAFLD) has increased substantially in the past decade²
- There are more people who need a liver than the supply available³

Hepatic Encephalopathy in Cirrhosis Patients

Up to 50% of cirrhosis patients will experience an overt HE episode in their lifetime¹

Overt HE is a debilitating, episodic, neurological disorder with a high recurrence rate

HE is a major complication of advanced liver disease - patients exhibit global neurological, psychiatric, and musculoskeletal deficits

HE has a complex pathophysiology that includes impairment of ammonia clearance and increased inflammatory cytokines

HE recurrence is common, despite use of standard-of-care therapies

Complications of overt HE include a need for transplantation, progression to coma, and mortality²

1-year survival for persons with HE is ~50%3

HE accounts for approximately 110,000 hospitalizations yearly in the United States⁴

Presence of Sarcopenia is Linked with Worse Clinical Outcomes

Impact of improvement in liver health and body composition

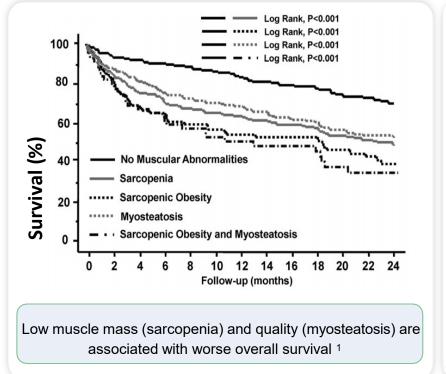
"If patients recover a significant amount of liver function and muscle mass from the time they had bouts of overt hepatic encephalopathy, they may well be able to stop standard HE therapy."

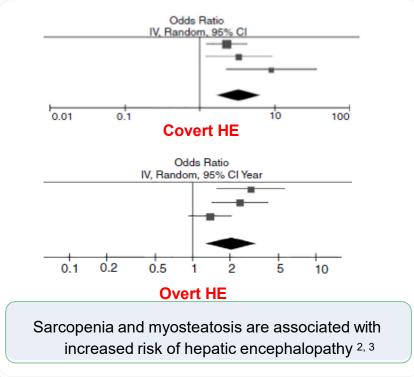
- AASLD Hepatic Encephalopathy Clinical Practice Guidelines

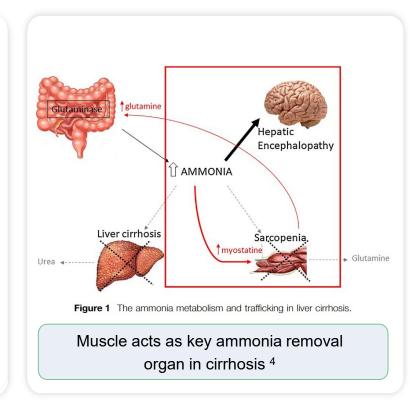
Vilstrup et al. Hepatology 2014 Lipocine, March 2024 34

Presence of Sarcopenia is Linked with Worse Clinical Outcomes

Higher rates of death and hepatic encephalopathy







LPCN 1148: Proof of Concept Study

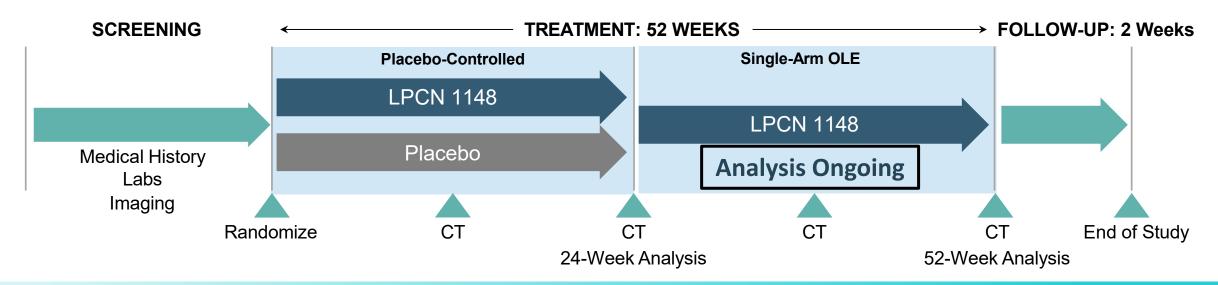
52-Week topline results - Q1 2024

Study Design

- Male subjects with liver cirrhosis and sarcopenia awaiting liver transplant
- Two-arm (1:1 randomization, N=29)
 - Oral LPCN 1148 vs. Placebo
 - Standard of care treatments/therapies allowed
- 24-week placebo-controlled
 - Followed by 28-week open-label extension (OLE)
 - All subjects receive LPCN 1148 during OLE

Endpoints

- Primary: Change in Skeletal Muscle Index (L3 region, L3-SMI) at Week 24 in LPCN 1148 treated participants compared to placebo
- Key secondary: rates of overt hepatic encephalopathy
- Other Endpoints:
 - Other major decompensation events, Patient Reported Outcomes (PROs), anemia, functional tests, muscle quality (myosteatosis)

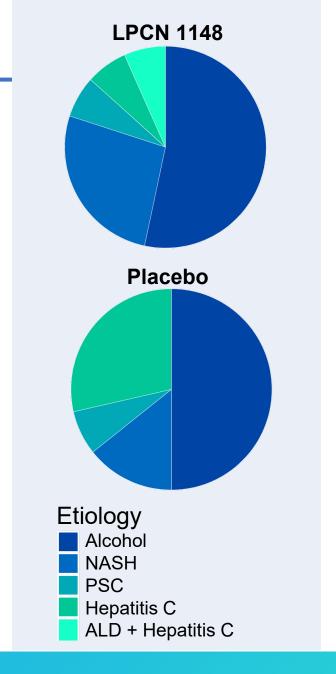




Baseline Characteristics

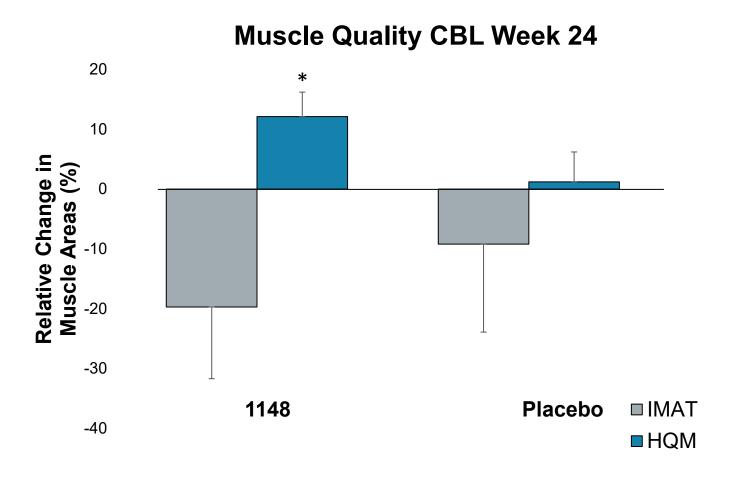
Generally well-balanced between treatment arms

	LPCN 1148 (N=15)	Placebo (N=14)
Age (years)	58.3 ± 7.5	58.8 ± 9.5
BMI (kg/m²)	29.2 ± 5.3	29.0 ± 8.6
L3-SMI (cm ² /m ²)	47.8 ±7.0	44.8 ± 8.5
MELD Score	15.9 ± 3.7	18.1 ± 4.6
Medical History		
≥ 1 Decompensation Event#	14 (93%)	14 (100%)
≥ 2 Decompensation Event	13 (87%)	12 (86%)
Hepatic Encephalopathy (HE)	11 (73%)	11 (79%)
Medical Therapy for HE*	11(100%)	10 (91%)
Ascites	11 (73%)	10 (71%)
Esophageal Varices	8 (53%)	8 (57%)





LPCN 1148 Improved Myosteatosis



Substantial Changes in Muscle Quality seen with LPCN 1148 Therapy

- Decrease in intramuscular adipose tissue (IMAT)
- Significant increase in high quality muscle (HQM)



Observed Hematologic Benefits

LPCN 1148 therapy resulted in significant increase in hemoglobin

Hemoglobin	LPCN 1148	Dlacaba	P-value		
Timepoint	(N=15)	Placebo (N=14)	Change from Baseline	Vs. Placebo	
Baseline (g/dL)	11.39 (0.75)	13.04 (0.8)	N/A	NS	
Week 24 CFB (g/dL)	1.30 (0.40)	-0.16 (0.23)	0.003	0.005	

Mean (SE)

Anemia Status	LPCN 1148 (N=15)	Placebo (N=14)
Anemic at baseline	11 (73%)	7 (50%)
Anemic at W24	7 (47%)	7 (54%)
Resolution	4 (36%)	1 (14%)
New onset	0 (0%)	1 (17%)

More LPCN 1148-treated subjects had resolution of anemia* at Week 24

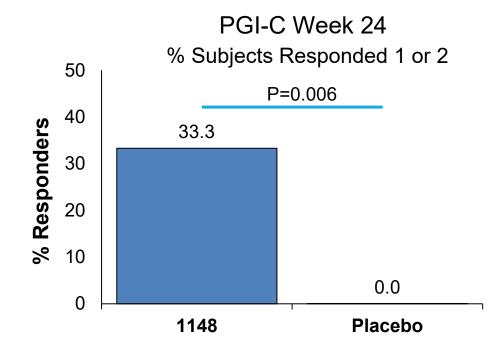
LPCN 1148: PGI - C

Participants reported significant symptom improvement with LPCN 1148 treatment

Patient Global Impression of Change (PGI-C) Scale

Please choose the response below that best describes the overall change in your symptoms since you started using the study treatment.

- 1) Very much better
- 2) Moderately better
- 3) A little better
- 4) No change
- 5) A little worse
- 6) Moderately worse
- 7) Very much worse



- Significantly more 1148-treated subjects reported feeling 'very much' or 'moderately' better
 - No 1148-treated subjects reported symptom worsening (>4) at Week 24
- Mean PGI-C score was significantly lower with 1148-treatment at Week 24
- Significant symptom improvement was noted as early as Week 4

Safety set, LOCF. LS Mean (SE); PGI-C: Patient Global Impression of Change Scale



ET Patient Journey and Commonly used medications

- First line treatment of propranolol frequently started at PCP
- 2nd and 3rd line treatments (e.g., primidone, benzodiazepine, gabapentin, topiramate) at general neurologist and movement disorder clinics
- Patient survey indicates on-going management by PCP (26%), general neurologist (23%), movement disorder specialist (19%)

ESSENTIAL TREMOR: COMMONLY USED MEDICATIONS

DRUG	PROPRANOLOL	PRIMIDONE	GABAPENTIN	ALPRAZOLAM	TOPIRAMATE	NIMODIPINE	ZONIZAMIDE
Brand	Inderal ®	Mysoline ®	Neurontin ®	Xanax ®	Topamax ®	Nimotop ®	Zonegran
Use in ET I	1 st line	1 st line	2 nd line	2 nd line	2 nd line	3 rd line	3 rd line
Class	beta-blocker	anti-convulsant	AED	anti-anxiety	AED	vasodilator	AED
MoA	beta blocker	barbiturate	GABA analog	benzodiazepine	complex	L-type Ca2+ chan.	CA inhibitor
daily dosing / frequency	80-160 mg BID	50-250 mg every bedtime	100-300 mg TID	up to 3mg TID	150-300 mg BID	120 mg QID	
Evidence- level	Level A; FDA approved	Level A	Level B	Level B	Level B	Level C	Insuff. Evidence
Response rate	~40-60%	~30-50%	30%	75%	30-40%	50%	50%
Tremor Reduction	50%	50-70%	30-40%	50%	20-37%	50%	25%
dropout rate	20-35%	20-30%	10%	<10%	30%	unknown	unknown
Side Effects	44.90% AE dizziness, fatigue	72% AE flu like symptoms significant sedation	"Generally well tolerated" sedation, dizziness, ataxia, weight gain in 30- 40% pts	sedation, cognitive impairment,	concentration difficulties,som nelence, fatigue	hypotension, edema, headaches in 10- 20% pts	trouble concentrating, body aches, flu symptoms, sore mouth; back pain
Alcohol DDI	Moderate	Major	can increase side effects	increased effects of EtOH	moderate, can increase side effects	moderate additive effect	can increase side effects
Number of major DDI	68	232	7	138	360	53	361

