LIPOCINE®
ENHANCING HEALTH

LPCN 1154

Oral Neuroactive Steroid for Depression Disorders

Topline Results
PK Bridge Clinical Study

Conference Call
May 16, 2023

Forward-Looking Statements

This release 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, the anticipated uses and benefits of LPCN 1154, the timing of a confirmatory pivotal PK study relating to LPCN 1154, the timing of any submission of an NDA filing relating to LPCN 1154, our ability to utilize the streamlined approval pathway under 505(b)(2), our strategic plans for developing products 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, including LPCN 1154, 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 release, except as required by law.

LPCN 1154

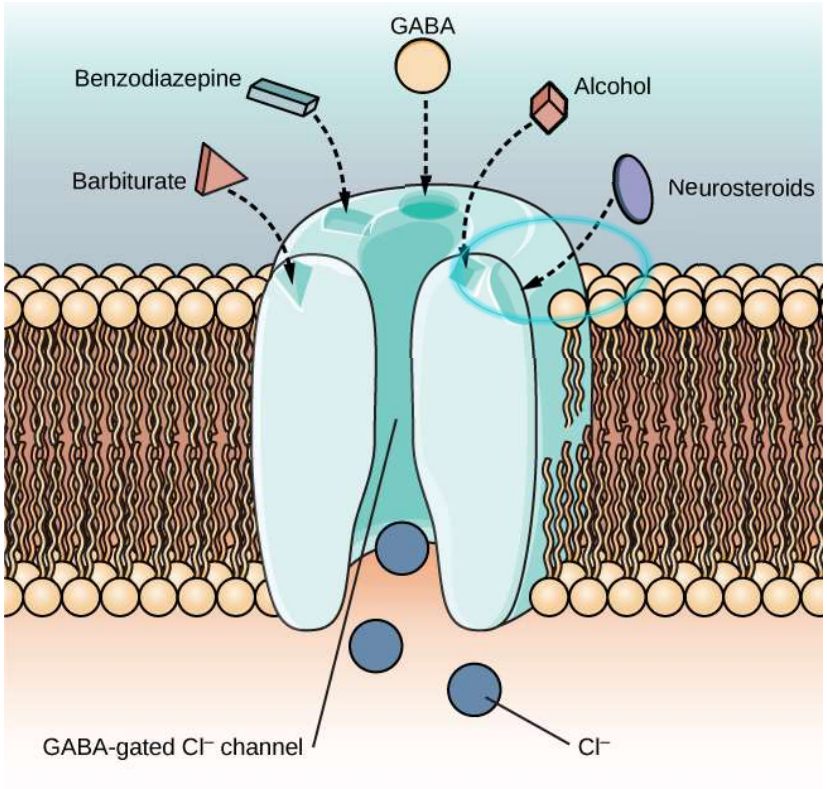
Strong Pharmacological Rationale

Mechanism of Action

Brexanolone is a positive Allosteric Modulator (PAM) of the $GABA_A$ receptor

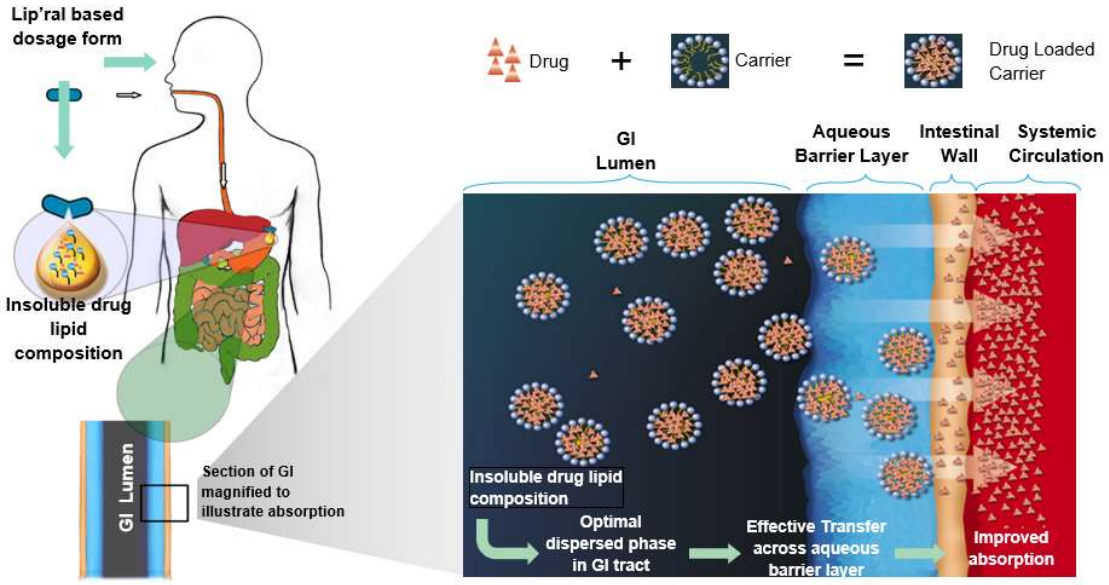
Hormonal changes leading to GABA dysfunction are common in depression and pregnancy

GABA Receptor Substrates Binding

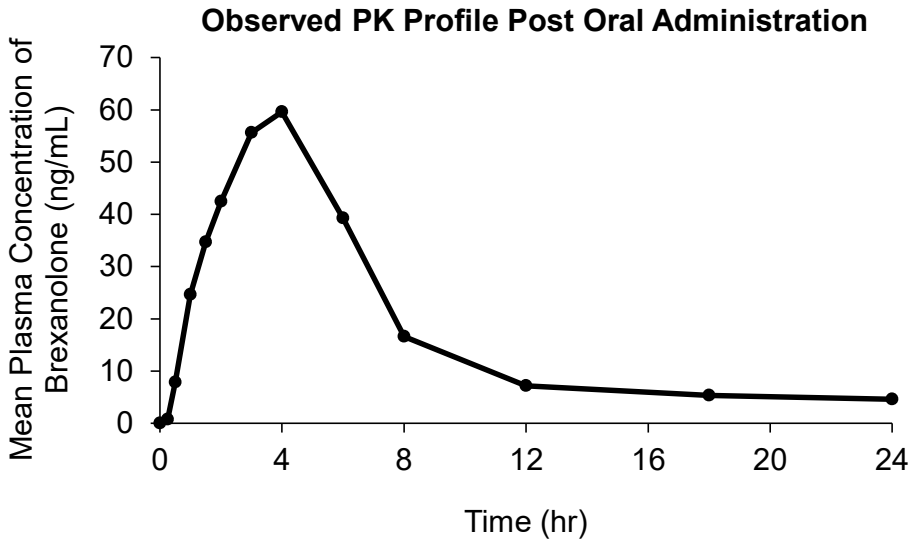


Validated Proprietary Lip'ral Technology Platform

Oral Enablement of Brexanolone



Achieved Relevant Systemic Levels in Phase 1 Study



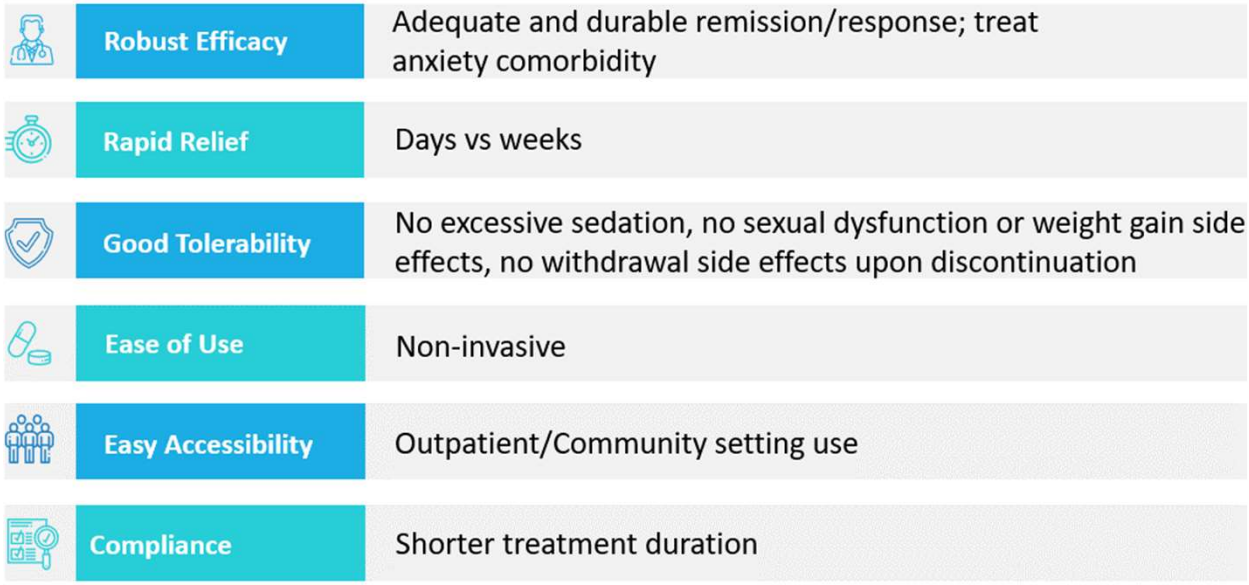
Study in post-menopausal women (n=12) with Lip'ral based oral dosage form

LPCN 1154 for Depression Disorders

New Treatment Paradigm for Depression

Significant Unmet Needs in Depression Disorders:

- Per NIMH, in 2020, an estimated 21.0 million (8.4%) adults in the US had at least one major depressive episode.[1]
- TRD: Prevalence ~2.8 million in US[2]
- The prevalence of comorbid anxiety disorder and major depressive disorder (MDD) is frequent and is as high as 60%.[3]
- PPD: 1 in 8 mothers suffer from PPD[4]



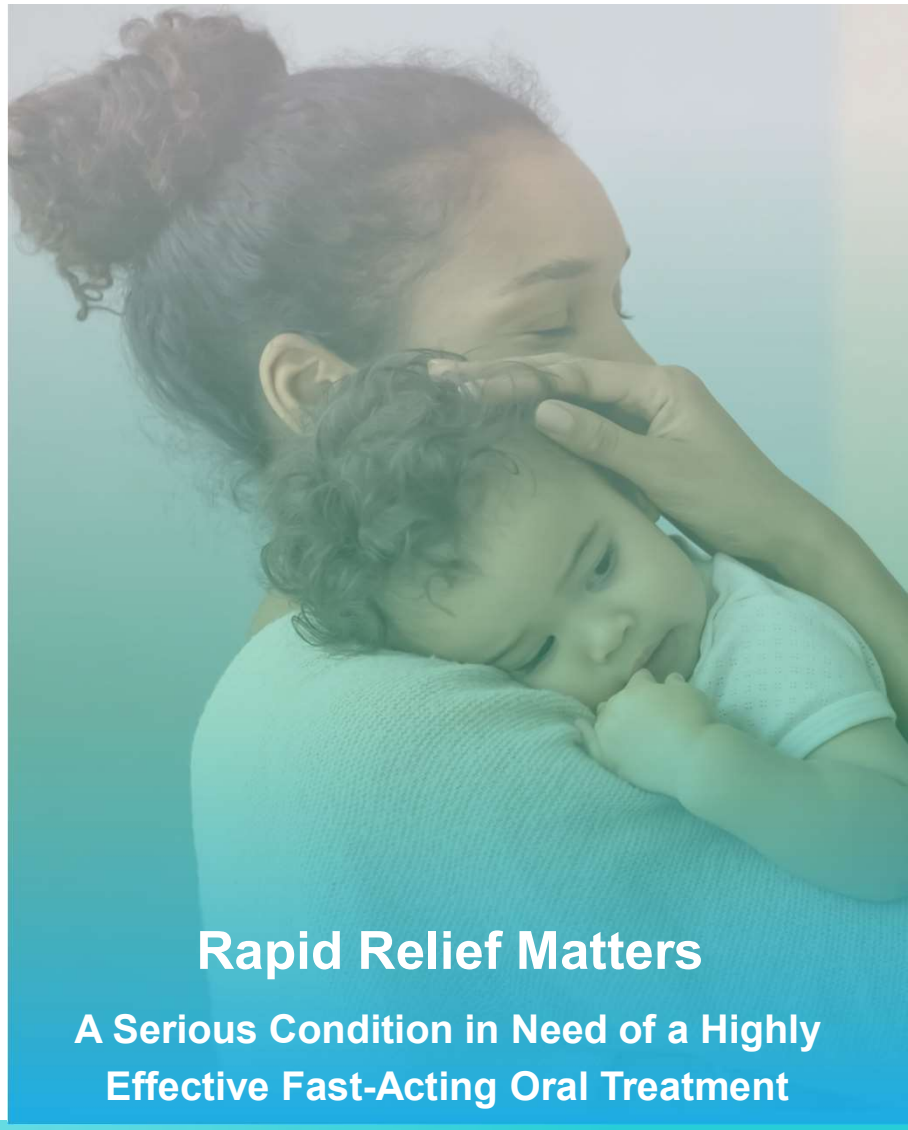
PPD = Postpartum Depression, TRD = Treatment Resistant Depression

Ref: 1. Monitoring System Survey–31 sites, 2018; 2. J Clin Psychiatry. 2021 Mar 16;82(2):20m13699. 3. Kaufman J, Charney D. Comorbidity of mood and anxiety disorders. Depress Anxiety. 2000;12:69-76. 4.CDC's Pregnancy Risk Assessment: https://www.cdc.gov/reproductivehealth/depression/index.htm

Postpartum Depression (PPD)

A Major Depressive Disorder Within Weeks of Childbirth

- Estimated patients in the U.S. with PPD: ~500K annually[1]
- The prevalence of adolescent-onset PPD is two-folds higher than adult-onset PPD[2]
- Suicide/suicide ideation, a significant concern: Suicide is a leading cause of maternal death in the first year following childbirth[3]
  - Up to 30% of women with PPD experience suicidal ideations[4]
- Warrants ensuring no harm done to mother and infant
- Negative impact on family



Rapid Relief Matters

A Serious Condition in Need of a Highly Effective Fast-Acting Oral Treatment

1. CDC's Pregnancy Risk Assessment: https://www.cdc.gov/reproductivehealth/depression/index.htm
2. sNDA 211371 S-007 Multi-disciplinary Review and Evaluation ZULRESSO (brexanolone) injection, for intravenous use
3. Chin et al. Curr Psychiatry Rep, 2022; 24(4):239-275
4. Mauri et al. Arch Womens Ment Health. 2012; 15(1): 39-47

Limitations of Current Pharmacological Treatment Modality for PPD

PPD – A Substantial Opportunity

SSRIs/SNRIs

(Not approved for PPD indication, off label use)

Slow onset of antidepressant action – may take 4-6 weeks[1]

Treatment duration – acute for 6–8 weeks, followed by 4–9 months of continuation treatment[2]

Efficacy – low pharmacotherapy response after 6-8 weeks[2]

Tolerability – side effects such as sexual dysfunction and weight gain[3]; side effects upon discontinuation[4]

Injectable Brexanolone

(The only FDA approved treatment)

Logistics of 60-hour IV infusion

Inpatient administration

~40% of AEs are related to IV infusion administration errors[5]

Frequent monitoring for excessive sedation

Accessibility Challenges: Overnight stays; providers and facility certification; affordability

Market in Need of a Highly Efficacious, Fast-Acting, and Convenient Antidepressant

1. Boesen et al., Epidemiol Psychiatr Sci. 2021; 30, e35, 1-10.
2. Kennedy et al. J Psychiatry Neurosci. 2002 Jul;27(4):269-80.
3. Ferguson JM. Prim Care Companion J Clin Psychiatry. 2001 Feb; 3(1): 22–27.
4. Warner et al. Am Fam Physician. 2006;74(3):449-456
5. FDA Adverse Event Reporting System (FAERS) Public Dashboard

LPCN 1154: A Potential Preferred Option for Rapid Relief in PPD

The Days After Childbirth are a Critical Time Period for the Care of Both Mother and Newborn

Product Candidate Attributes

- Monotherapy or add-on therapy for patients (including adolescents) with unresolved symptoms
- Convenient oral for outpatient use
- Bioidentical to naturally occurring neuroactive steroid, allopregnanolone

Product Candidate Differentiation

Ideal for patients

- in need of rapid relief with high remission rate and short treatment duration
- with severe PPD; with acutely elevated suicide risk

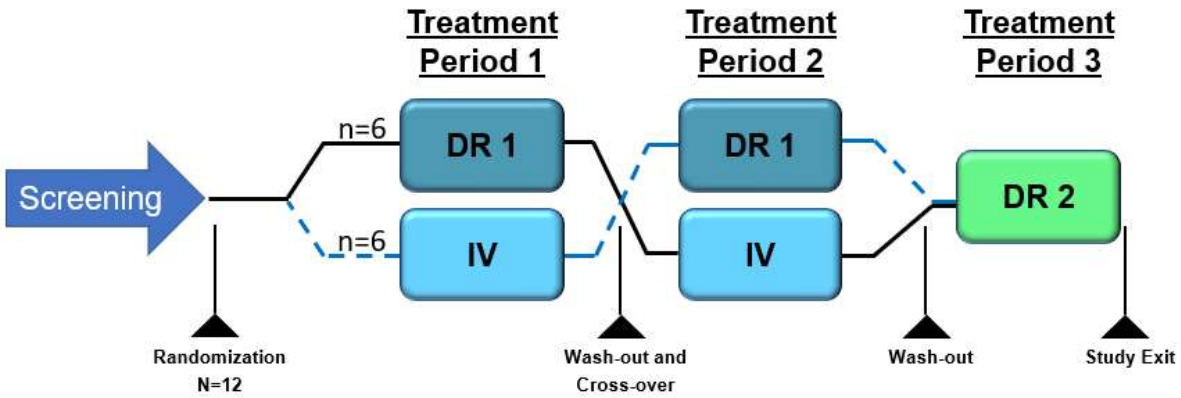
No IV infusion challenges - anxiety, resource demands, preparation/administration errors, patient counseling, burdensome on family

No sexual dysfunction and weight gain side effects

LPCN 1154: Pilot PK Bridge Study

Rationale and Clinical Design

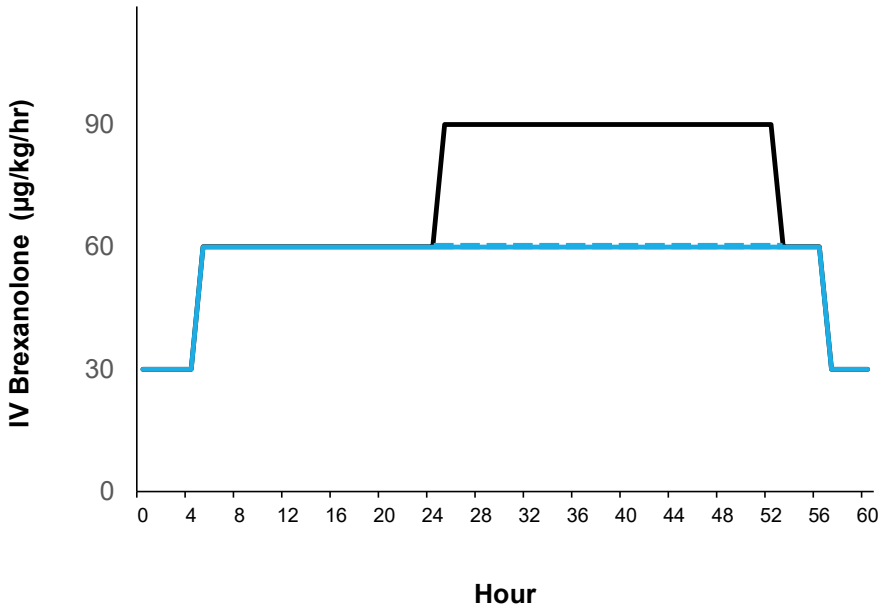
- FDA agrees with Lipocine's proposal to establish efficacy through a pharmacokinetic (PK) bridge to IV brexanolone
- An open-label, randomized, three-period, 3-arm partial crossover study to compare the PK of oral LPCN 1154 (brexanolone) and intravenous brexanolone in healthy postmenopausal women
- Primary Objective: To compare the PK (AUC_{inf} and C_{max}) of two multi-dose regimens of orally-administered LPCN 1154 and a continuous I.V. infusion dosing regimen of Brexanolone in healthy postmenopausal women.
- Secondary Objective: To evaluate the safety and tolerability of single and multi-dose regimens of oral LPCN 1154 in healthy postmenopausal women.

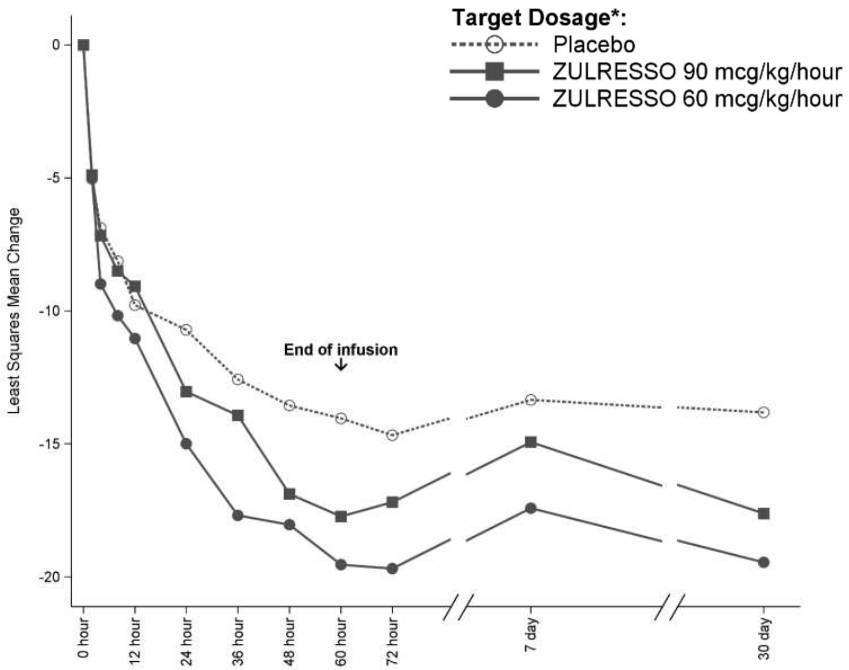


DR 1: LPCN 1154 Oral Multi-Dose Regimen 1 (3.5 days)
IV: Zulresso® Continuous Infusion (up to 90 µg/kg/hr) (2.5 days)
DR 2: LPCN 1154 Oral Multi-Dose Regimen 2 (2.5 days)

IV Brexanolone Demonstrated Efficacy with Two Dosing Regimens

- Maximum infusion rate of 90 µg/kg/hr and 60 µg/kg/hr





Pharmacokinetic Results

Dosing Regimen Identified for Confirmatory PK Study

Ratios (%) of geometric mean
LPCN 1154 regimens vs IV brexanolone regimens

PK Parameter	DR 1 vs IV 60 µg*	DR 1 vs IV 90 µg	DR 2 vs IV 60 µg*	DR 2 vs IV 90 µg
AUC_{∞}	98%	77%	106%	83%
C_{max}	114%	68%	134%	79%

- DR 1 resulted in comparable brexanolone exposure (C_{max} and AUC_{∞}) to IV brexanolone 60 µg/kg/hr regimen
- DR 2 resulted in exposure levels (C_{max} and AUC_{∞}) within the two clinically-effective IV brexanolone dosing regimens (60 µg/kg/hr and 90 µg/kg/hr)

*Interpolated from 90 µg/kg/hr IV infusion data
60 µg and 90 µg refer to the maximum dose in the IV regimen (60 µg /kg/hr and 90 µg /kg/hr)

LPCN 1154 Was Well-Tolerated

Consistent with Prior LPCN 1154 Clinical Experience

- All AEs were mild or moderate in severity
  - AEs were similar across trial arms
  - Majority (63%) AEs were venipuncture site pain (PK draws) or venipuncture site reactions (IV infusions)
- No Serious Adverse Events were observed
- No hypoxia or sedation-related adverse events were observed
- No concerning safety signals related to vital signs were observed throughout the study
- No dropouts - All participants completed all dosing periods

LPCN 1154

Streamlined Pathway to NDA Submission

Initiate 2H 2023

Phase 1

Successful single dose study completed
Established feasibility of oral administration

Pilot PK Bridge Study

Positive Topline Results

PK Pivotal Study

Confirmatory trial to establish efficacy for NDA submission*

*Labeling studies may be needed for NDA submission

LPCN 1154: A New Paradigm in Oral Treatment for Depression

Conclusions

- Differentiated product attributes address unmet needs
    - Oral , rapid relief, short treatment duration, high remission rate*
- Brexanolone is an approved neuroactive steroid for depression with validated unique mechanism of action
- Positive results from the pilot PK bridge study propels LPCN 1154 into an advanced development stage
    - Planning on a single confirmatory pivotal PK study (2H 2023) to establish efficacy, pending FDA feedback
    - Advantageous streamlined pathway to NDA submission
    - Goal to submit NDA for PPD in 2024
- Study results support expansion into additional depression indications

*Remission defined as HAMD-17 score ≤7