Corporate Presentation

July 2025

LIPOCINE®
ENHANCING HEALTH

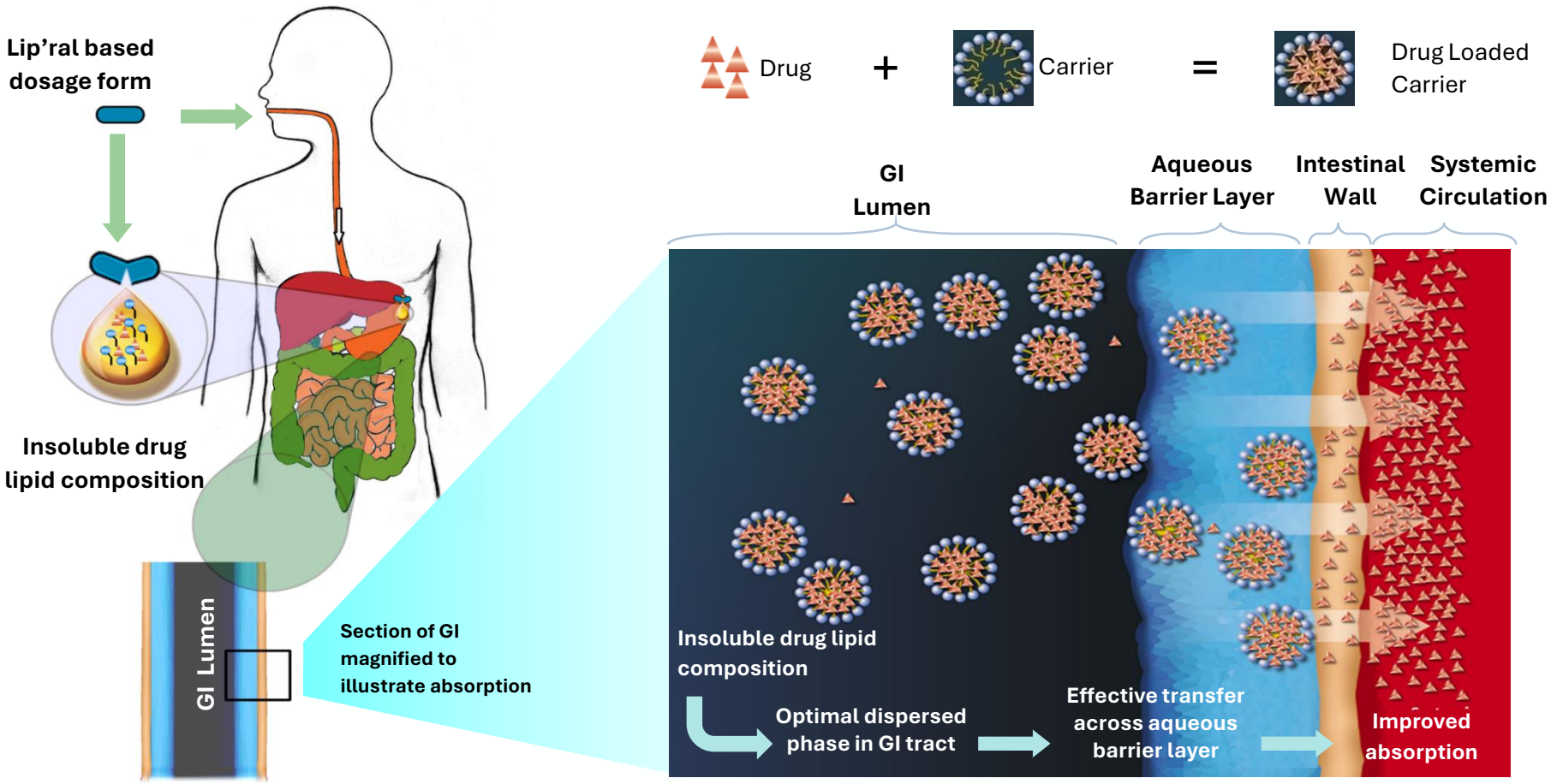
Forward-Looking Statements

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 candidates and strategic plans and related development efforts with the FDA, including with respect to LPCN 1154, our current intention to conduct a safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, the timing of our submission of a NDA with the FDA for LPCN 1154, and the potential uses and benefits of our product candidates, the application of our proprietary platform in developing new treatments, 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, we may not have sufficient capital to complete the development processes for our product candidates or we may decide to allocate our available capital to other product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, safety and efficacy studies, including those relating to LPCN 1154, may not be successful or may not provide results that would support the submission of a NDA, the FDA may 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.

Lipocine Pipeline

Development Candidate (*Indication*)	Pre-Clinical	Phase 1	Phase 2	Pivotal	Next Steps/Status
LPCN 1154 *Postpartum Depression*					Phase 3 Topline results Q2/26
LPCN 2401 *Obesity Management - adjunct to GLP-1*					POC study with GLP-1 – expected patient dosing Q3/25
LPCN 1148 *Decompensated Liver Cirrhosis*					P2 study completed
LPCN 2101 *Women With Epilepsy*					IND cleared for P2
LPCN 1107 *Prevention of Preterm Birth*					EOP2 meeting completed
LPCN 2203 *Essential Tremor*					P1 study completed
LPCN 1144 *Non-Cirrhotic NASH*					P2 study completed

Validated Proprietary Lip'ral Technology Platform



Superior Oral Bioavailability

e.g., TLANDO®

Enable Effective Oral Delivery

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

Giliyar et al. Drug Delivery Technology, Jan 2006, Vol 6 No.1

TLANDO® - FDA-Approved Oral Testosterone Replacement Therapy

Established commercialization partnerships in multiple territories

First and only oral testosterone replacement therapy (TRT) option that does not require dose titration

- **TLANDO® licensed to Verity Pharma in January 2024 for commercialization in the U.S.**
  - $11 million upfront payment to Lipocine
  - Entitled to receive tiered royalty payments ranging from 12% up to 18% on net sales of TLANDO franchise
- **TLANDO® licensed to 5 territories including US and Canada**
- **FDA labeling changes for testosterone products**
  - Removal of Boxed Warning related to an increased risk of adverse cardiovascular outcomes
  - Include results from required post market ambulatory blood pressure (ABPM) studies
- Approved product utilizing Lip'ral technology

TRT is a large and growing market with ~8M annual prescriptions in the U.S. and ~650,000 in Canada.

IMPORTANT SAFETY INFORMATION
https://www.tlando.com/

LPCN 1154 (BRLIZIO™)

Oral Brexanolone for Postpartum Depression (PPD)

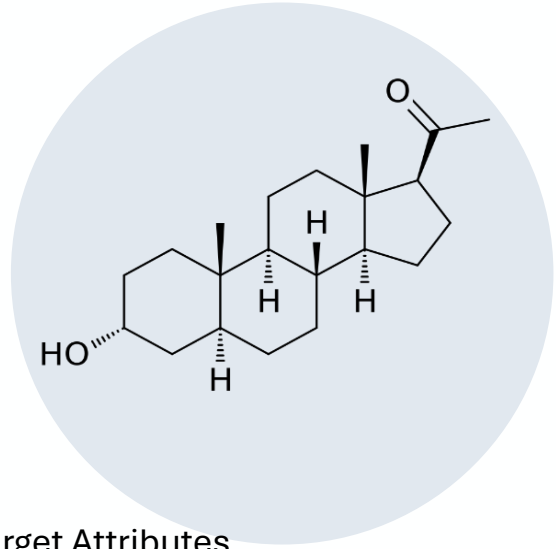
Brlizio™ is a brand name conditionally approved by FDA

LPCN 1154 - Oral Bioidentical Neuroactive Steroid (NAS) for PPD

Potential as “first line” therapy

Brexanolone

- Brexanolone is a positive allosteric modulator (PAM) of the $GABA_A$ receptor



Brexanolone (allopregnanolone)

Molecular Weight: 318.5 g/mol

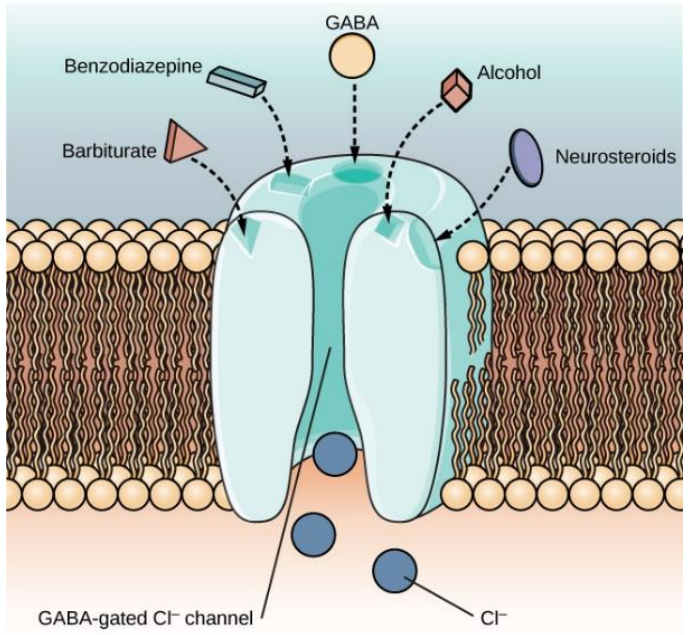
Lipophilic: Log P ≈ 5.0

Poor aqueous solubility: Saq <1.0 µg/mL

Target Attributes

- Oral solid dosage form
- No titration or taper required
- 48-hour outpatient dosing
- No Monitoring requirement

Mechanism of Action



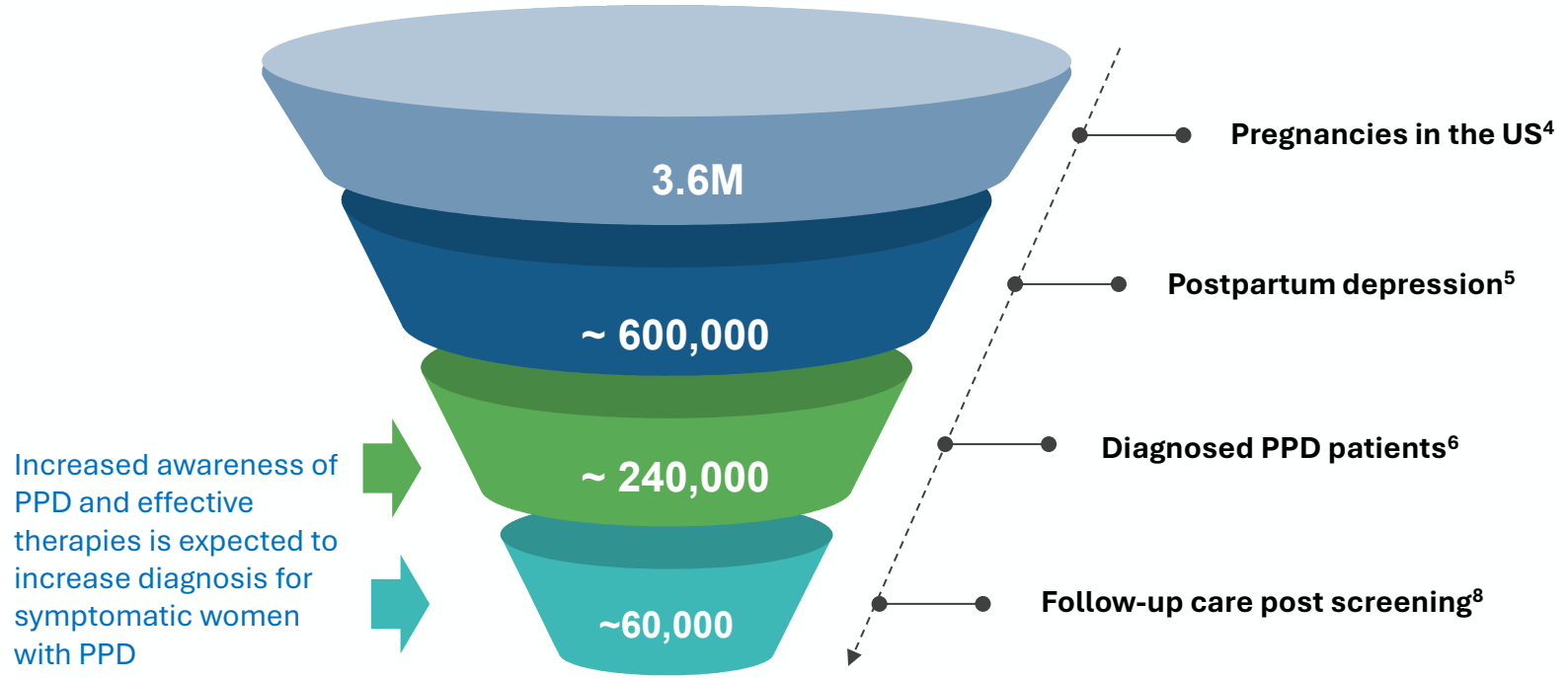
https://opentext.wsu.edu/psych105nusbaum/chapter/substance-use-and-abuse/

Postpartum Depression (PPD) Market Opportunity

Compelling pharmacoeconomic rationale

- High economic burden
- Goal of medical intervention is to prevent harm to mother and infant
- Negative impact on family/society
- Among women reporting PPD symptoms, 64% reported comorbid anxiety symptoms[7]
- Suicide is a leading cause of maternal death in the first year following childbirth[1]
  - Up to 30% of women with PPD experience suicidal ideations[2]

Estimated patients in the U.S. with PPD[3]



ZURZUVAE® Rx price: $15,900

Projected peak ZURZUVAE® sales of $1.2B in 2033[9]

ZURZUVAE® is an FDA-approved oral treatment for adults with PPD

1. Chin et al. Curr Psychiatry Rep, 2022; 24(4):239-275
2. Mauri et al. Arch Womens Ment Health. 2012; 15(1): 39-47
3. Foster Rosenblatt market research 2023 (Lipocine internal data)
4. National Vital Statistics Report vol 72, num 1, 2023; Vital Statistics Rapid Release, report 26, 2023
5. Van Niel et al. Cleveland Clinic J of Medicine. 2020;87(5):273-277
6. Cox et al. J Clin Psychiatry. 2016;77:9, Beck. AJN. 2006;106:5
7. Farr et al. J Womens Health (Larchmt). 2013 Oct 26;23(2):120–128
8. Goodman et al J Womens Health (Larchmt). 2010 Mar;19(3):477-90
9. Goldman Sachs on Sage Therapeutics estimate on February 2024

LPCN 1154 - Oral Bioidentical NAS for PPD

Potential for compelling advantages over current therapies

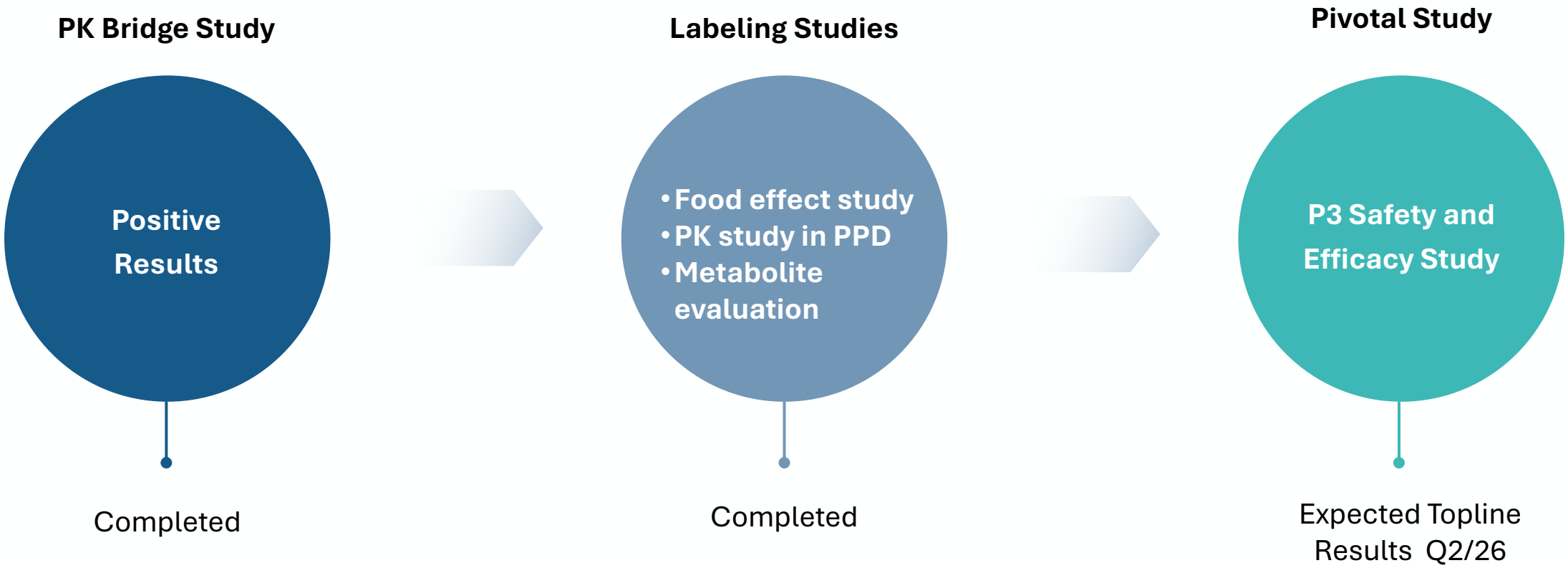
	LPCN 1154 (*BRLIZIO™*)	**Zuranolone** *(Zurzuvae®)*	***SSRIs / SNRIs*** *Off-Label Use*
Description	**Bioidentical NAS**	Synthetic NAS Derivative	Synthetic SSRI/SNRI
Administration	**Oral**	**Oral**	**Oral**
Onset of Action	**Hours***	Days	Weeks
Treatment Duration	**48 hours**	14 days	Months
Remission Rate at Day 3	**Up to 61%***	Up to 19%	N/A

1. Zulresso label
2. Brexanolone Briefing Book, November 2, 2018
3. In adolescent patients per sNDA 211371 S-007 Multi-disciplinary Review and Evaluation ZULRESSO)
4. Zurzuvae label
5. Kristina M. Deligiannidis et al., JAMA Psychiatry. 2021 Sep; 78(9): 1–9
6. https://www.ncbi.nlm.nih.gov/books/NBK594292/

*Projected based on Zulresso published reports (Brexanolone Briefing Book, November 2, 2018 and Meltzer-Brody et al. Lancet. 2018 Sep 22;392(10152):1058-1070)

LPCN 1154 (Oral Brexanolone) Development

Streamlined 505(b)(2) pathway to NDA submission



LPCN 1154 PK Bridge Study Results

LPCN 1154 met standard bioequivalence criteria to IV Brexanolone

Comparative Exposure

PK Parameter	GMR (%) Test vs. Reference	90% CI LB Test vs. Reference	90% CI UB Test vs. Reference
C_{max}	**105**	92	118
$AUC_{0-\infty}$	**97**	89	107
AUC_{0-t}	**89**	81	98

- LPCN 1154 was well tolerated
  - No sedation or somnolence events observed
  - All events were mild to moderate
  - No severe or serious AEs
  - Reported study related events were venipuncture site related, arthralgia, fatigue, dizziness, back pain, hematoma, and pelvic pain
  - No event was reported by >2 participants

n=23; Outlier participant presented PK results for the IV administration period greater than 70 standard deviations away from the PK data set mean for all PK parameters included above

GMR = Geometric Mean Ratios, CI = Confidence Interval, LB = Lower Bound, UB = Upper Bound, t = 100 hours for AUC_{0-t}

LPCN 1154 Phase 3 Safety and Efficacy Study

Based on FDA feedback – outpatient setting with no medical monitoring requirement

Study design

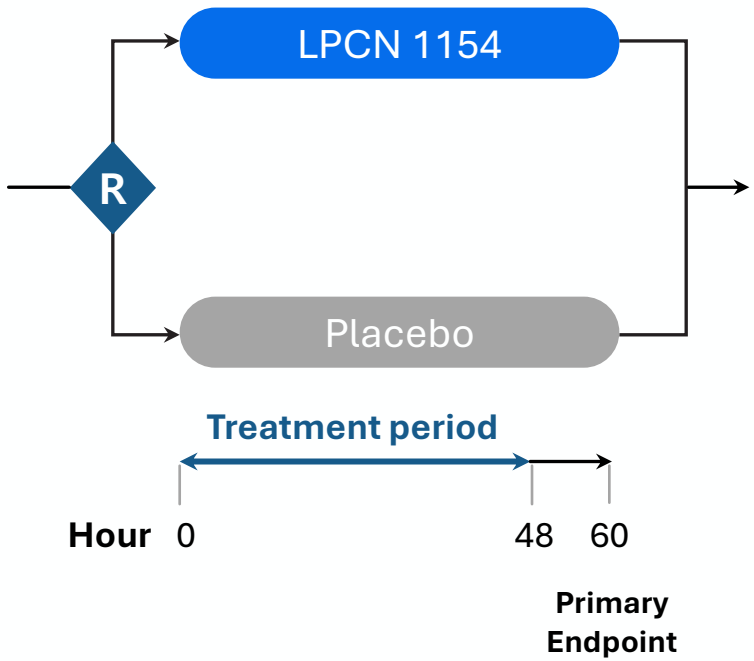
Two arm, outpatient, randomized, blinded, placebo-controlled in women with postpartum depression

Inclusion criteria

Severe PPD

Age ≥15 yrs

N= ~80 women



Endpoints

Primary endpoint:
HAM-D change from baseline at hour 60

Additional endpoints:
MADRS, HAM-A (anxiety), safety and tolerability, etc.

Prospective advantages

- Brexanolone has established efficacy (IV infusion)
- LPCN 1154 has demonstrated comparable exposure to IV infusion
- Study size, duration, and population similar to IV infusion P3 study
- Generate safety and efficacy data in women with PPD
- Investigate potential for treatment of anxiety disorders
- May qualify for pediatric study waiver
- Support global registration package
- Eligible for clinical investigation exclusivity

LPCN 1154 “Best in Class” Oral Treatment for Depression

Key takeaways

- **Significant market opportunity**
- **Differentiated product attributes addressing unmet needs**
- **Streamlined pathway to NDA submission**
    - PK bridge study: *completed with positive results*
    - Phase 3 safety & efficacy study: *ongoing*
    - Topline data expected Q2/2026
- **Issued and pending patents**
- **Potential to expand for other depression indications**

LPCN 2401

Obesity Management

Unprecedented Demand and Usage of GLP-1 Receptor Agonists[1-3]

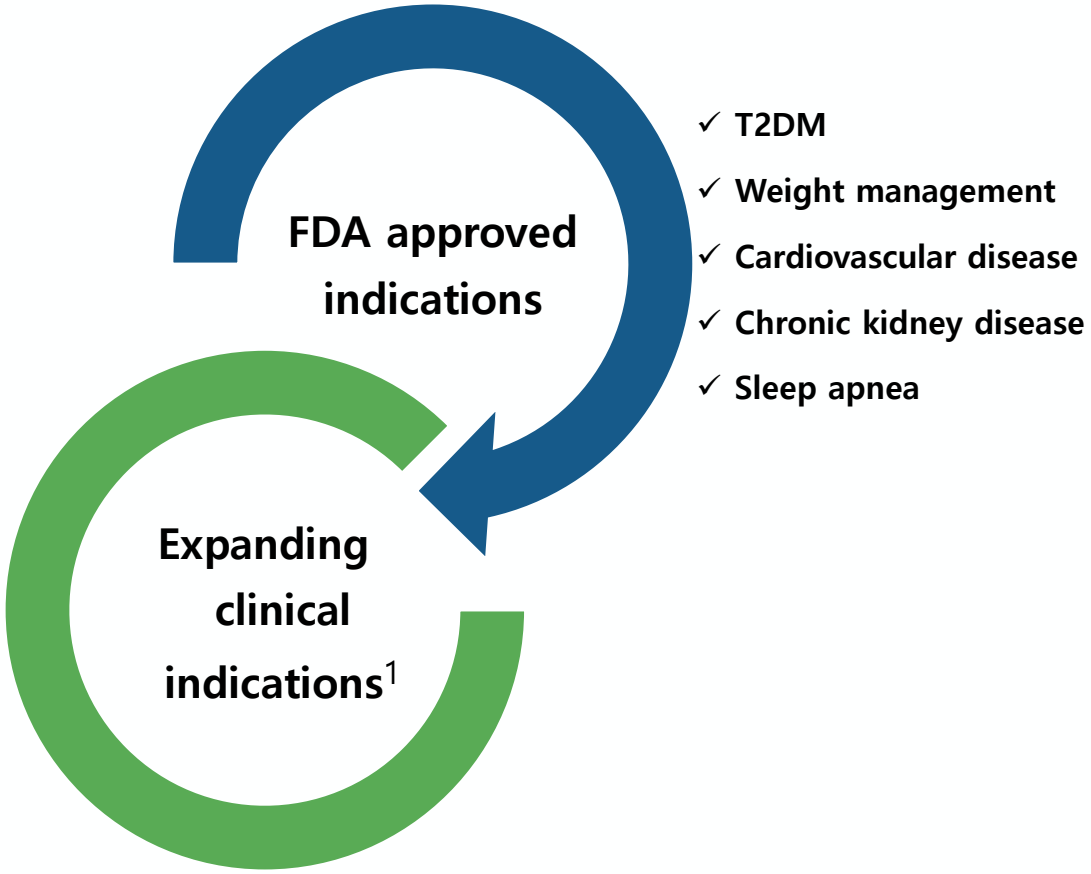
GLP-1 market trending toward oral once daily dosing

Semaglutide: $30 billion sales in the US in 2024[4]

Tirzepatide: $14 billion sales in the US in 2024[5]

As of 2024, around 12 percent of U.S. adults reported having used a GLP-1 medication at some point[6]

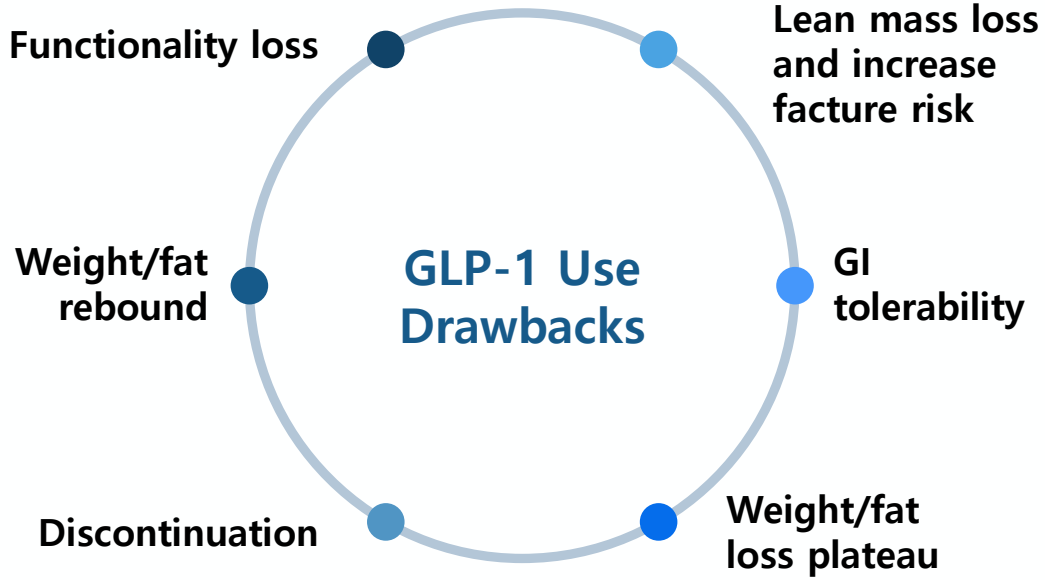
Over 150 GLP-1 drug candidates in development for multiple indications[7]



1. https://www.biospace.com/drug-development/7-indications-for-glp-1s-beyond-weight-loss
2. https://www.pwc.com/us/en/services/consulting/business-model-reinvention/glp-1-trends-and-impact-on-business-models.html
3. https://www.nature.com/articles/s41574-024-01066-9
4. Novo Nordisk SEC filing 2025
5. Eli Lilly SEC filing 2025
6. https://jamanetwork.com/journals/jama/article-abstract/2819949
7. https://www.globenewswire.com/news-release/2025/03/18/3044263/28124/en/

Limitations of GLP-1 Use and Unmet Medical Needs

2 out of 3 patients on drugs like Wegovy stop within a year[1]



Unmet Medical Needs

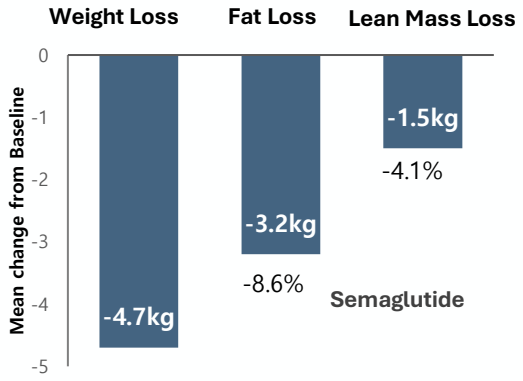
- Improve (quality/extent) weight/fat loss
- Preserve lean mass/functionality
- Improve tolerability & compliance
- Amplify weight/fat loss
- Prevent weight/fat rebound

1. https://www.reuters.com/business/healthcare-pharmaceuticals/most-patients-using-weight-loss-drugs-like-wegovy-stop-within-year-data-show-2023-07-11/

Drawbacks of Approved GLP-1 Receptor Agonists

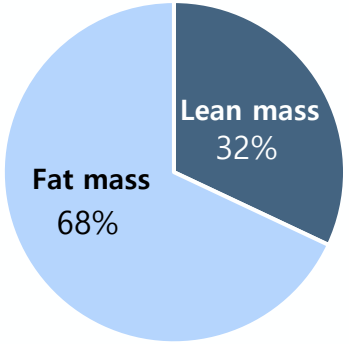
Rapid loss of lean mass and functionality in elderly GLP-1 users

Low Quality Weight Loss[1]



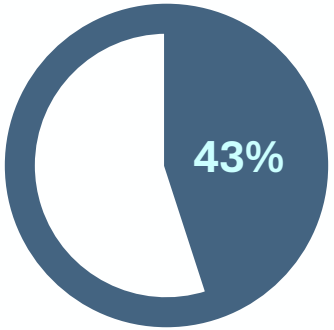
Significant weight loss is from lean mass loss in **16 weeks**[1]

Lean Mass Loss[1]



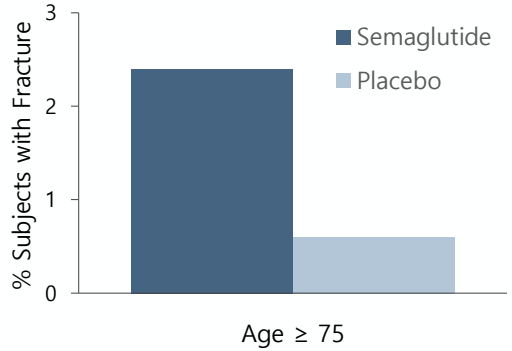
The median percentage of total body weight loss that is due to lean mass:
32% in **16 weeks**[1] (elderly 60+)
35% in 24 weeks[3] (adults 18-80)

Functionality Loss[1]



43% of elderly (60+) lost ≥10% Stair Climb Power from baseline in **16 weeks** of GLP-1 use[1]

Fracture Risk[2,3]



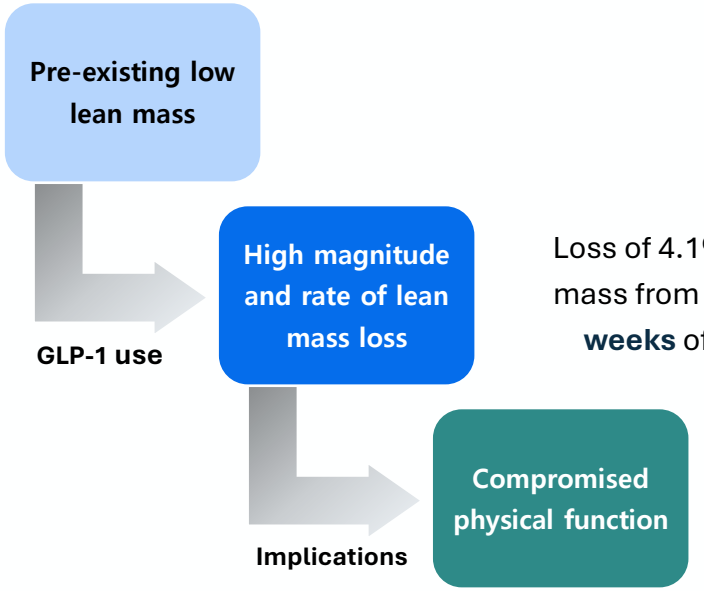
Patients on semaglutide had significantly more fractures of the hip and pelvis[2]

1. The data were adapted from Veru Corporate Presentation Jones Healthcare and Technology Innovation Conference, April 8-9, 2025
2. Wegovy label (Revised 03/2024)
3. https://investor.regeneron.com/news-releases/news-release-details/interim-results-ongoing-phase-2-courage-trial-confirm-potential

Target Population - Elderly GLP-1 Users, Most Vulnerable Population

8 years of expected age-related stair climb power loss in 4 months of GLP-1 use

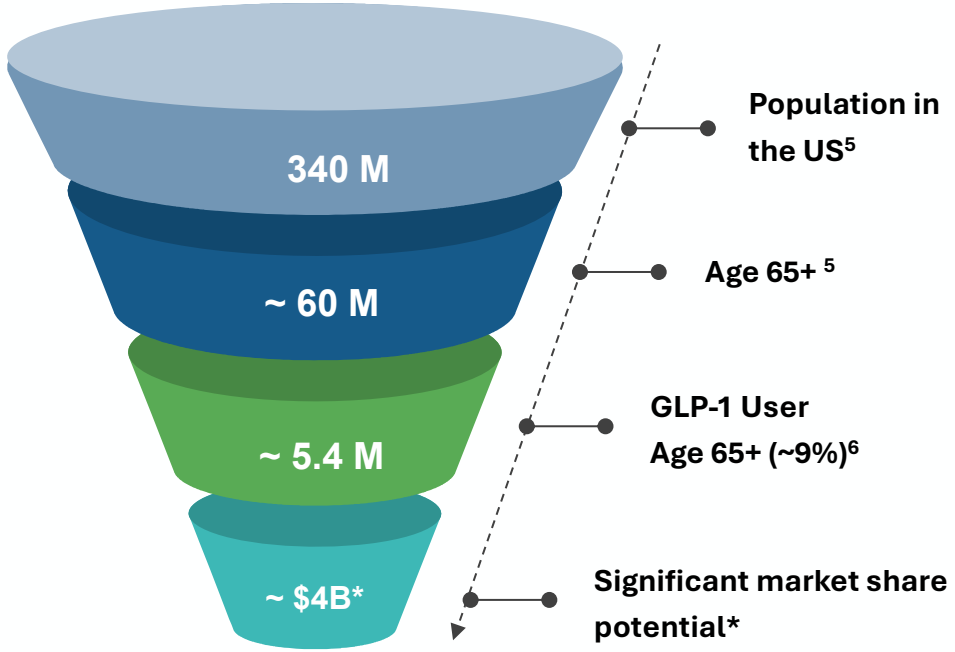
GLP-1 Use Related Decline in Elderly



Loss of 4.1% of total lean mass from baseline in **16 weeks** of GLP-1 use[4]

- Muscle mass decreases at an annual rate of 1% after about age 60[1]
- Muscle strength declines by 1.5% annually between ages 50 and 60 and by 3% thereafter[2]
- Older patients lose 1.38% stair climb power each year with aging[3]

Estimated Elderly GLP-1 Users



*10% market share with price assumption $7,500 per year

1. Mitchell et al., Front Physiol 2012 Jul 11; 3(260)
2. Haehling et al., J Cachexia Sarcopenia Muscle. 2010 Dec 17;1(2):129–133
3. Van Roie E PLOS ONE 14:e0210653, 2019
4. https://ir.verupharma.com/news-events/press-releases/detail/225/veru-announces-positive-topline-data-from-phase-2b-quality/
5. https://www.census.gov/quickfacts/fact/table/US#
6. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-may-2024-the-publics-use-and-views-of-glp-1-drugs/

LPCN 2401 Once Daily Oral Treatment for Obesity and Weight Management

Proven potential to improve body composition - quality weight loss with quality fat loss

Product Candidate Attributes

- Proprietary androgen receptor agonist, testosterone ester(s), targeted for once-a-day treatment - “LPCN 2401”
  - Androgen receptor agonist with α-tocopherol for once-a-day treatment – “LPCN 2401+E”
  - A bioidentical to physiological regulator of myostatin that indirectly inhibits its expression and signaling

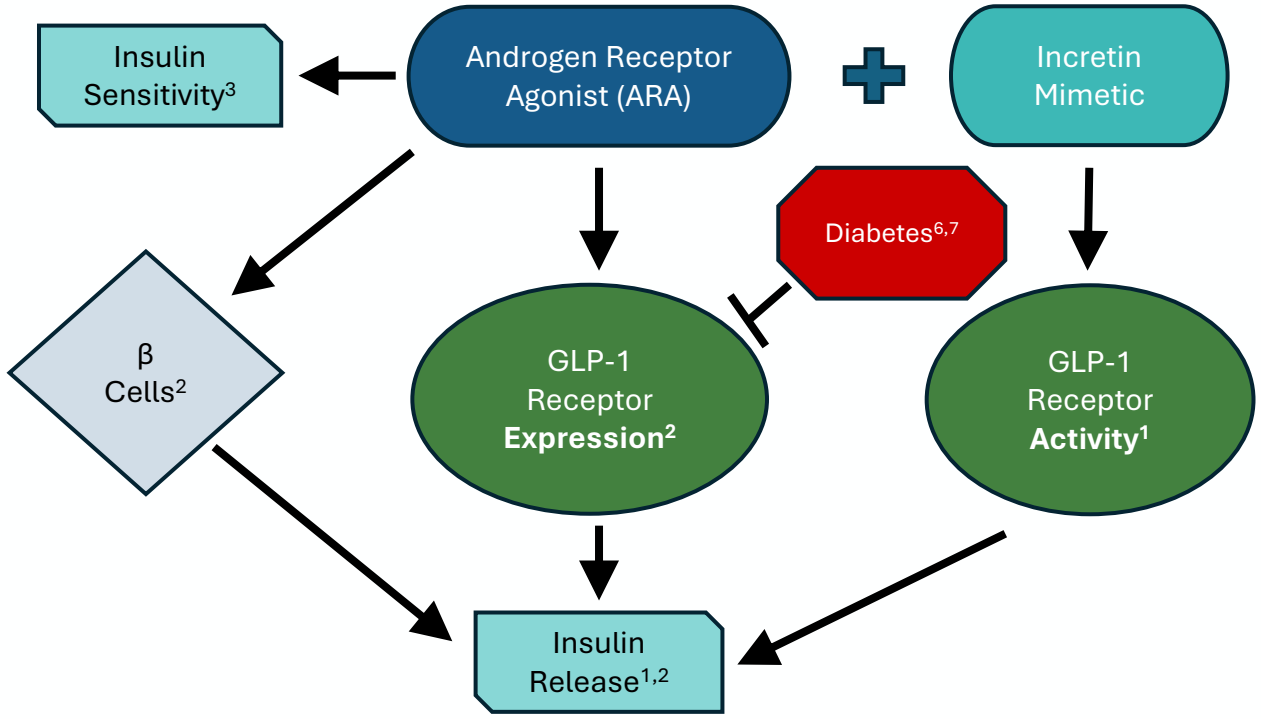
Targeted Mechanism of Actions

	Fat	Muscle	Bone
Androgen Receptor Agonist	• Induces lipolysis[1] • Lowers lipogenesis[1] • Inhibits expression of adipocytokines (e.g., leptin, TNF-α, IL-6, IL-1) [2]	• Stimulates muscle satellite activator, FGF2[3] • Modulates muscle growth suppressors MRF4 and myostatin (GDF8) expression in skeletal muscle[3]	• Acts directly on osteoblasts and consequently promotes bone formation[4] • Increases AR expression level in osteoblasts[4,5]

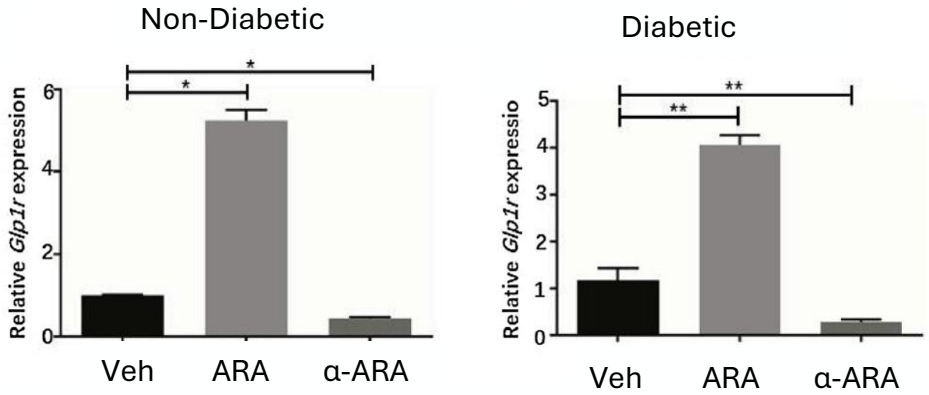
1. Biochimie,87(1):39-43, 2005
2. J Endocr Soc. 2019 Jan 1; 3(1): 91–107
3. J Clin Endocrinol Metab, 104(6): 2094–2102, 2019
4. Clin. Interv. Aging 2016, 11, 1317–1324
5. Horm. Metab. Res. 2004, 36, 674–678

LPCN 2401 - Potential to Amplify Effects of Incretin Mimetics

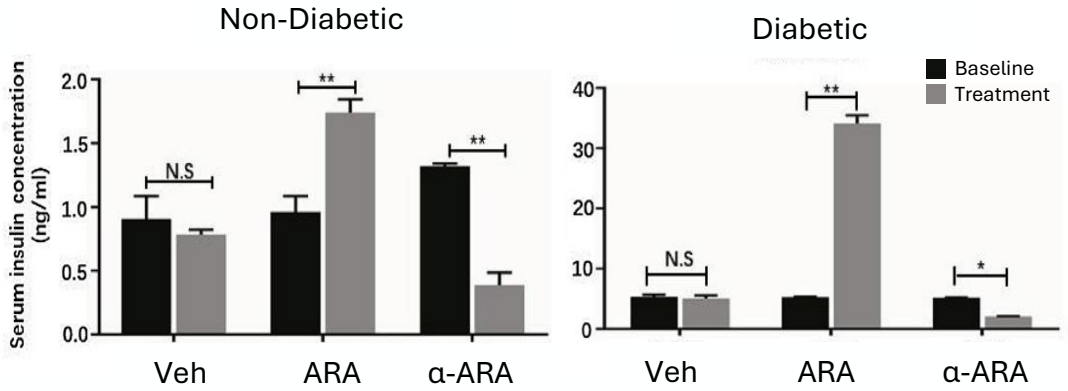
ARA may increase weight loss through increased expression and activity of GLP1R [4,5]



GLP-1 expression increase with ARA[2]



Insulin activity increase with ARA[2]



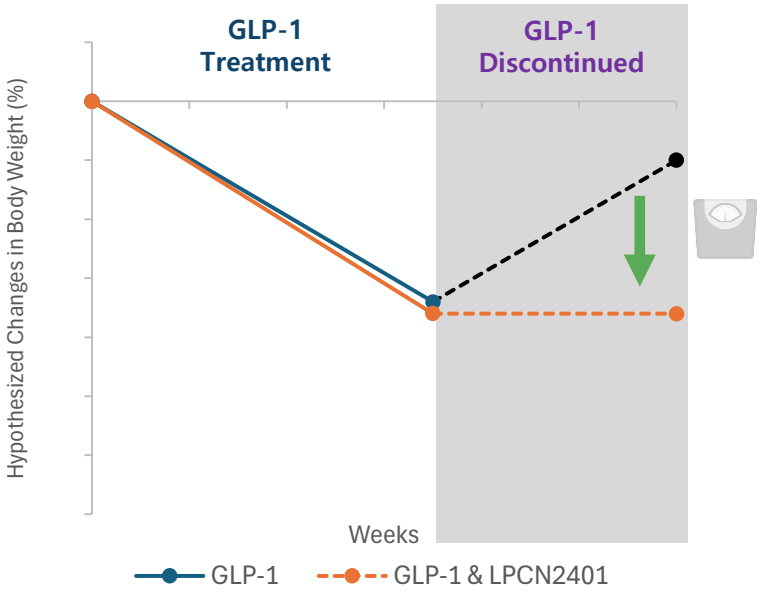
ARA: Androgen receptor agonist; α-ARA: Androgen receptor antagonist

1) Xu et al., Cell Reports 2023. 2) Zhu et al., Biomed Pharmacoth, 2019 (images modified). 3) Wittert et al., Lancet Diabetes and Endo, 2021 (appendix 2). 4) Xu et al., Diabetes, 2007. 5) Rajan et al., Molecular Metabolism. 2015. 6) Xu et al., Pathophysiology 2007. 7) Shu et al., Hum Mol Genet, 2009.

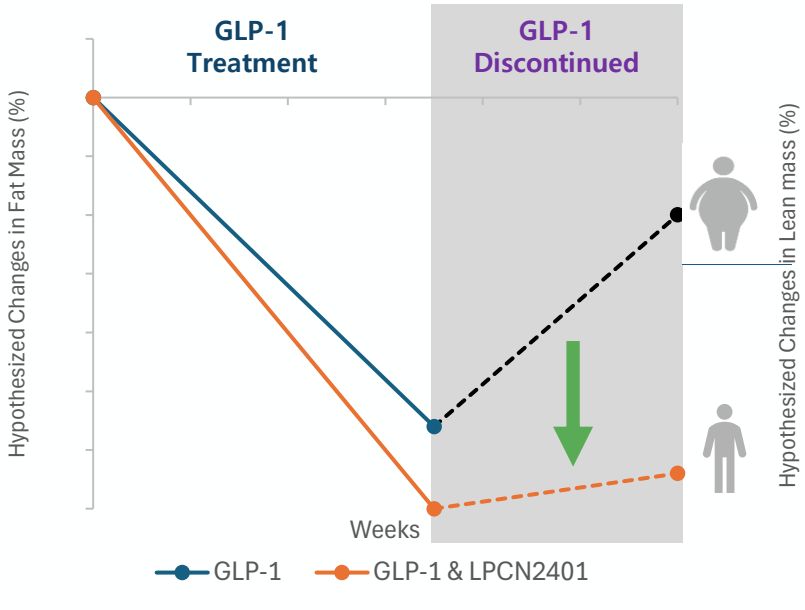
LPCN 2401 Novel Oral Treatment for Obesity Management

Hypothesized benefits - improve body composition and functionality in weight management

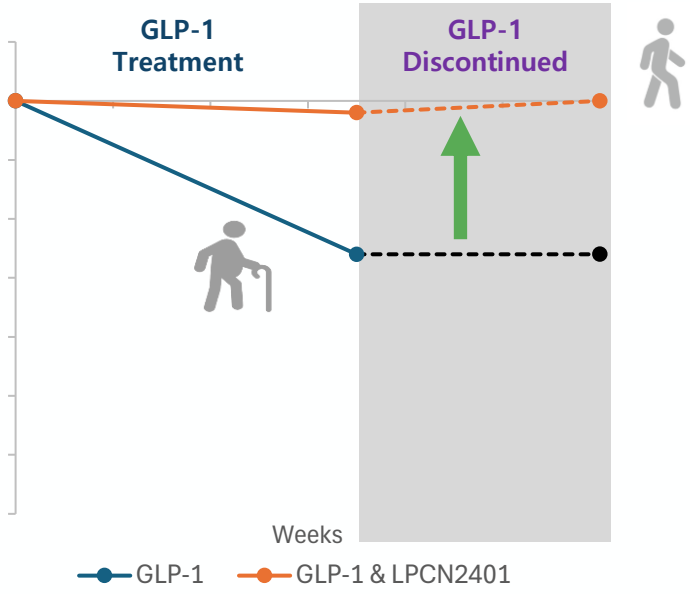
Quality weight loss
Minimize weight rebound



Amplify fat loss
Minimize fat regain



Improve lean mass
Preserve functionality



- Rapid loss of LM has multiple negative health implications[1]

1. Larsson et al., Physiol Rev. 2019 Jan 1; 99(1): 427–511

LPCN 2401 Novel Oral Treatment for Obesity Management

Target benefits to improve weight loss and functionality

LPCN 2401 + GLP-1 agonist treatment

Quality weight loss

- Preserve lean mass
- Primarily fat loss

- Attenuate functionality loss
- Amplify fat loss
- More abdominal fat loss
- Improve bone health

LPCN 2401 treatment post GLP-1 cessation

Maintain weight loss

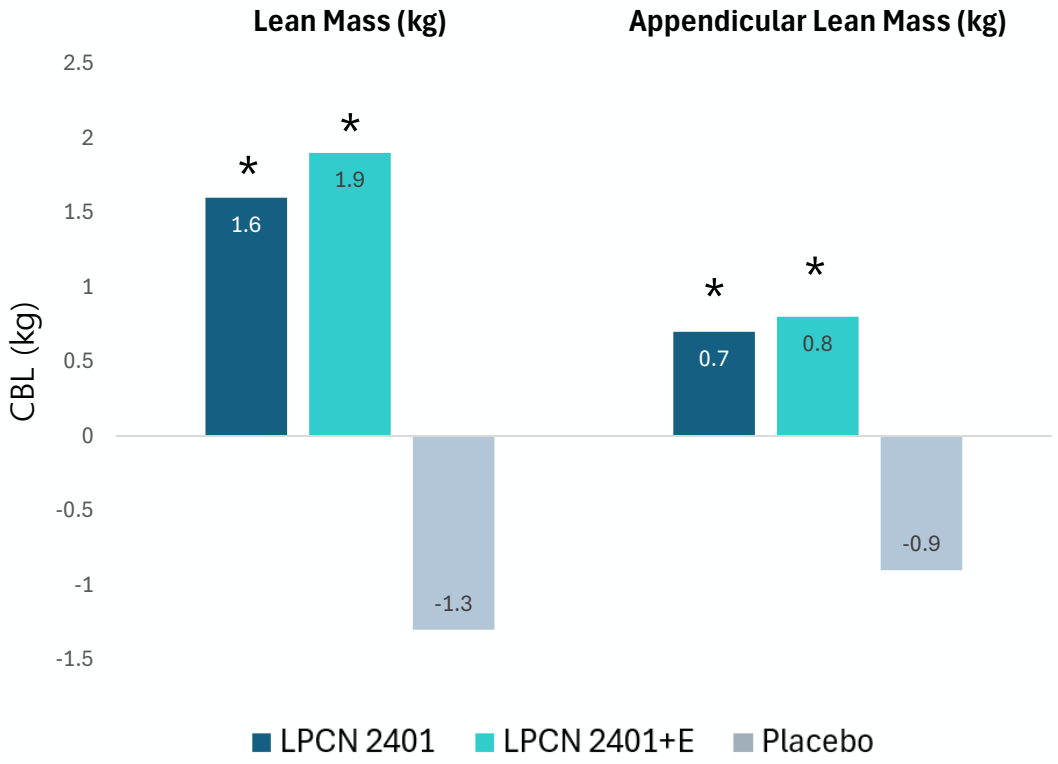
- Minimize fat regain
- Minimize weight regain

- Maintain/improve functionality
- Improve lean mass
- Sustain glycemic status

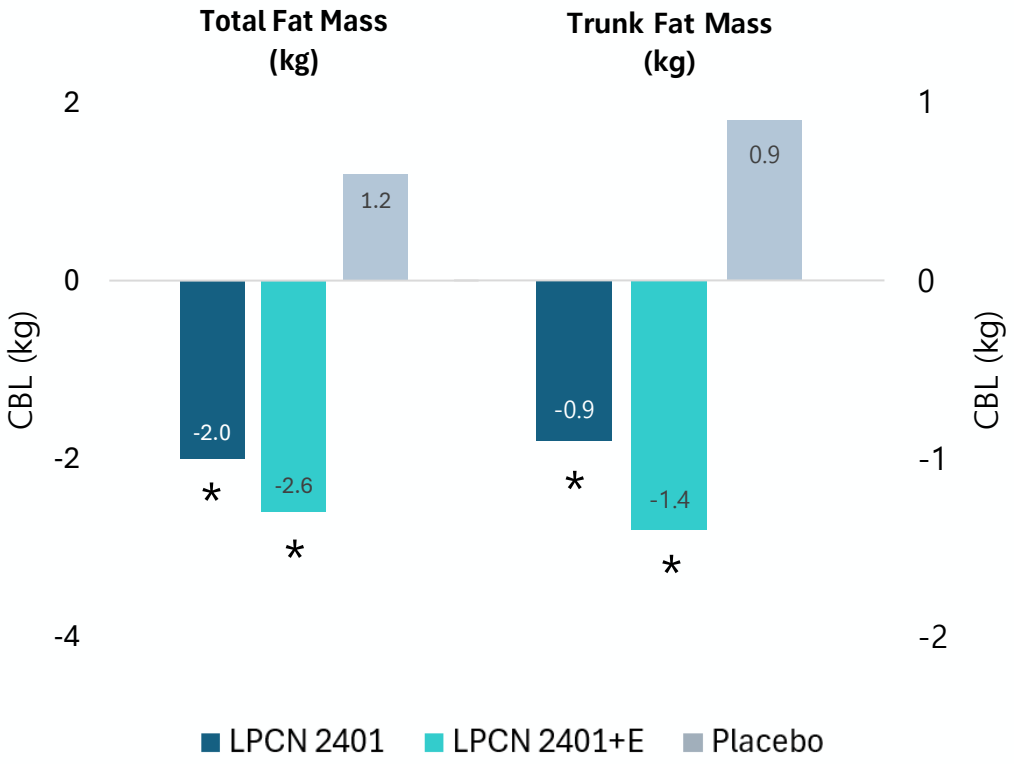
LPCN 2401 – Clinical Data Show Significant Improvement in Body Composition

Phase 2 results demonstrate increased lean mass and decreased fat mass at Week 20

Lean Mass



Fat Mass

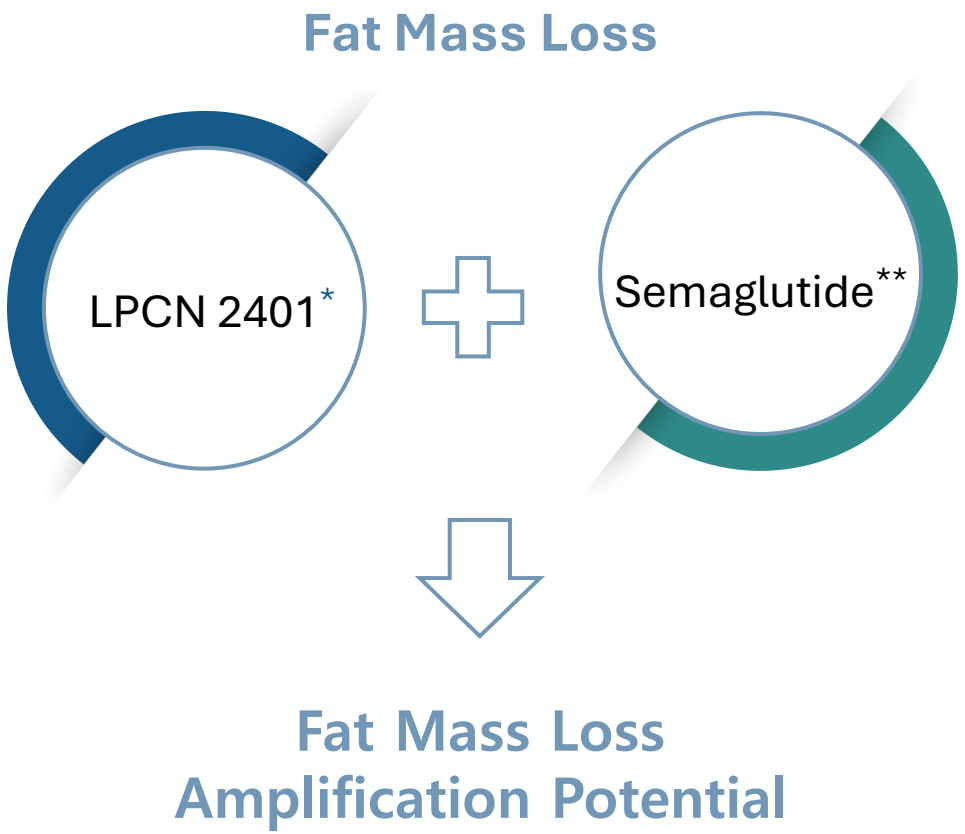


*p<0.05 vs placebo
Phase 2 clinical trial - NCT04134091
n=12 for LPCN 2401; n=13 for LPCN 2401+E; n=13 for placebo

LPCN 2401 – Amplify/Accelerate Fat Loss in Obesity Management

Per FDA, weight reduction is a long-term reduction in excess adiposity (body fat) with a goal of reduced morbidity and mortality[1]

Excess total body fat increases the risk of death and major comorbidities such as type 2 diabetes, hypertension, dyslipidemia, cardiovascular disease, osteoarthritis of the knee, sleep apnea, and some cancers[1,2,3]

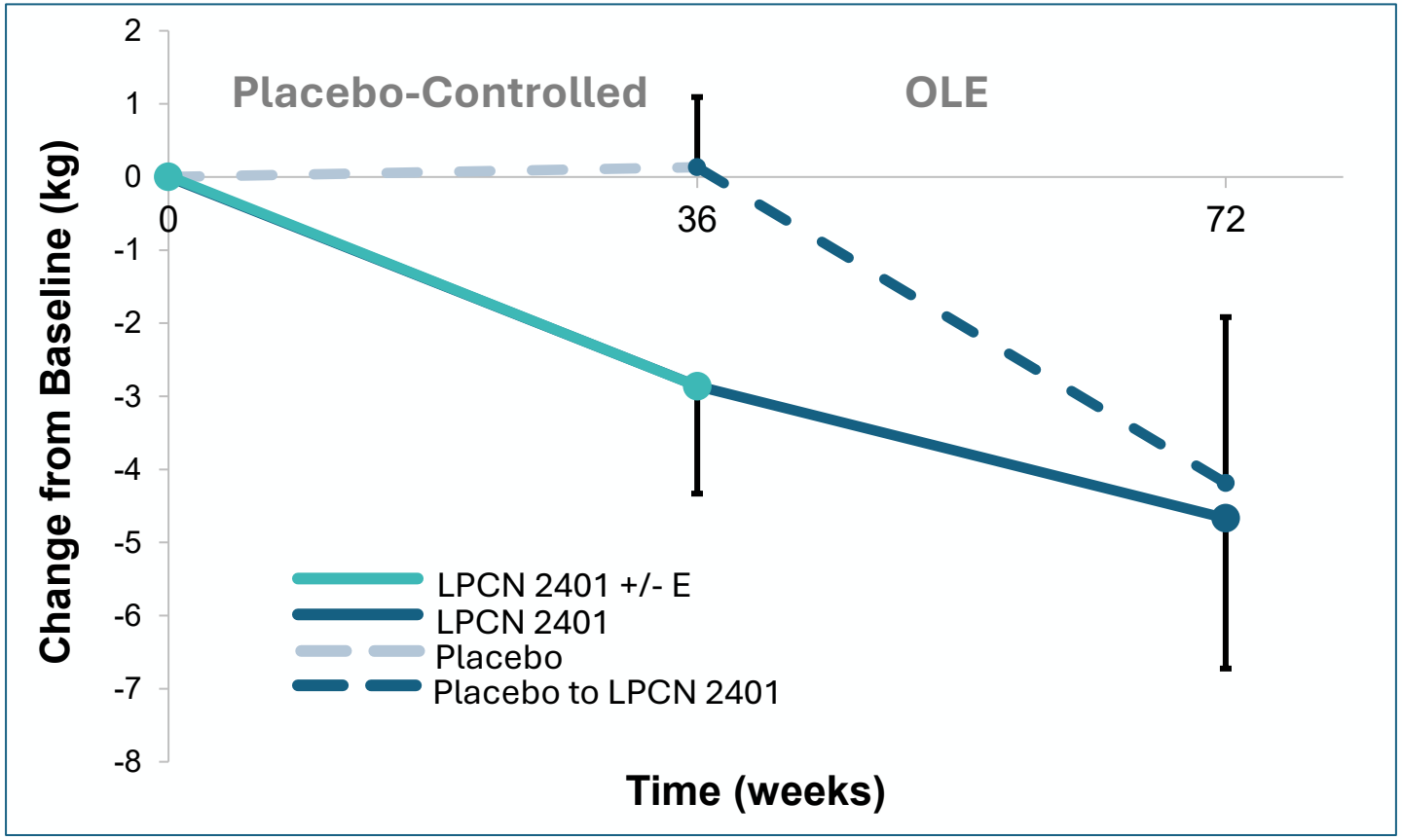


*Placebo adjusted value at Week 20 - NCT04134091
**Absolute value at Week 16 from https://ir.verupharma.com/news-events/press-releases/detail/225/veru-announces-positive-topline-data-from-phase-2b-quality/

1. FDA Guidance to Industry (2025), https://www.fda.gov/media/71252/download
2. New England Journal of Medicine, 341:10971105, 1999.
3. Circulation.,110:e476-e483, 2004.

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.

LPCN 2401 - Body Weight Changes During 72 Weeks of Treatment

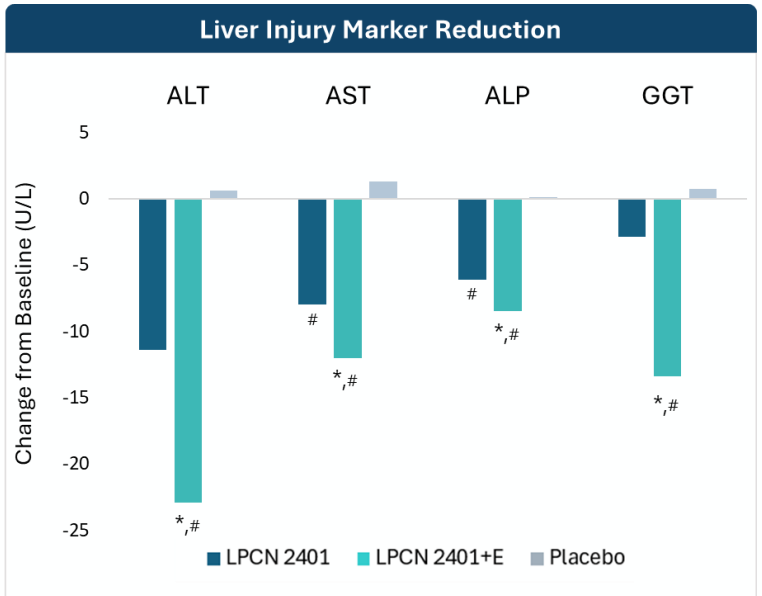


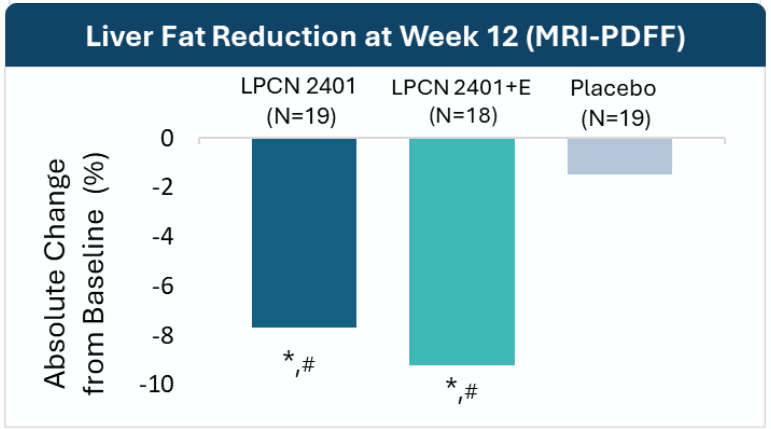
- **Participants who took placebo for 36 weeks then switched to LPCN 2401 during the 36-week OLE experienced similar weight loss**

Body weight change from baseline (CFB), baseline is week 0; data are mean (SE); includes only subjects who participated in OLE, pooled treatment group (LPCN 2401+E and LPCN 2401) N=15 and excludes one outlier, placebo N=9

LPCN 2401 Safety Data Support Differentiated Product Profile

Well-tolerated with liver benefits and no safety signals upon 72-week exposure





- POC study in relevant obese and overweight population
- Frequency and severity of TEAEs with LPCN 2401 were comparable to placebo
- Frequency of SAEs with LPCN 2401 were comparable to placebo
- No reported cases of hepatocellular carcinoma or Drug Induced Liver Injury (“DILI”)

Safety set. * $p < 0.05$; vs placebo; # $p < 0.05$ vs baseline.
All Subjects: ITT Dataset, n = 56, missing data imputed using multiple imputation. * $p < 0.05$; vs placebo; † $p < 0.05$ vs baseline.
TEAEs = Treatment Emergent Adverse Events; SAEs = Serious Adverse Events; PSA = Prostate-Specific Antigen

LPCN 2401 POC Phase 2 Study Objectives

Quality weight loss phase (Stage 1, GLP-1 treatment)

- **Objective 1**
  - Assess the **co-administration of LPCN 2401** and incretin mimetic for weight loss and prevention of functional loss associated with incretin mimetic monotherapy

Weight maintenance phase (Stage 2, GLP-1 discontinued)

- **Objective 2**
  - Evaluate the use of LPCN 2401 **upon stopping incretin mimetic** to prevent fat/weight rebound (LPCN 2401 naive)

- **Objective 3**
  - Assess the **continued use of LPCN 2401** after discontinuing incretin mimetic to prevent fat/weight rebound

LPCN 2401 - Potential for Differentiated Benefit to Risk Profile for Chronic Use

A liver beneficial approach[6] with no increased risk of adverse cardiovascular outcomes[7]

LPCN 2401 Target Attributes

- Oral, QD, prodrug of bioidentical hormone
- Fat loss amplification
  - Lower fat mass (preferentially VAT and android fat)
- Improve/preserve lean mass
  - Muscle mass, quality, and functionality
  - Bone health
- GLP amplification: through genomic and non-genomic pathways
- GI side effects: minimal
- Muscle spasm AE: none observed
- Liver Health: beneficial effects (MASH resolution, injury markers improvement)
- Impact on sex hormone (FSH, LH, and Estradiol): minimal

Competitive Landscape*

- **Myostatin /activin receptor modulators** (e.g. bimagrumab, taldefgrobep, KER-065, garetosmab, and trevogrumab)[1,2]
  - Invasive - IV/SC
  - Moderate to high GI side effects [2,3]
  - Reports of muscle spasms [2,3]
  - Increased serum alkaline phosphatase [3]
  - Sex hormone changes (FSH/LH) [4]
  - Unclear muscle functionality improvement
  - High discontinuation & long-term exposure risks unknown
- **SARM** (e.g. Enobosarm) [5]
  - Oral
  - Bone health concerns (estradiol suppression?)
  - Liver toxicity concerns

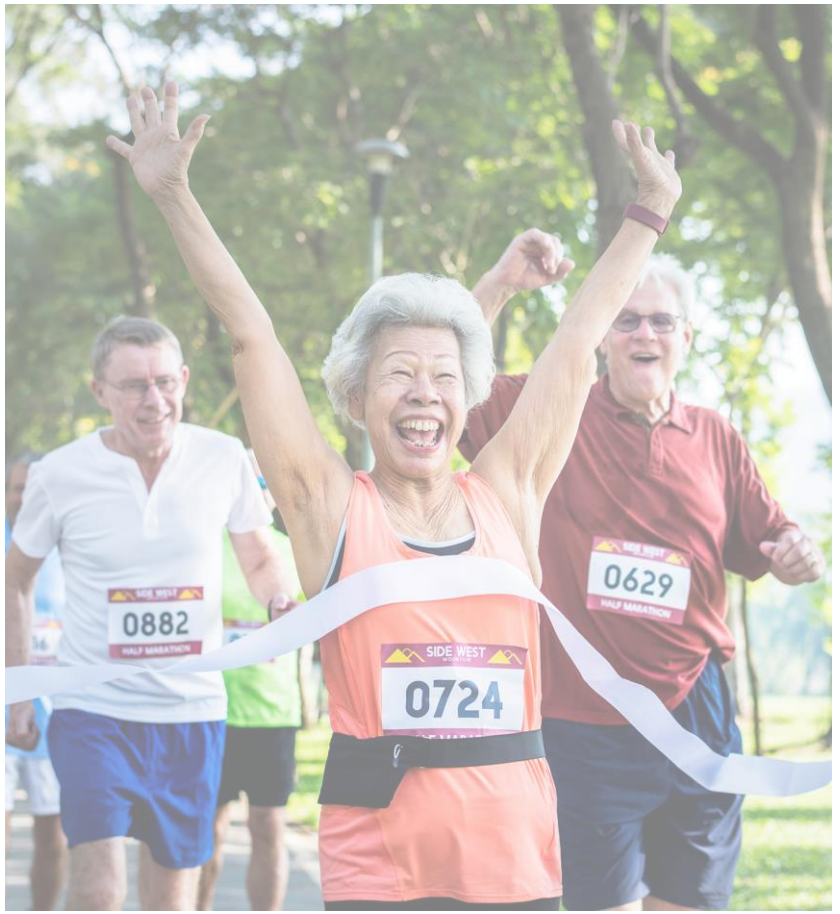
*select list with reported body composition improvement P2 results

1. J Bone Metab. 2020 Aug; 27(3): 151–165
2. J Cachexia Sarcopenia Muscle. 2020 Dec; 11(6): 1525–1534
3. JAMA Netw Open. 2021;4(1):e2033457.
4. Clin Endocrinol (Oxf) 2018 Jun;88(6):908-919
5. Sex Med Rev. 2019 Jan;7(1):84-94
6. Hepatol Commun. 2020 Aug 2;4(10):1430-1440
7. https://www.fda.gov/drugs/drug-safety-and-availability/fda-issues-class-wide-labeling-changes-testosterone-products

LPCN 2401 – Key Takeaways

Compelling opportunity with favorable benefit to risk profile

- **Addressing huge GLP-1 user market with unmet needs**
- **Differentiated oral product for use in combination with GLP-1 or post-cessation of GLP-1**
- **Positive Phase 2 results in relevant subjects**
- **Planned clinical study with GLP-1 agonist in appropriate population and endpoints**
- **Issued and pending patents**
- **Potential for line extensions**



LPCN 1148

Management of Liver Cirrhosis

- Overt Hepatic Encephalopathy (OHE)
- Sarcopenia in Decompensated Cirrhosis (Fast Track Designation)

LPCN 1148 - Unique Opportunity Addressing Two Distinct Liver Disease Markets

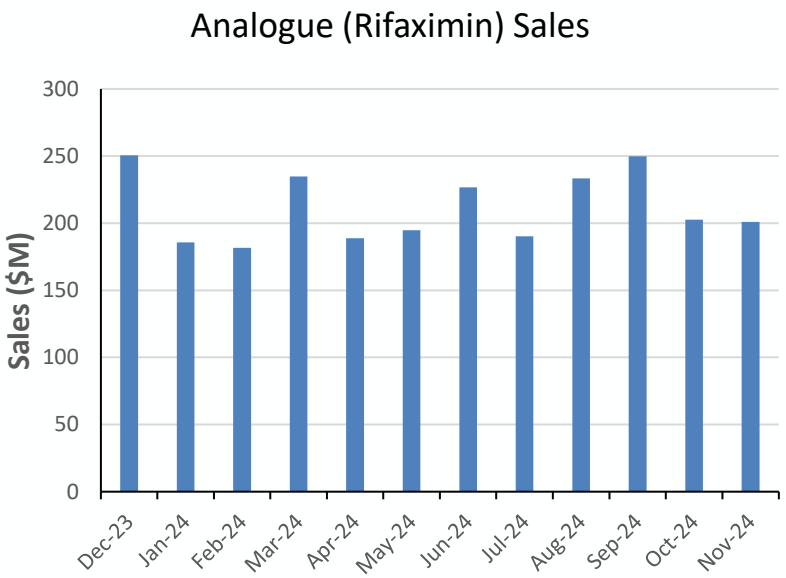
Positive POC Phase 2 results in treatment of sarcopenia and OHE in cirrhosis

Sarcopenia in Cirrhosis

- Positive P2 results in sarcopenia
- FDA granted Fast Track Designation
- Acceptable endpoints on sarcopenia
- No competition in development
- Unique ARA with patent protection through 2044

Overt Hepatic Encephalopathy (OHE)

- Positive P2 results with background SOC
- Validated regulatory pathway
- A commercially successful surrogate
- Sparse competitors in development
- Unique ARA with patent protection through 2044

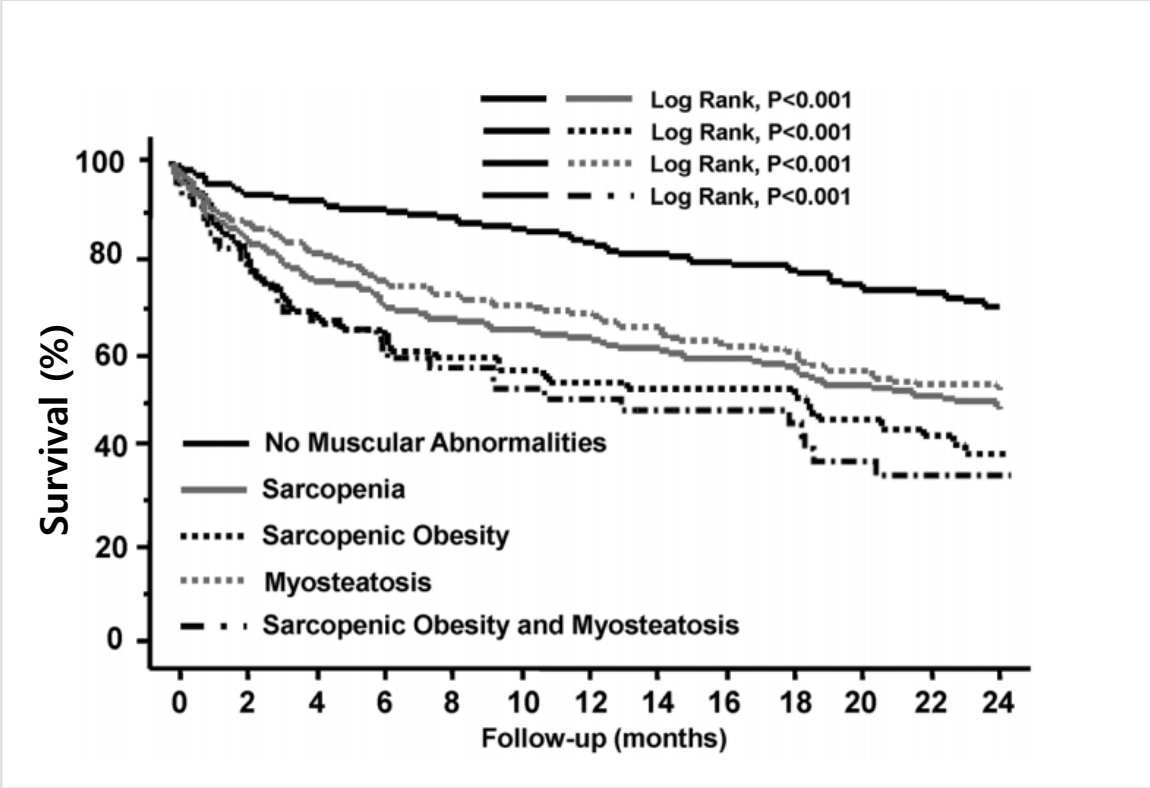


BofA Global Research, Pharmaceutical Scripts/Sales Data Report 21 January 2025

POC = Proof of concept; SOC = Standard of care; ARA = Androgen receptor agonist

Sarcopenia in Cirrhosis

A serious comorbidity



Low muscle mass (sarcopenia) and quality (myosteatosis) are associated with worse overall survival [1]

Sarcopenia is a predictor for increased morbidity and mortality in cirrhosis[2]

- 3-fold higher mortality rate compared to no sarcopenia[2]

Sarcopenia in cirrhosis correlates with decompensation events, particularly hepatic encephalopathy (HE)[3]

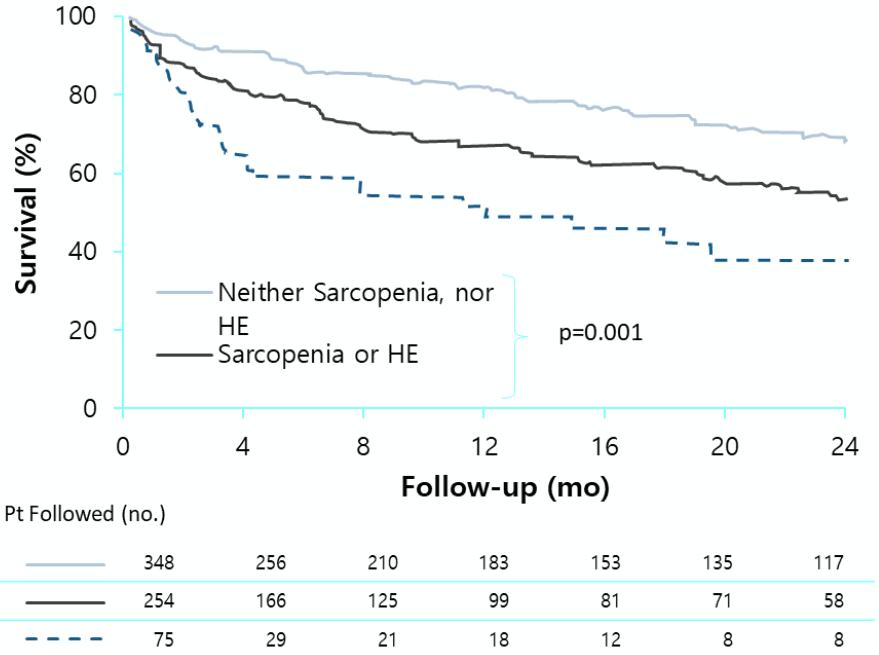
- Presence of sarcopenia increases the risk of overt HE ~2 fold [3]
- Primary pathophysiology associated with sarcopenia and decompensated cirrhosis include a catabolic state, progressive immobility, imbalance between muscle breakdown and formation, and hormonal changes[3]

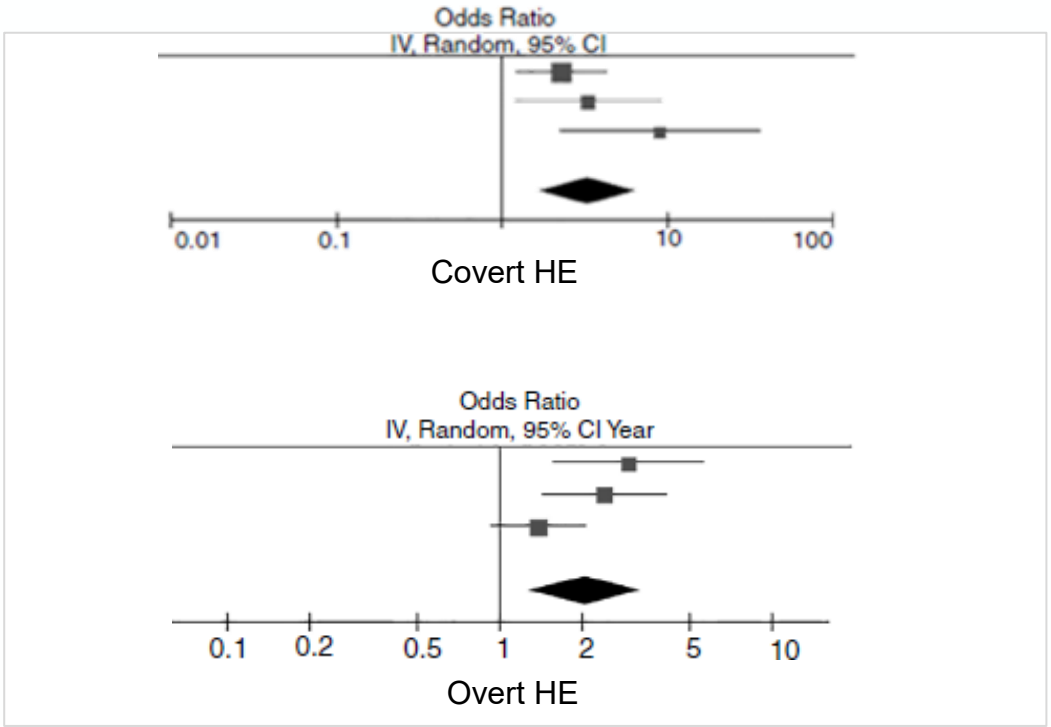
1. Montano-Loza, J Cach, Sarco, and Musc, 2016
2. Kim. PLoS One. 2017
3. Tandon. J Hepatol. 2021

Overt Hepatic Encephalopathy (OHE) in Cirrhosis

Presence of both sarcopenia and HE further increases risk of mortality[5]

Survival Rate of Patients with Cirrhosis[1]





Sarcopenia and myosteatosis are associated with increased risk of hepatic encephalopathy[1,2]

1. Bhanji et al. Hepatology International (2018) 12:377–386
2. Wijarnpreecha. Ann Hep, 2020. 3. Bhanji, Hep Int, 2018.

LPCN 1148 for the Management of Cirrhosis

Product Candidate Attributes

Oral androgen receptor agonist; dosage form comprising testosterone dodecanoate, a unique prodrug of an endogenous hormone

Targeted Mechanism of Action

Anabolic[1]

Stimulates muscle satellite activator, FGF2[2], inhibit myostatin[3], increase muscle mass and strength[4], and reduce fat mass[5]

Androgenic

Induce hematopoiesis[9]; improve endocrine/sexual dysfunction[10]

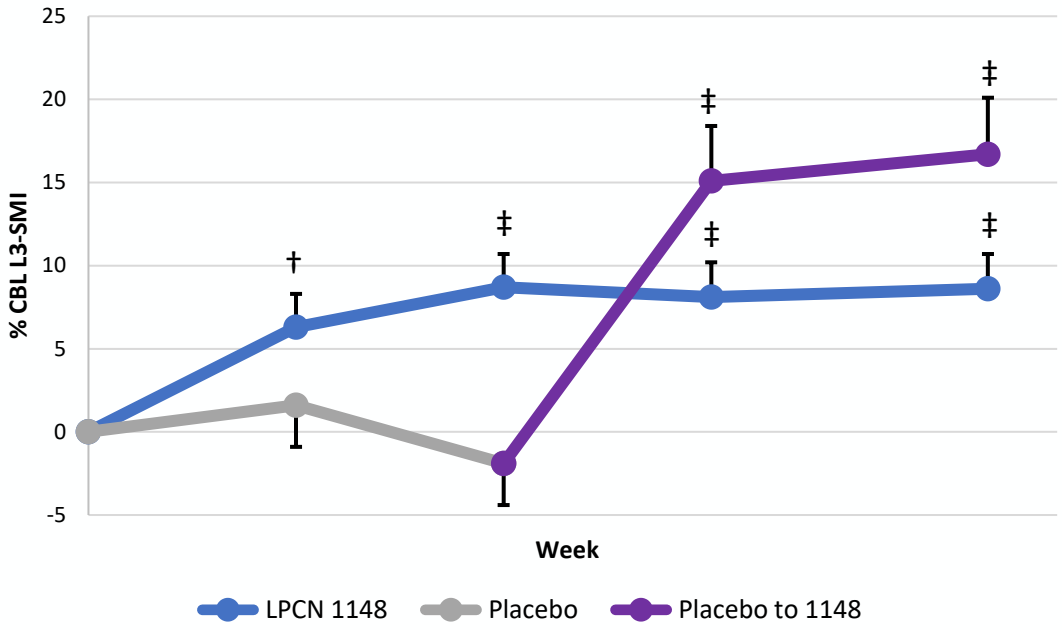
Ammonia Lowering

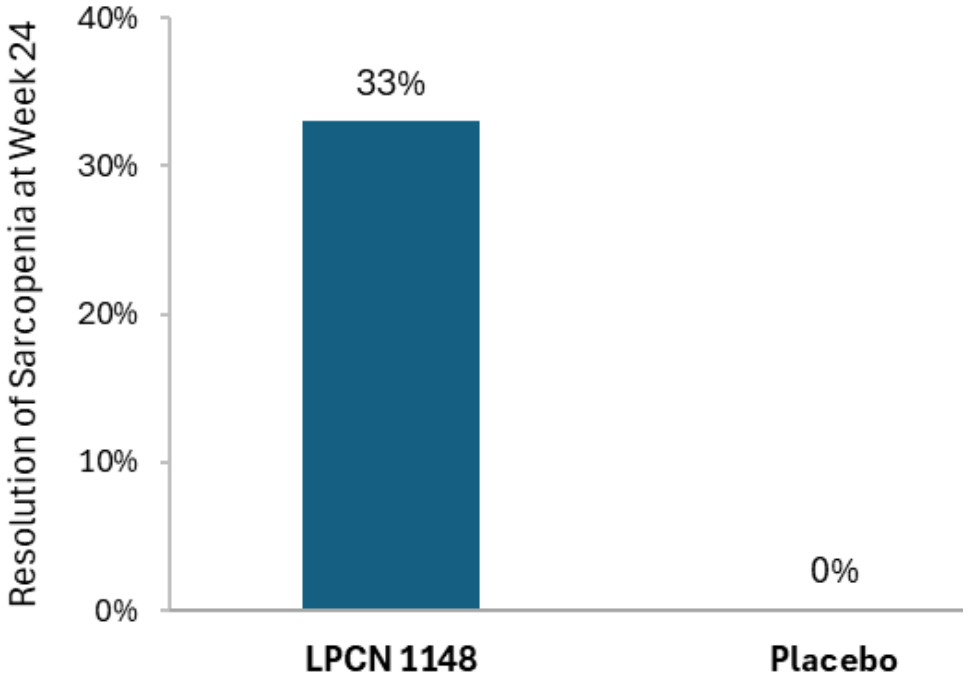
Via improved liver health[6] and improved muscle health[7]; antibacterial[8]

1. Gentile MA et al., J Mol Endocrine 2010
2. J Clin Endocrinol Metab. 2019 Jun; 104(6): 2094–2102
3. Dasarathy and Merli, J Hepatol 2016
4. Sinclair et al., J Gastroenterol Hepatol 2016
5. Bhasin, Clin Infect Dis 2003
6. Kenston et al., J Gastro Hep 2018
7. Di Cola et al., J Clin Med 2022
8. Jin et al., J Microbiol Biotechnol 2021
9. Basaria and Dobbs, Androgens and the Hematopoietic System. In: Bagatell, C.J., (ed) Androgens in Health and Disease, 2003
10. Rizk et al., Curr Opin Urol 2017

LPCN 1148 Phase 2 Results – Sarcopenia Primary Endpoint Met

Resolution for sarcopenia and significantly increased skeletal muscle mass index (SMI)





- ~9% increase in L3-SMI at week 24
- 33% of patients had resolution of sarcopenia* at week 24

LS mean (SE), † P<0.01 for change from baseline; ‡ p<0.01 vs. Week 24 placebo; L3-SMI = L3 skeletal muscle index

*Using protocol-defined sarcopenia thresholds. All data is LOCF

LPCN 1148 Phase 2 Results – HE Endpoint Met

Fewer overt hepatic encephalopathy events

Parameter	Through Week 24		Week 24 to EOS	
	Placebo N=14	LPCN 1148 N=15	LPCN 1148 N=11	LPCN 1148 switch from placebo N=8
History of HE prior to randomization (n)	11 (79%)	11 (73%)	7 (64%)	6 (75%)
Recurrent Overt HE (events)	6	1*	1	1
Time to first recurrent event (days)	35	114	294	140

OHE is defined as an adverse event of HE with CTCAE severity > grade 1. * P<0.05 vs placebo
HE events post study drug discontinuation for liver transplant excluded

LPCN 1148 Phase 2 Results Safety Data

Overall LPCN 1148 was well tolerated

- Rates and severities of AEs similar to those in Stage 1 with placebo
- Fewer participants experienced severe AEs when switched from placebo to LPCN 1148

Parameter	Placebo (Through Week 24) N=14	LPCN 1148 (Through Week 24) N=15	LPCN 1148 (Week 24 to EOS) N=11	LPCN 1148 switch from placebo (Week 24 to EOS) N=8
Total AEs	9 (64%)	9 (60%)	7 (64%)	7 (88%)
Serious AEs	5 (36%)	5 (33%)	5 (45%)	1 (13%)
Severe AEs	4 (29%)	4 (27%)	3 (27%)	1 (13%)
Deaths	2 (14%)	0	1 (9%)	0

Safety set; includes all participants who received study drug in a given stage. Post-transplant AEs excluded. Severe AEs: CTCAE severity ≥ Grade 3

Value Through Partnering

LPCN 1107 for Prevention of Preterm Birth

Product candidate highlights

Oral dosage form comprising 17-hydroxyprogesterone caproate

Oral, a Major Contribution to Patient Care (MC to PC), including no injection site reaction

>$2B market potential with no approved drug

Compelling efficacy rationale

Strong pharmaco-economic justification

Accelerated approval pathway and ODD (Orphan Drug Designation)

Potential to be SOC in prevention of preterm birth

LPCN 1144

Novel MOA in non-cirrhotic NASH

Product Candidate Highlights

Oral dosage form comprising testosterone ester

Fast Track Designation

Compelling P2 biopsy results in the FDA approvable endpoint

✓ Safety support with 72 weeks exposure

Mono or adjunct therapy

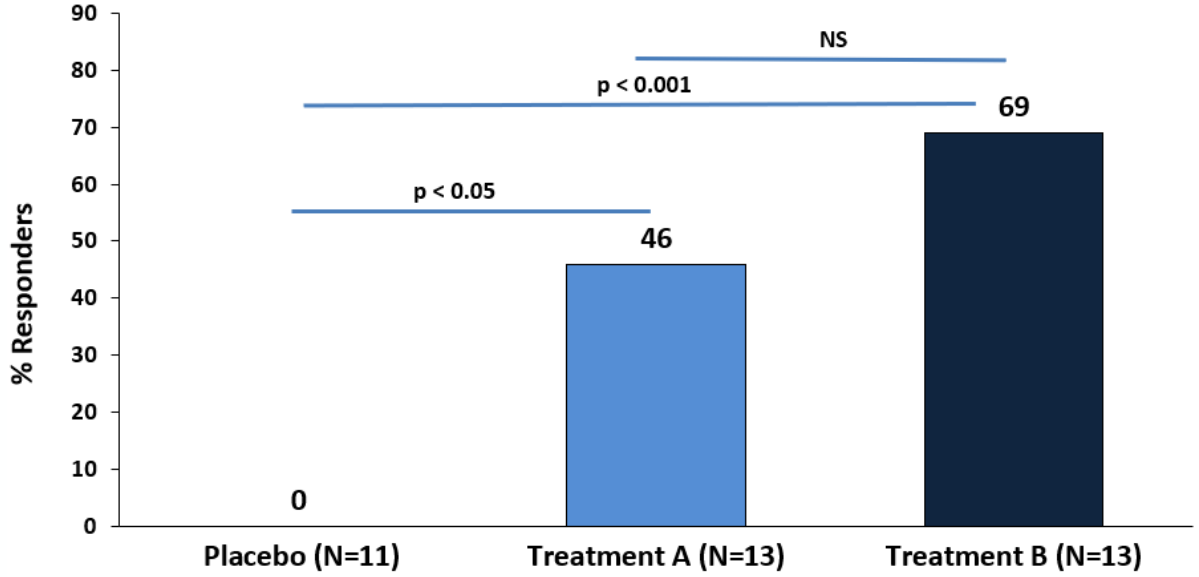
Differentiated profile

✓ Oral with unique benefit to risk profile

✓ Potential for additional benefits including sexual/mental and musculoskeletal domain

Accelerated approval pathway

NASH Resolution with No Worsening of Fibrosis[1]



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

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

Appendix

LPCN 1154 Opportunities in Additional Depression Disorders

Prevalence

MDD: Per NIMH, in 2020, an estimated 21.0 million adults (8.4%) in the US had at least one major depressive episode[1]

The prevalence of comorbid anxiety disorder and MDD is as high as 60% [2]

TRD: Prevalence ~2.8 million in US [3]

PPD: An estimated 1 in 6 mothers suffer from PPD [4]

Significant Unmet Needs in Depression Disorders

Robust Efficacy

Adequate and durable remission/response; treat anxiety comorbidity

Rapid Relief

Days vs weeks

Good tolerability

No excessive sedation, no sexual dysfunction or weight gain side effects, no withdrawal side effects upon discontinuation

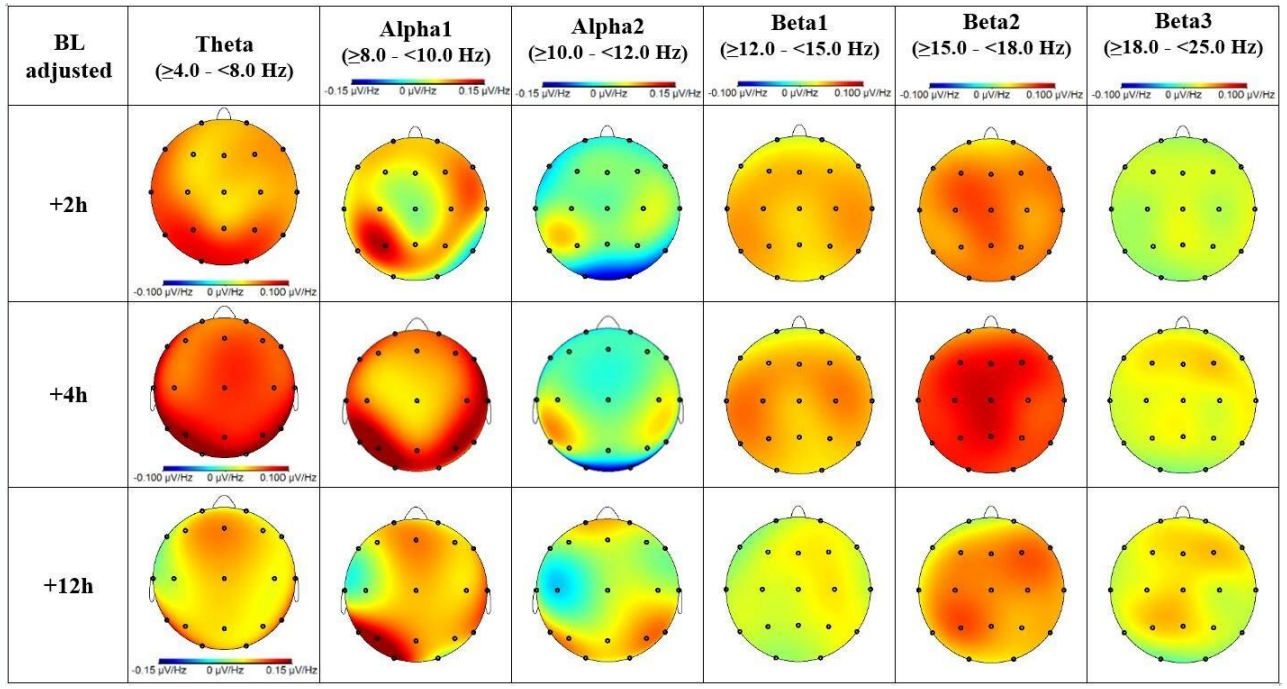
LIPOCINE® ENHANCING HEALTH

MDD = Major Depressive Disorder, PPD = Postpartum Depression, TRD = Treatment Resistant Depression

1. Monitoring System Survey–31 sites, 2018
2. Kaufman J, Charney D. Comorbidity of mood and anxiety disorders. Depress Anxiety. 2000;12:69-76.
3. J Clin Psychiatry. 2021 Mar 16;82(2):20m13699.
4. Van Niel et al. Cleveland Clinic J of Medicine. 2020;87(5):273-277

Oral Brexanolone - Potential Additional Neuropsychiatric Indications

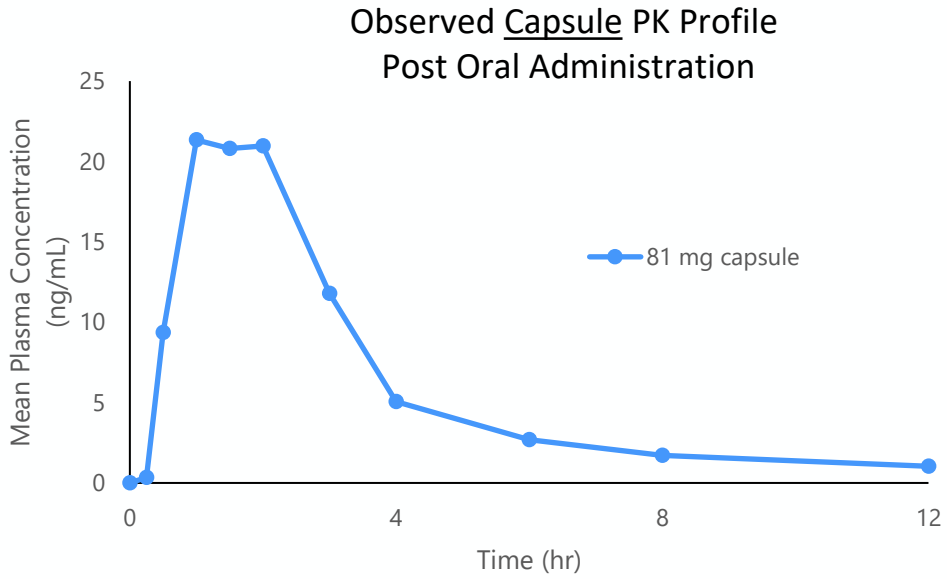
qEEG in healthy subjects administered single doses of oral brexanolone



- ✓ Rapid and durable CNS target engagement confirms effective oral delivery of bioidentical brexanolone and supports development of oral brexanolone for the treatment of other neuropsychiatric disorders[1-5]

Indications Requiring Rapid Onset (e.g. anxiety)

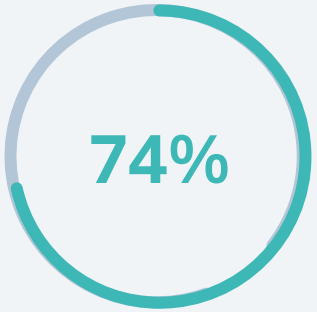
- Capsule formulations allow for rapid delivery of neuroactive steroids (Tmax 1.5 hours)



1. Meltzer-Brody et al. Lancet 2018; 392(10152): 1058-1070.
2. Buchsbaum et al. Biol Psychiatry 1985; 20(8): 832-842.
3. Ibanez et al. Plos One 2014; 9(3): e93159.
4. Huang and Shen Clin Electroencephalography 1994; 24(4): 179-187
5. Biondi et al. Sci Rep 2022; 12(1): 1919.

Obesity and Overweight: A Growing Epidemic in US

Increases the risks of heart disease, stroke, type 2 diabetes and certain types of cancer[1,2]

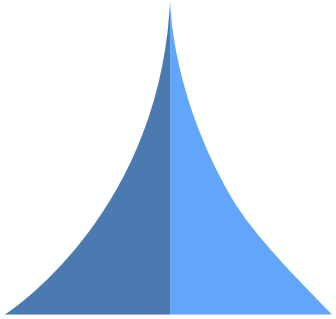


of adults age 20 and older are obese or overweight (2017-2018)[3]

~24M obese elderly, group most vulnerable to losing muscle mass [3,4]

~110M adults[4]
Diabesity population

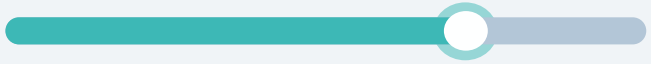
GLP-1 users in the US projected to reach **30 million** by 2030[5]



38% of men and 51% of women would be interested in taking a prescription drug for weight loss[6]

38% of men

51% of women



1. New England Journal of Medicine. 1999; 341:10971105
2. Circulation. 2004; 110:e476-e483.
3. https://www.cdc.gov/nchs/fastats/obesity-overweight.htm
4. Flynn et al. Morgan Stanley Research, February 27, 2024
5. https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs#
6. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/
7. Br Med J (Clin Res Ed) 1984;289:1257–1261
8. Physiol Rev1994;74:761–811

Eligible GLP-1 Agonist Users in U.S. for Chronic Weight Management

Total GLP-1 users in the U.S. may reach around 9% (30M) of the overall population by 2030[9]

Obesity Prevalence
(BMI at or above 30.0)

Adult with Obesity[1,2]

111 M

60+ yr[6,7]

34 M

Sarcopenic[6,8]

59 M

Overweight Prevalence
(BMI 25.0 to 29.9*)

Adult with Overweight[1,2]

79 M

60+ yr[6,10]

31 M

Sarcopenic[6,8]

29 M

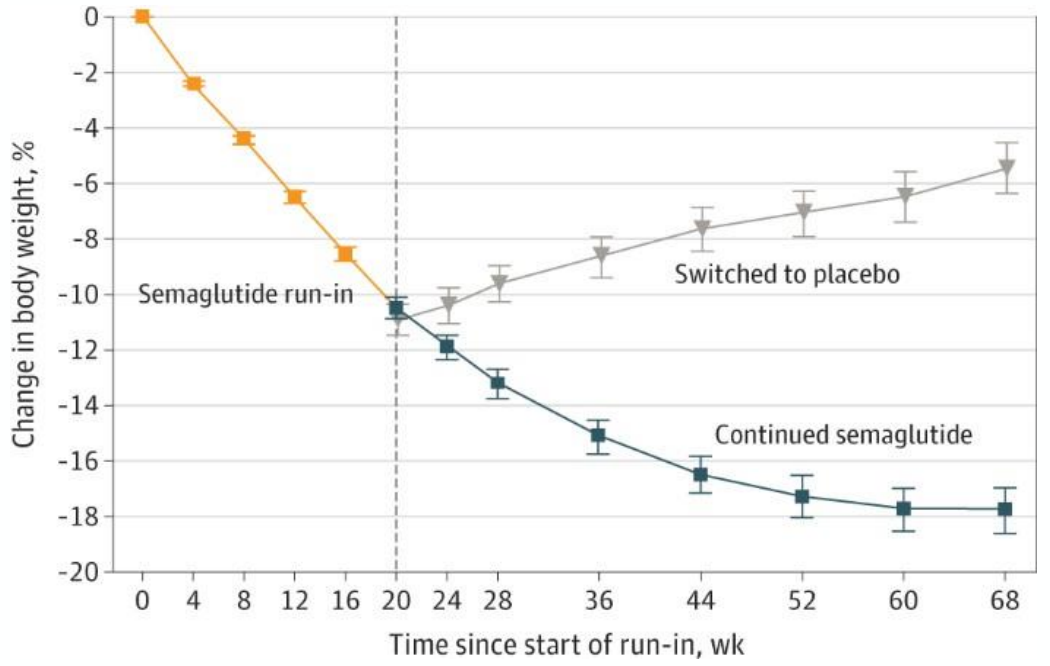
Overweight with related comorbidity: 30% Type 2 diabetes[3], 50% Dyslipidemia[4], 67% Hypertension[5]

*Currently, CWM agent indicated for BMI 27 kg/m^2 or greater in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

1. https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.html
2. https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity
3. https://news.harvard.edu/gazette/story/2012/03/the-big-setup/
4. https://www.ncbi.nlm.nih.gov/books/NBK305895/
5. https://pmc.ncbi.nlm.nih.gov/articles/PMC6316192/#sec3-nutrients-10-01976
6. https://acl.gov/sites/default/files/Profile%20of%20OA/ACL_ProfileOlderAmericans2023_508.pdf
7. https://www.cdc.gov/nchs/products/databriefs/db360.htm
8. https://www.cdc.gov/pcd/issues/2020/20_0167.htm
9. https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs
10. https://hpi.georgetown.edu/obesity2/

Drawbacks of Approved GLP-1 Receptor Agonists

Rebound weight/fat gain drawback post GLP-1 cessation



Greatest amount of weight loss is by week 20, and plateaus at ~1 year[1]

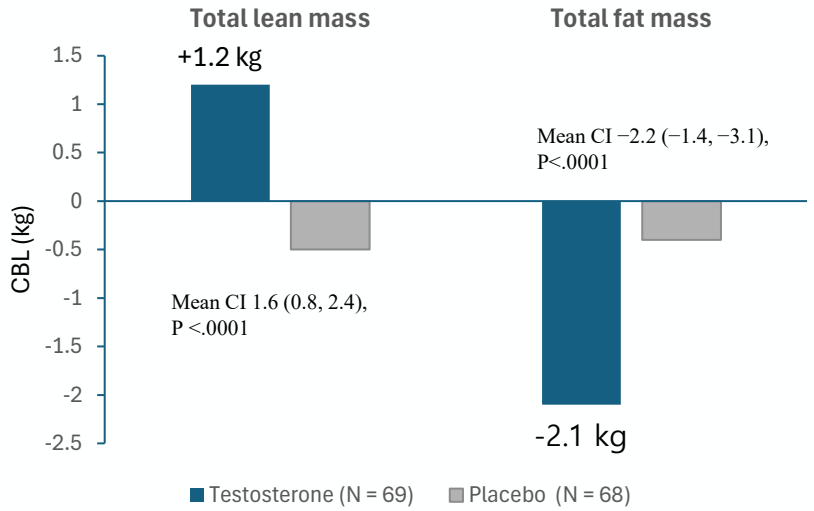
Patients who discontinued treatment at week 20 had significant weight gain[2] and HbA1c increase[3]

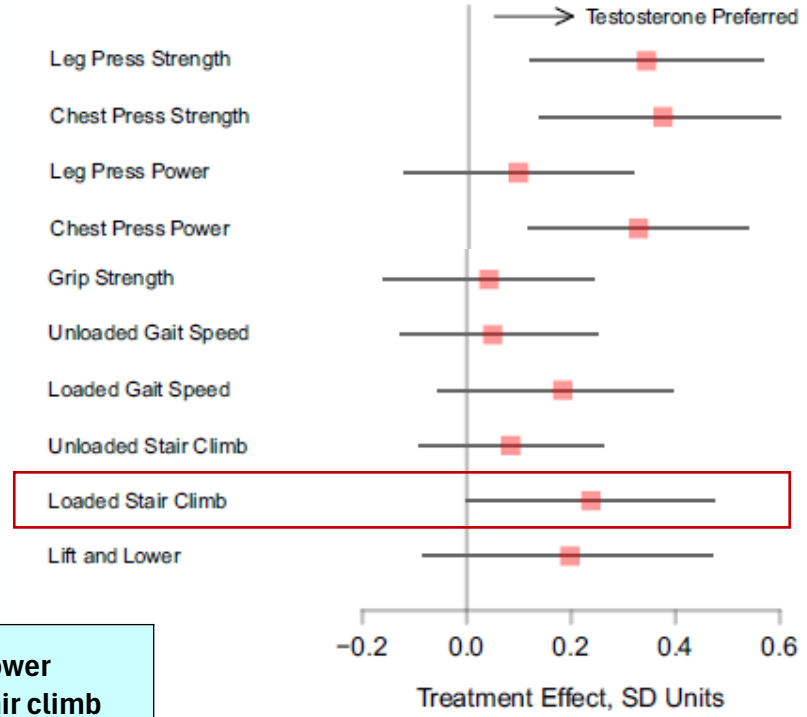
1. N Engl J Med, 384:989-1002, 2021
2. JAMA, 325(14):1414-1425, 2021
3. Cureus 15(10): e46490

Androgen Treatment Improved Body Composition and Functionality

Six months intervention in older men

Body Composition Improvement → **Improve in functionality**





Spearman correlation between selected change and in outcome measures	Loaded Stair Climb Power 20% extra load with 12 stair climb
Change in Lean Body Mass	0.27 (P=0.009)

The Testosterone in Older Men with Mobility Limitations (TOM) study- aged 65 and older, 6 months of study medication (daily T or placebo)
Ref: All figures and table were remade based on published data from Travison et al., J Gerontol A Biol Sci Med Sci. 2011 October;66A(10):1090–109

LPCN 2401 – Regulatory Outlook on Efficacy

Appropriate population and endpoints selection

Per FDA Guidance (2025)[1,2], for efficacy claim related to changes in body composition, trial design should include **appropriate choice of population** and **selection of endpoints** that measure how a **patient feels, functions, or survives**, to potentially support such a claim

Appropriate Population

Obese and overweight GLP-1 eligible

- Elderly
- Sarcopenic

Appropriate Functional Endpoint

Stair climb performance measure

- Previously accepted by FDA[3,4]

✓ **Pre-IND meeting completed**
✓ **Plan to meet with FDA to discuss appropriate population and endpoints for pivotal study**

1. FDA Guidance to Industry (2025), https://www.fda.gov/media/71252/download
2. LPCN 2401 Pre-IND Meeting Minutes
3. Duvyzat Package Insert, https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217865Orig1s000lbl.pdf
4. ELEVIDYS Package Insert, https://www.fda.gov/media/169679/download

Stair Climb Test: A Relevant Clinical Functional Measurement

Clinically relevant with patient-centric outcomes

Regulatory Perspectives

- High reliability and validity[1]
- Well-defined, standardized, supporting multicenter trials[1,2]
- Regulatory precedents: DUVYZAT®, ELEVIDYS®

Patient & Physician Perspectives

- Key physical function reflecting lower extremity strength & power[1]
- Physical mobility & function measurements[1-3]
- Predictor of physical decline & fall risk[1]
- Important function to activities of daily living[1,4]

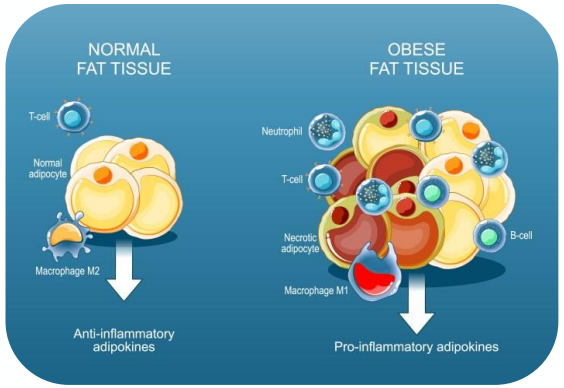
$$\text{Stair Climb Power (W)} = \frac{\text{Body weight (kg)} \times 9.81\ (\text{m/s}^2) \times \text{Vertical height (m)}}{\text{Time (s)}}$$

1. Ni el al. Phys Ther 2017 Jul 1;97(7):767-773
2. Sørensen et al. Musculoskelet Sci Pract. 2025 Apr 25:78:103339
3. Gagliano-Jucá et al. J Gerontol A Biol Sci Med Sci. 2019 Jul 6;75(6):1167–1175
4. Unver et al. Hip Int. 2015 Mar-Apr;25(2):160-3

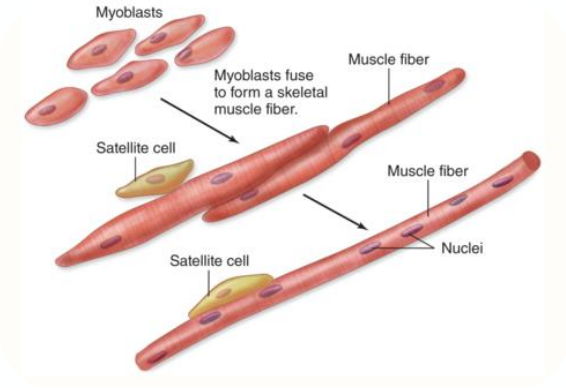
LPCN 2401+E – Targeted Mechanisms of Action

Obesity is associated with systemic chronic inflammation and oxidative stress

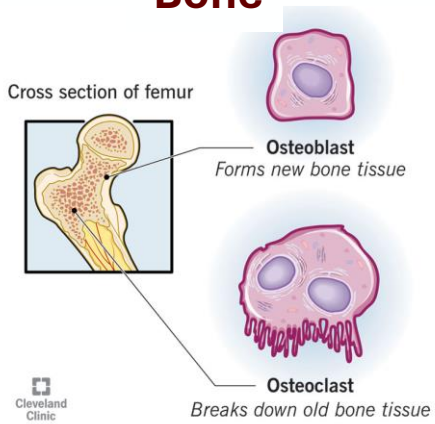
Fat



Muscle



Bone



Androgen Receptor Agonist	• Induces lipolysis[1] • Lowers lipogenesis[1] • Inhibits expression of adipocytokines (e.g., leptin, TNF-α, IL-6, IL-1[2])	• Stimulates muscle satellite activator, FGF2[3] • Modulates muscle growth suppressors MRF4 and myostatin (GDF8) expression in skeletal muscle[3]	• Acts directly on osteoblasts and consequently promotes bone formation[4] • Increases AR expression level in osteoblasts[4,5]
α-Tocopherol	• Decreases the activation of cytokines and adhesion molecules[6] • Scavenging peroxyl radicals inhibit peroxidation of lipids[7,8 9] • Important in maintaining membrane stability for cell signaling[9]	• Repairs the myoblasts membrane by protecting against oxidative stress and maintains membrane fluids [10-12]	• Counters oxidative stress associated with osteoclasts differentiation and osteoblast apoptosis[13]

1. Biochimie,87(1):39-43, 2005
2. J Endocr Soc. 2019 Jan 1; 3(1): 91–107
3. J Clin Endocrinol Metab, 104(6):2094–2102, 2019
4. Clin. Interv. Aging 2016, 11, 1317–1324
5. Horm. Metab. Res. 2004, 36, 674–678
6. Ann N Y Acad Sci., 1031:195-203, 2004
7. N Engl J Med. 2010;362(18):1675–85
8. Curr Opin Clin Nutr Metab Care. 2012;15(6):641–8
9. Vitamin E in Human Health, P. Weber et al. (eds.), Nutrition and Health, Chapter 23, 2019
10. Nutr J., 15: 71, 2016.
11. Arch Toxicol,97(10):2499-2574, 2023
12. Oxid Med Cell Longev. 2014
13. Int. J. Mol. Sci., 20(6), 1453, 2019.

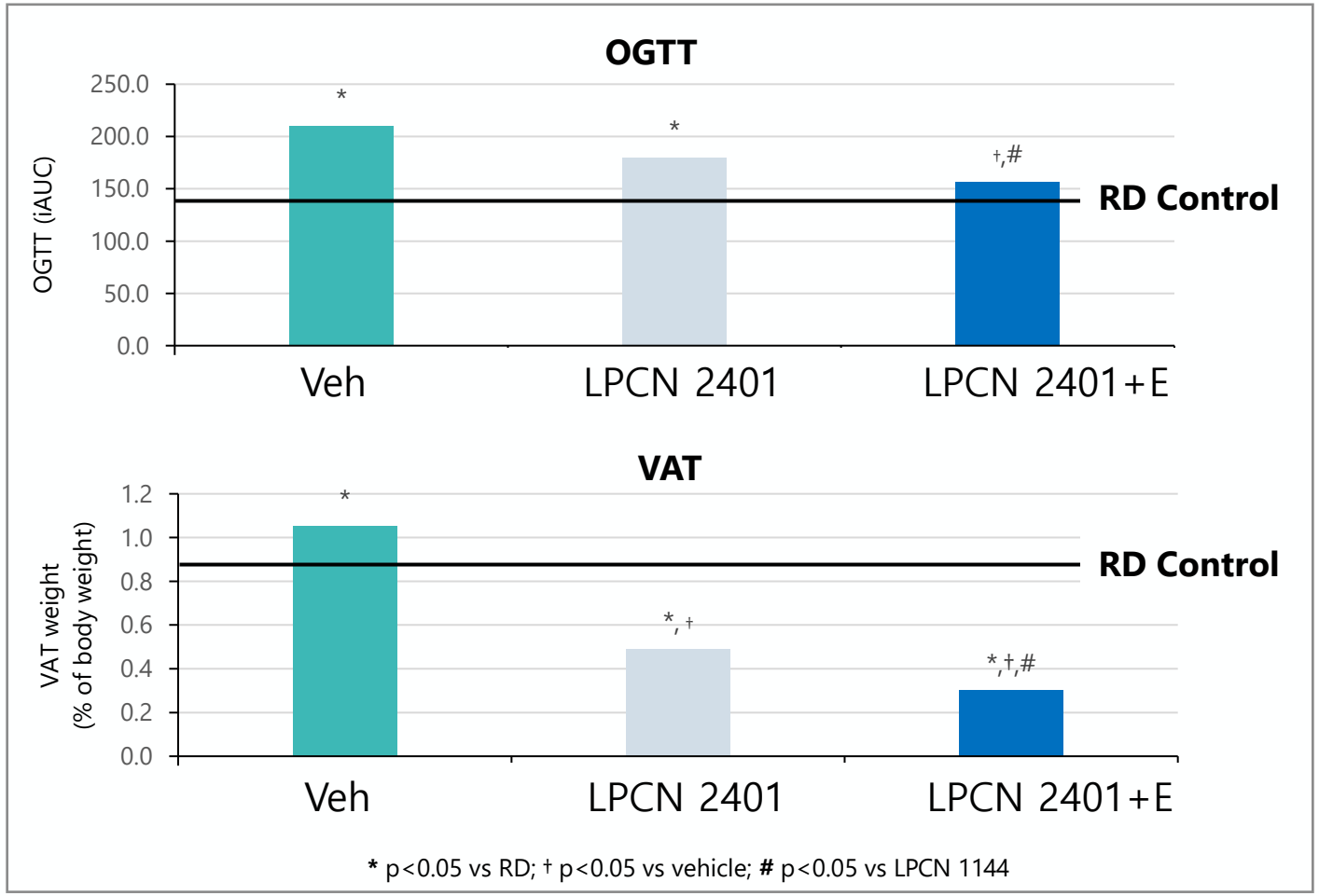
Summary of Preclinical Results in Diet Induced Model

LPCN 2401+E significantly improved oral glucose tolerance test and reduced VAT

12-week study in male rabbit model of metabolic syndrome

- Regular Diet (RD control), n=10
- High Fat Diet (HFD), n=10
- HFD + vehicle, n=7
- HFD + LPCN 2401 (TU monotherapy), n=8
- HFD + LPCN 2401+E (TU + α-tocopherol), n=8

LPCN 2401+E resulted in a significantly improved OGTT and reduced VAT compared to vehicle and LPCN 2401



TU: Testosterone undecanoate; VAT: visceral adipose tissue; OGTT: incremental area under the curve (iAUC) of glucose blood level during oral glucose tolerance test.
J Endocrinol Invest. 2021; 44(10): 2175–2193

Phase 2 Study in Patients with Obesity

NCT04134091 study design

Three-arm, blinded, placebo-controlled trial in male subjects with metabolic dysfunction associated steatohepatitis (n=56)

- High prevalence of obesity and weight related comorbid conditions such as dyslipidemia, T2DM, and hypertension

- 1:1:1 randomization across three oral treatment arms; Treatment duration of 36 weeks
  - Treatment A: T undecanoate monotherapy capsule (2401)
  - Treatment B: T undecanoate + α-tocopherol capsule (2401 + E)
  - Treatment C: Matching placebo

- Dual Energy X-Ray Absorptiometry (DEXA, n=40) at baseline, 20 weeks, and 36 weeks
  - Prespecified endpoints: change in lean mass and fat mass

- Low testosterone was not a requirement for study eligibility

LPCN 2401 Significant Improvement in Patients' Body Composition

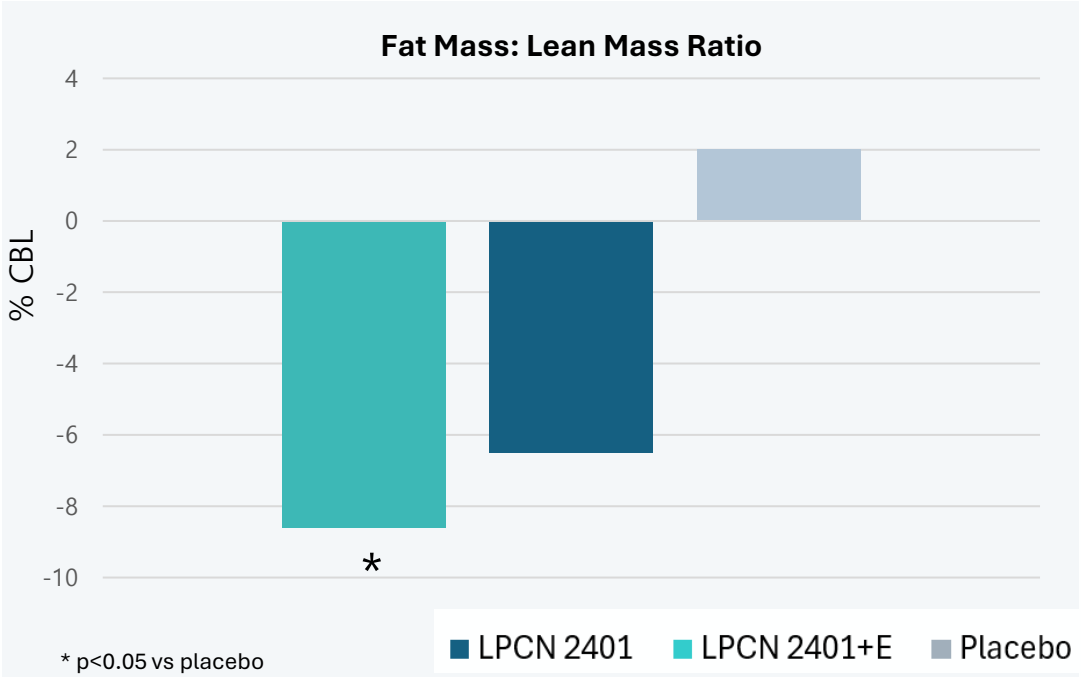
Increased lean mass and decreased fat mass

Body Composition Analysis Set[1]

Parameter at Baseline	LPCN 2401 (N=13)	LPCN 2401 + E (N=13)	Placebo (N=14)
Mean Age (years)	53.2	53.8	51.1
Mean Weight (kg)	111.3	107.8	118.6
Mean BMI (kg/m²)	35.9	34.7	37.2
Fat Mass (DXA) % of total mass	39.5	37.2	39.3
Lean Mass (DXA) % of total mass	60.5	62.8	60.7
Fat Mass:Lean Mass Ratio	0.67	0.60	0.66
Android Fat Mass (DXA) % of FM	11.5	11.9	11.2
BMC (DXA), kg	3.1	3.1	3.0

All participants met criteria for a weight management therapeutic*

Body Composition Results (36 Weeks)



- **Significant improvement in fat to lean ratio**
- Weight-neutral at week 36
- Trend towards weight reduction in OLE (72 weeks of treatment)

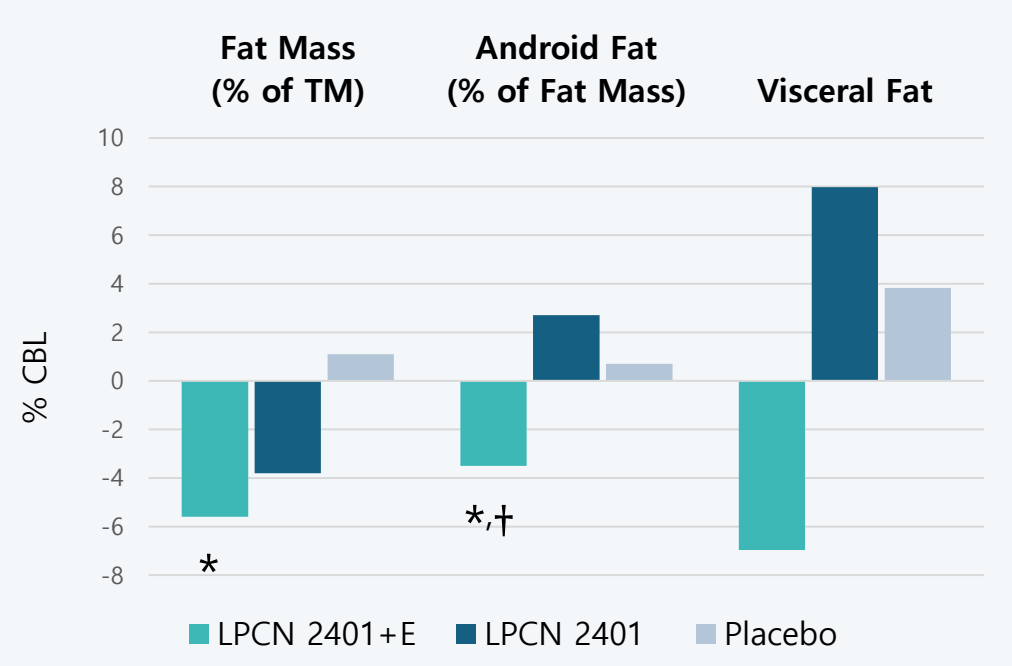
*NCT04134091, Population was consistent with FDA's guidance on developing products for weight management. All Participants had either BMI ≥ 30 (n=36) or BMI ≥ 27 with at least one weight-related comorbid condition (n=4).

1. Patient who completed baseline and at least one post-baseline DEXA. *p<0.05 vs placebo. Body composition analysis set; N=40.

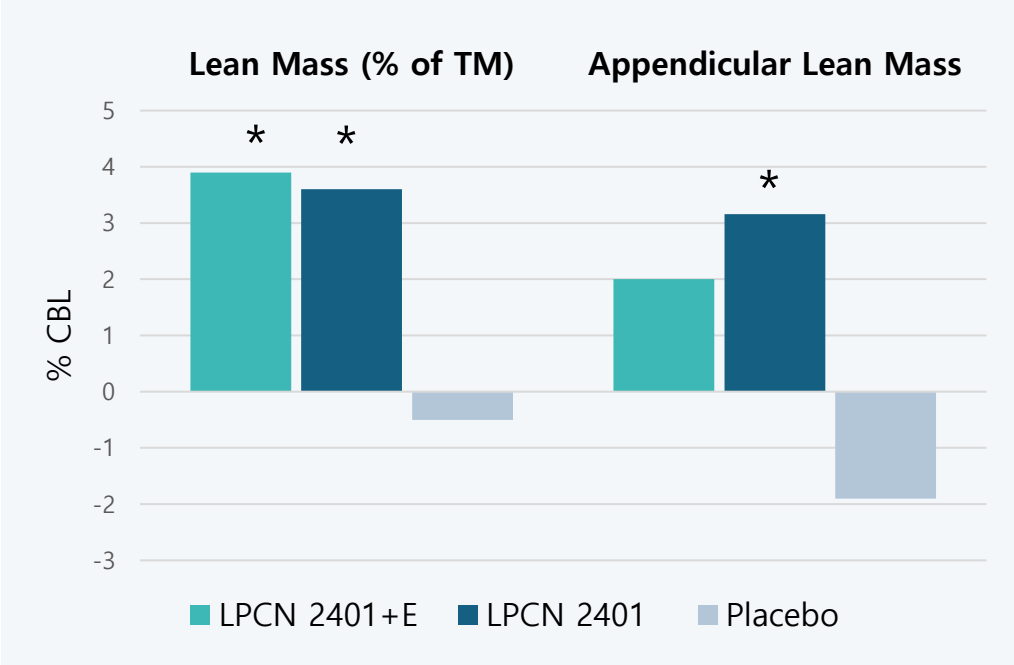
LPCN 2401 Significant Improvement in Patients' Body Composition

Increased lean mass and decreased fat mass

Fat Mass (36 Weeks)



Lean Mass (36 Weeks)



Significant reductions in fat mass

- Reduction in android fat
- ~8% reduction in visceral fat with 2401 + E

Significant increases in lean mass

- ~1.8 kg increase in whole body lean mass
- ~1.2kg increase in appendicular lean mass

p<0.05 vs placebo; † p<0.05 vs 2401;
Visceral fat n=11 for 2401 Mono; n=13 for placebo

LPCN 2401+E – Amplify Total Fat and Visceral Fat Loss in Obesity Management

- Visceral fat is primarily responsible for the risks associated with abdominal fat such as cardiovascular, cerebrovascular, metabolic, liver, renal, and joint diseases[2,3]

Combination of LPCN 2401+E and GLP-1 may amplify VAT loss

Placebo adjusted	LPCN 2401+E	Semaglutide*
Visceral fat mass loss (kg)	-0.29	-0.27
Total fat mass loss, TFM (kg)	-3.16	-6.99
% of TFM loss as Visceral Fat	9	4

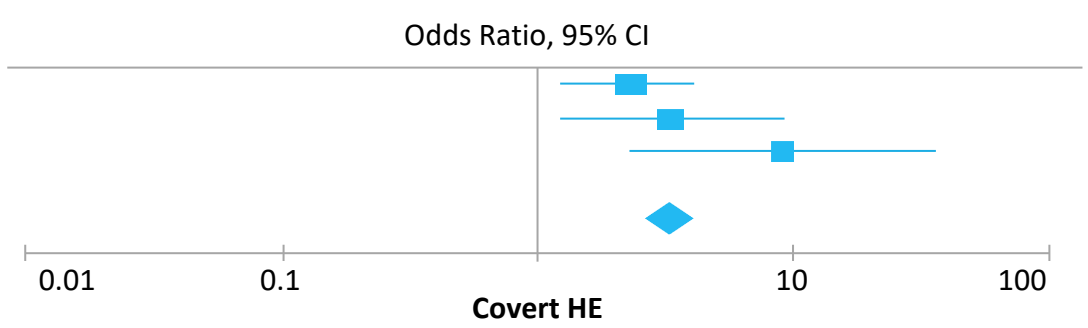
*Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations. No head-to-head clinical trials have been conducted. Semaglutide/Wegovy® CDER Clinical Review. Study 4373; N=140; n=95 semaglutide, n=45 placebo. 68 weeks of intervention.

1. Larsson et al. Br Med J. (1984) 288(6428):1401–4
2. Liu et al. Frontiers in Endocrinology 2023; 14: 1114963.

Presence of Sarcopenia is Associated with Higher Risk of HE

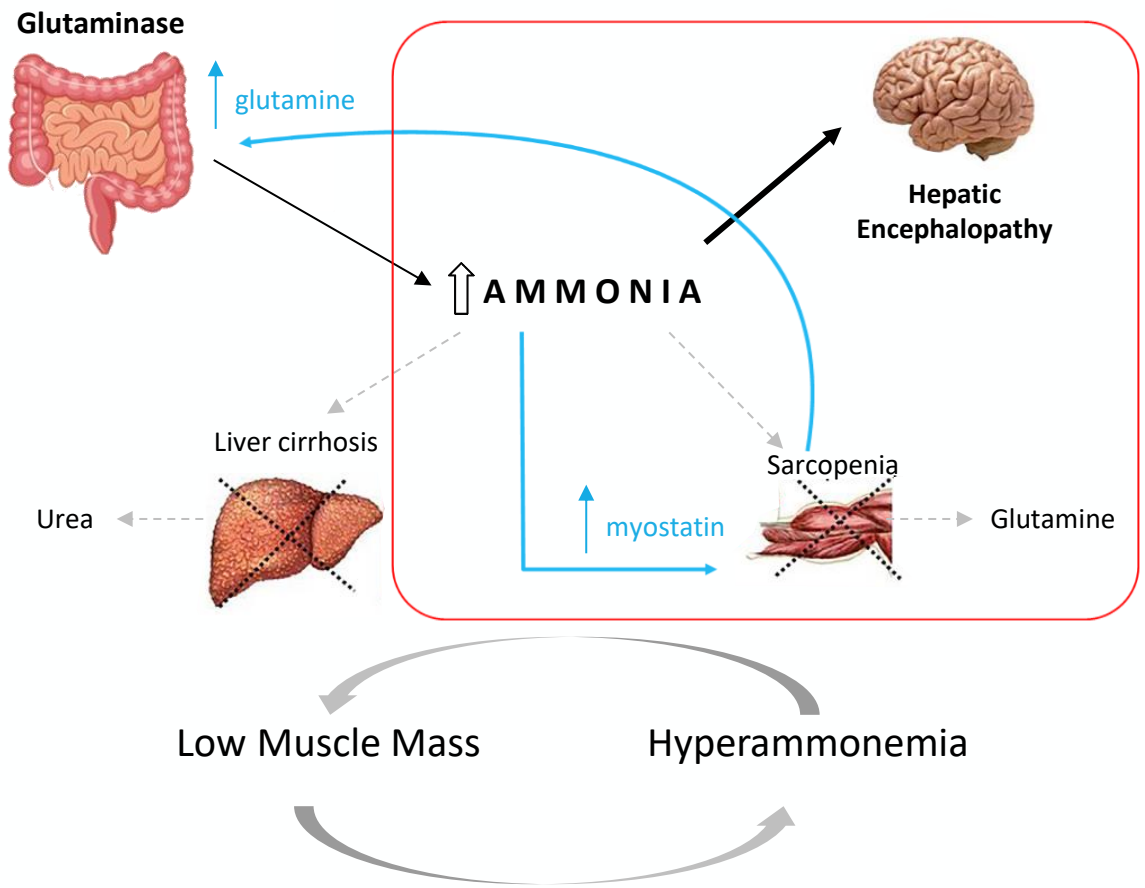
Muscle key organ for ammonia detoxification in the setting of decompensated cirrhosis

Sarcopenia and the Increased Risk of HE



Sarcopenia and myosteatosis are associated with increased risk of hepatic encephalopathy[1, 2]

Ammonia Metabolism and Trafficking in Liver Cirrhosis[3]



1. Montano-Loza, J Cach, Sarco, and Musc. 2016.
2. Wijarnpreecha. Ann Hep. 2020.
3. Bhanji, Hep Int. 2018.

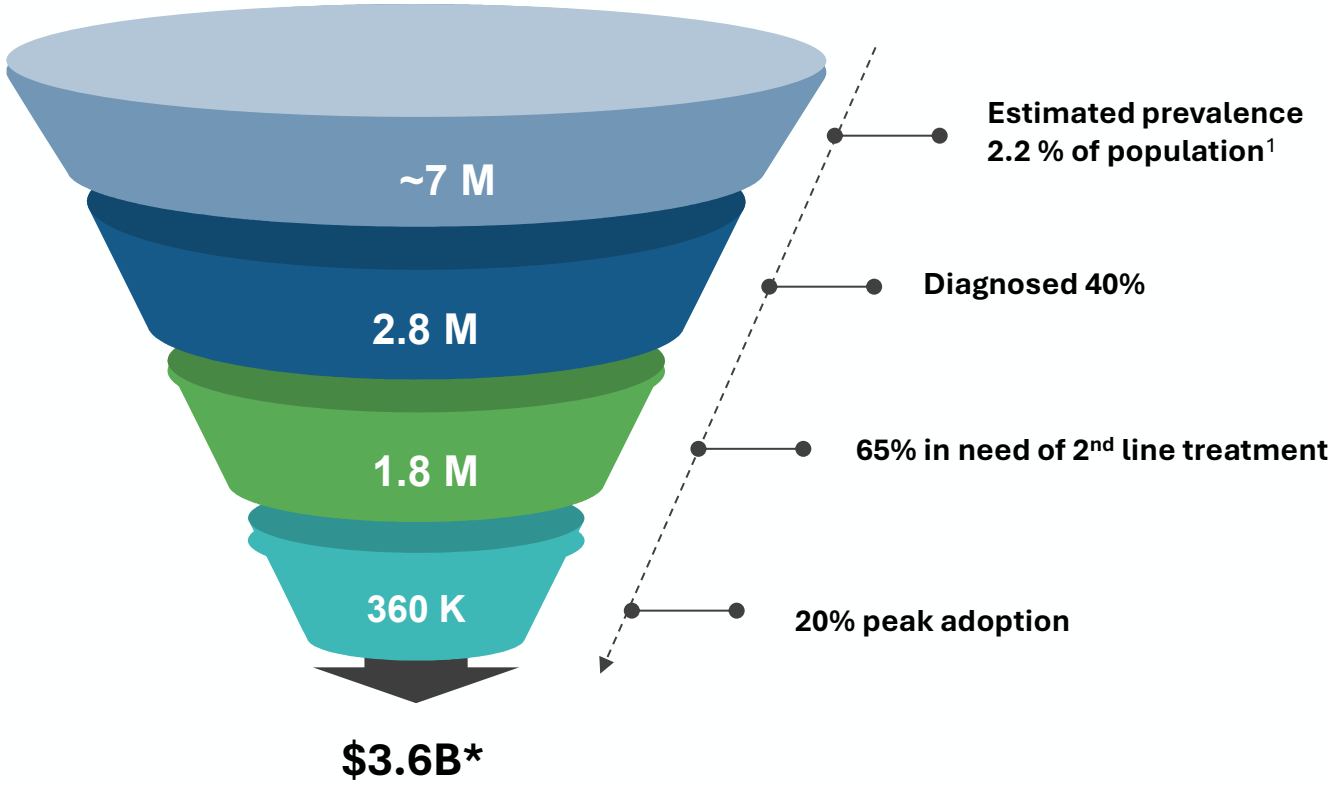
Rifaximin History and Current Status

- Rifaximin was initially approved in 2004 for the treatment of Travelers Diarrhea
- It was repurposed and approved by the FDA in March 2010 for the reduction of risk of recurrence of overt hepatic encephalopathy in adult patients
- Approved in 2015 for IBS-D
- 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 reduction in breakthrough HE events: 22.1% of patients with breakthrough HE events in rifaximin group vs. 45.9% in placebo group ($p<0.001$).
- Xifaxan annual sales > $2B in 2024[1]

1. BofA Global Research, Pharmaceutical Scripts/Sales Data Report 21 January 2025

Essential Tremor (ET)

Market potential - $3B+ blockbuster opportunity as 2nd line with 20% peak adoption



- Tremor is highly disabling and stigmatizing
- Stress can aggravate tremor in social setting
- Major impact on activities of daily living leading to unemployment, anxiety and depression[2]
  - 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 caregiving[2]

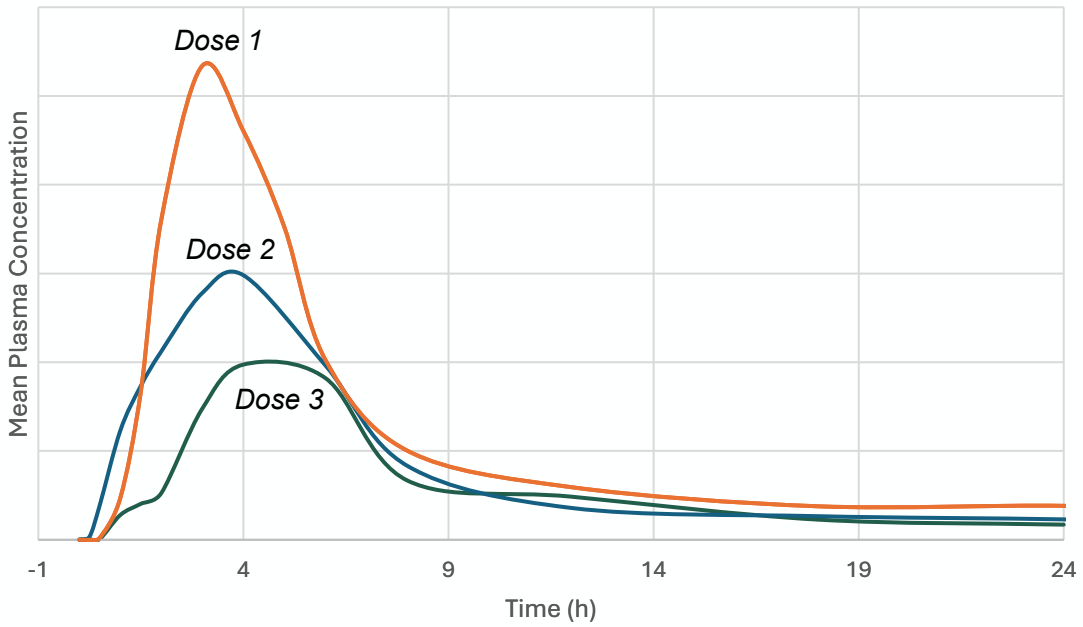
1. Louis ED, Ottman R. Tremor Other Hyperkinet Mov (N Y). 2014;4:259
2. Gerbasi et al. Patient experiences in essential tremor: Mapping functional impacts to existing measures using qualitative research. MDS 2023.

*indicative pricing ~ $10K/patient/year

LPCN 2203 Oral GABA Positive Allosteric Modulator

Achieved relevant target levels with good tolerability in Phase 1 studies

Typical single dose PK profiles



84 doses administered across 4 single dose studies to 37 participants

No sedation or dizziness AE reported

LPCN 2101 – Novel Potential Alternative for Women With Epilepsy (WWE)

Endogenous neuroactive steroid

Product Candidate Attribute

Positive Allosteric Modulator (PAM) of the $GABA_A$ receptor

Oral dosage form comprising a neuroactive steroid

Product Candidate Differentiation

Novel MOA specifically addressing unmet needs in WWE

Active is endogenous to women

Potential to address psychiatric comorbidities (depression, anxiety, sleep disorders)

Potential for minimal/no drug-drug interactions