Virtual KOL Event Highlighting Unmet Needs in Postpartum Depression and the Clinical Profile of LPCN 1154

June 12, 2026

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Agenda

Session	Moderator
Opening Remarks	Dr. Mahesh Patel President and CEO, Lipocine
Postpartum Depression: Clinical Burden, Treatment Landscape, and Remaining Unmet Needs	Dr. Kristina Deligiannidis
LPCN 1154: Clinical Outcomes Highlights	Dr. Ben Bruno, VP of Clinical Development, Lipocine
Recent LPCN 1154 Clinical Data: Clinical Interpretation and Relevance to Practice	Dr. Rakesh Jain
Recent LPCN 1154 Clinical Data: Clinical Interpretation and Relevance to Practice	Dr. Deligiannidis
Why LPCN 1154 Matters Now, Next Steps, and Concluding Remarks	Dr. Mahesh Patel
Moderated Q&A	LifeSci Advisors

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, the timing and potential results of additional studies relating to LPCN 1154, the timing of our submission of a NDA with the FDA for LPCN 1154, 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, including required studies, 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.

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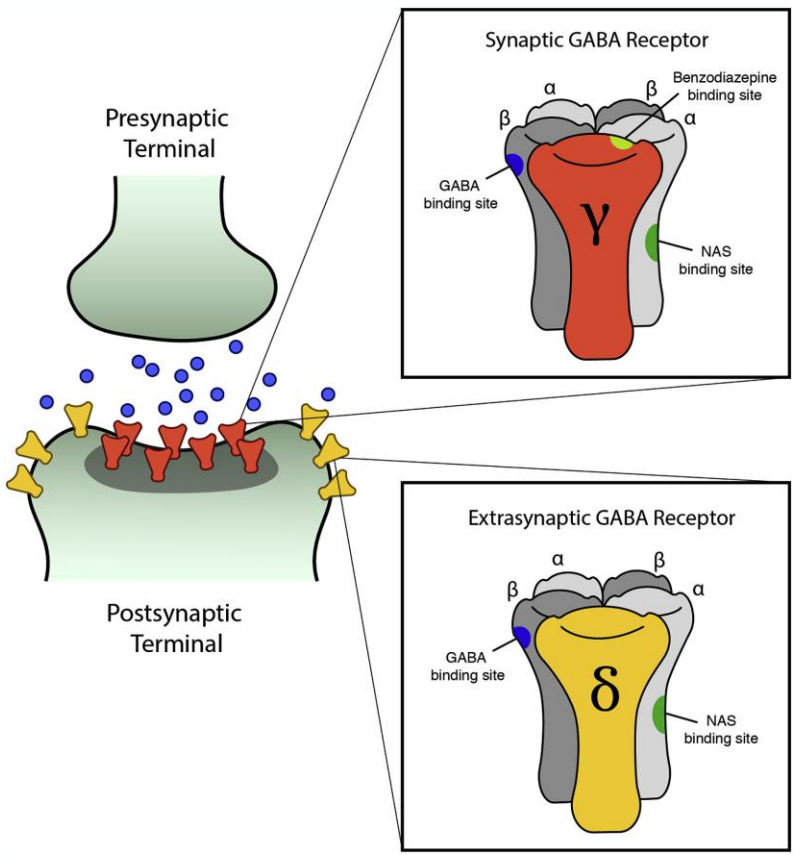
Opening Remarks

Dr. Mahesh Patel,
President and CEO Lipocine

LPCN 1154 (Oral Brexanolone)

Antidepressant $GABA_A$ PAM mechanism validated through FDA approved drugs, Zulresso® and Zurzuvae®



Endogenous Neuroactive Steroid (NAS)

Potent **positive allosteric modulator (PAM)** of the $GABA_A$ receptor
Metabolite of progesterone

Synaptic Engagement

Acts on both **synaptic and extra-synaptic** $GABA_A$ receptors

Persistent antidepressant effects

Mediated via $GABA_A$ modulation, **neuroimmune regulation**, **HPA axis modulation**, and **increased BDNF** levels [1,2]

High lipophilicity (logP ~5)

Previously limited delivery to non-oral routes (IV, IM)

BDNF: Brain-derived neurotrophic factor

1. Balan et al., eBio Medicine, 2023;89: 104473
2. Balan et al., Transl Psychiatry. 2026 Jan;16:119
3. Image from: Meltzer-Brody and Kanes, Nurobiol Stress 2020;12:100212

Dr. Deligiannidis received her medical degree from and completed her psychiatry residency and chief residency in psychopharmacology research at the University of Massachusetts Medical School. Prior to and during medical school she trained in neuroscience research at the National Institutes of Health (NIH). After residency she completed additional research training in behavioral endocrinology and experimental therapeutics at the NIH and in multimodal neuroimaging at the Martinos Center for Biomedical Imaging at Mass General Hospital. Dr. Deligiannidis is the Director of Women's Behavioral Health at Zucker Hillside Hospital, Northwell Health and a Professor of Psychiatry, Molecular Medicine and Obstetrics and Gynecology at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. As a reproductive psychiatrist, she has expertise in treating women with mood and anxiety disorders linked to the menstrual cycle, perinatal and perimenopausal periods. Dr. Deligiannidis is a nationally recognized leader in the field of perinatal depression and in novel therapeutics research. Her research program includes a focus in neurosteroids and hormones, and multimodal neuroimaging. Dr. Deligiannidis's research is supported by NIH, foundation, donor and industry funding. For the past decade she served as a principal investigator on the series of clinical trials that led to the FDA approval of two rapid-acting antidepressants for postpartum depression. Dr. Deligiannidis is a current Board of Directors member and President Elect for the Marcé of North America, past Council member of the Society of Biological Psychiatry, past Board of Directors member for the American Society of Clinical Psychopharmacology and currently is a full member of the American College of Neuropsychopharmacology. Dr. Deligiannidis also serves as a reviewer on over 20 scientific journals and on Editorial Boards of national and international journals.

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Postpartum Depression:
Clinical Burden, Treatment Landscape, and Remaining Unmet Needs

Dr. Kristina Deligiannidis

Perinatal Depression is common and costly

- Perinatal mental health disorders are among the most common complications of pregnancy and the year after delivery *(Wisner KL et al, 2013; Fawcett EJ et al, 2019; Masters GA et al, 2022).*
- Globally, mean prevalence rates of depression during pregnancy or after delivery (**perinatal depression**) = 26.3% *(Al-abri K et al, 2023)*
- Cost of not treating perinatal depression/anxiety among US births in 2017 = **$14.2 billion** with the average cost per affected mother-child dyad through age 5 =**$31,800**
  - Reduced economic productivity
  - Increased number preterm births
  - Increased maternal health expenditures (inpatient, ambulatory, emergency services, prescriptions)

(Luca DL et al, 2020; Pollack LM et al, 2022)

Perinatal depression is under-diagnosed and undertreated

- Numerous professional organizations, including the U.S. Preventative Services Task Force (USPSTF) and American Psychiatric Association (APA), recommend screening for depression in pregnant and postpartum individuals *(JAMA 2016; APA position statement 2018)*
- American College of Obstetricians and Gynecologists (ACOG) recommends screening individuals for depression and anxiety symptoms using a standardized, validated tool at the initial prenatal visit, later in pregnancy and at a postpartum visit *(ACOG Clinical Practice Guideline June 2023, Obst Gynecol)*

increased screening and initiation of pharmacotherapy by OBGYNs

- Prevalence of health care provider inquiry about depression during prenatal visits increased significantly during 2016–2018, from 76.2% to 79.3% and during the postpartum visit increased significantly from 84.1% to 88.0% ($p<0.05$) during 2016–2018 *(Bauman BL et al, 2020 CDC MMWR weekly report)*
- 73% of postpartum women initiate treatment *(Avalos LA et al, 2022)* but far fewer receive adequate (dose and duration) treatment *(Cox, EQ et al, 2016)*
- 62.7-76.4% of women discontinue treatment at least once during the year after PPD diagnosis, with 27.8-38.5% discontinuing treatment within 60 days (Miller DC et al, 2025)

Perinatal depression is associated with adverse maternal, obstetrical, infant and child developmental outcomes

- Decreased maternal functioning *(Field, T, 2010)*
- Psychosis, suicidal ideation and suicide attempt are psychiatric emergencies that lead to psychiatric hospitalization, maternal death *(Rodriguez-Cabezas et al, 2019)*
- Bidirectional relationship between depression and gestational diabetes mellitus *(Fischer et al, 2023)*
- Preterm birth (Grigoriadis S et al, 2013), stillbirth/neonatal death and hypertensive disorders of pregnancy *(Staub et al, 2012, Thombre et al, 2015, Delanerolle et al, 2022)*
- Increased requirement for surgical delivery interventions *(Wang SY & Chen CH, 2010)* and cesarean delivery *(Bansil P et al, 2010)*
- Inadequate maternal-infant bonding prenatally and post-delivery *(Rossen et al, 2016; Betcher et al, 2020, Dagher et al, 2021)*
- Lactation failure or unplanned weaning *(Dennis CL & McQueen K, 2009; Stuebe AM et al, 2014)*
- Impaired child cognitive, behavioral and emotional development *(Tuovinen S et al, 2018; Leis JA et al, 2014; Pearson RM et al, 2013)*

Postpartum depression is not the baby-blues

The baby blues is not a clinical diagnosis, is experienced by approximately 80% of women in the first 2 weeks following delivery and although can include fluctuating mood changes, self-resolves without treatment and does not impair functioning.

A patient example:

"Abby" is a 34-year-old married female with a past psychiatric history of depression and anxiety presented for clinical care 8 weeks after delivering her 2nd child via c-section…

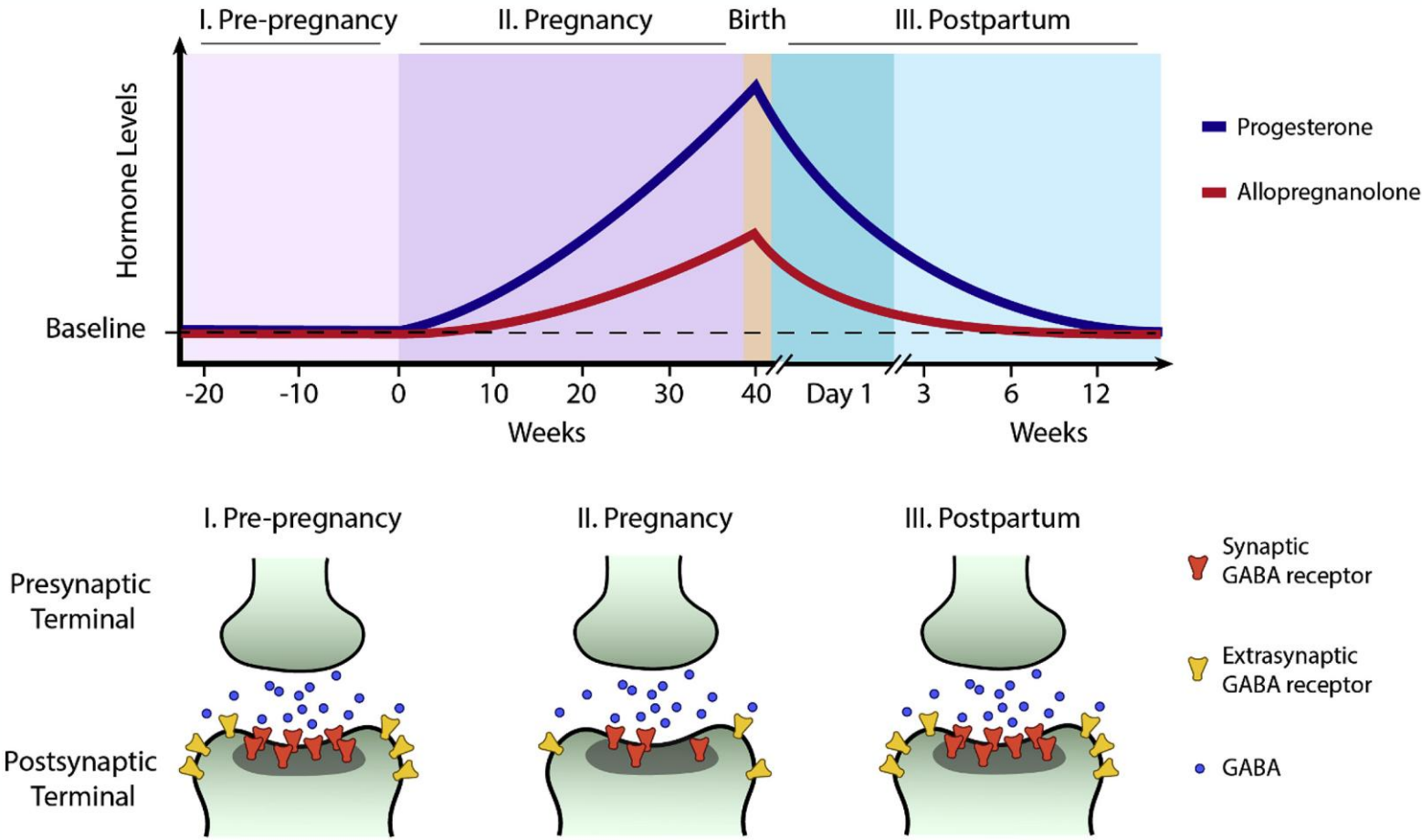
(PII and PHI was altered to maintain confidentiality; description is a conglomeration of patient presentations and does not represent any single patient experience)

Psychotherapies and serotonergic/traditional antidepressants have been the cornerstone of postpartum depression treatment for decades

- **Psychotherapies:** may be used as monotherapy for mild to moderate perinatal depression *(Grote NK et al, 2010; Ammerman RT et al, 2013; Dimidijian S et al, 2014; Goodman JH 2014)*
- **Serotonergic antidepressants:** used alone or in combination for moderate/severe unipolar perinatal depression; FDA approved for major depressive disorder
- Meta-analysis of 11 postpartum RCTs showed that there *may* be a benefit of SSRIs over placebo in response (55% versus 43%; pooled risk ratio (RR) 1.27, 95% CI 0.97 to 1.66) and remission (42% versus 27%; RR 1.54, 95% CI 0.99 to 2.41) at 5 to 12 weeks' follow-up. *(Brown JVE et al, Cochrane Database Syst Rev, 2021)*

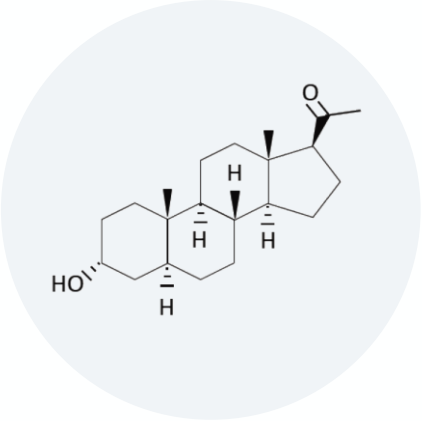
Neuroactive steroids (NAS) modulate GABAergic and glutamatergic neurotransmission

- Natural or synthetic steroids act on the brain by serving as transcription factors in the regulation of gene expression or by interacting with membrane-bound neurotransmitter receptors *(Paul SM & Purdy RH 1992)*
- Many NAS are positive allosteric modulators (PAMs) of the GABAA-R, enhancing tonic or phasic GABAergic inhibition via facilitating negatively charged Cl- ion flow *(Callachan H et al 1987)*
- CNS NAS have important roles in HPA response in both acute and chronic stress conditions *(Maguire J 2019; Crowley & Girdler, 2014)*

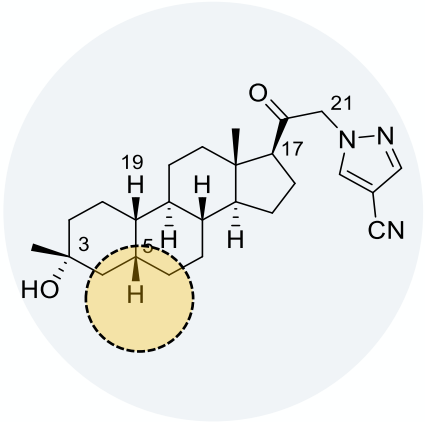


NAS as a first-in-class antidepressant

- The breakthrough FDA-approval of brexanolone in 2019 represented a first-in-class antidepressant that had rapid-acting antidepressant actions which were maintained even after the acute treatment course was complete.
- The company that developed brexanolone, then developed zuranolone, a synthetic derivative of pregnanolone (also a GABA-AR positive allosteric modulator) which was orally bioavailable and could be dosed once daily, at home. It was FDA approved in 2023.
- Brexanolone was withdrawn from the clinical market and has not been available as of January 2025.



Allopregnanolone;
Brexanolone (3α, 5α NAS)



Synthetic derivative of pregnanolone;
Zuranolone (3α, 5β NAS)

Pharmacologic Treatment Landscape Comparison

IV Brexanolone (ZULRESSO®) is no longer available related to the prolonged inpatient 60-hour monitored infusion, creating logistical and access challenges

Zuranolone (ZURZUVAE®) treatment is associated with frequent CNS depressant effects such as somnolence, dizziness, and sedation

SSRIs / SNRIs have slow onset, longer treatment duration, and lower response rates. Additionally side effects such as sexual dysfunction, changes in sleep pattern and weight gain are common

	IV Brexanolone *(ZULRESSO®)*	**Zuranolone** *(ZURZUVAE®)*	***SSRIs/SNRIs*** *Off-Label Use*
Description	Bioidentical NAS	Synthetic NAS derivative	Synthetic SSRI/SNRI
FDA label black box	Excessive sedation and LOC	Driving impairment	Increased risk of suicidal ideations and behaviors
CNS depressant AEs	Moderate[2]	High[3]	Moderate[5]
Onset of Action	Hours	Days	Weeks
Treatment Duration	In-patient IV, 60 hours	14 days	Months

No head-to-head clinical trials have been conducted. Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations.

1. Deligiannidis et al., Am J Psychiatry 180:9, September 2023
2. Zulresso label; Somnolence (15%), LOC (4%), dizziness/presyncope/vertigo (12%)
3. Zurzuvae label; Somnolence (36%), dizziness (13%), dose Reduction (14%), and discontinuation (2%),
4. Defined as less than 5% with no drug discontinuations, drug-related SAEs, loss of consciousness, or excessive sedation
5. https://www.uptodate.com/contents/image?imageKey=PSYCH%2F143603

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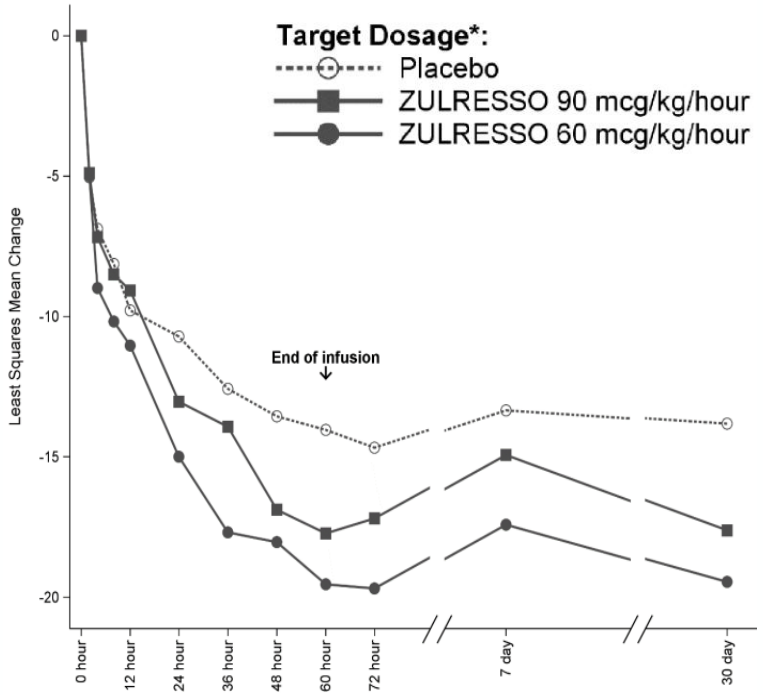
LPCN 1154: Clinical Outcomes Highlights

Dr. Benjamin Bruno
VP of Clinical Development

LPCN 1154 – Achieved Standard Bioequivalence to IV Brexanolone

Dosing regimen confirmation study results

IV Brexanolone (ZULRESSO®) is Efficacious in PPD[1]



Efficacious with lower (60 µg/kg/hr) and higher dose (90 µg/kg/hr) regimens

LPCN 1154: Bioequivalent to ZULRESSO®

PK Parameter	LPCN 1154	IV Brexanolone	GMR Test vs. Reference (90% CI)
C_{max} (ng/mL)	120	115	105% (92%-118%)
$AUC_{0-\infty}$ (h*ng/mL)	4884	5019	97% (89%-107%)
AUC_{0-100} (h*ng/mL)	4266	4784	89% (81%-98%)

LPCN 1154 multi-dose regimen resulted in bioequivalent blood levels compared to IV brexanolone administered per label at higher dose regimen (90 µg/kg/hr)

Bioequivalence to IV Brexanolone enables a streamlined regulatory strategy, leveraging Zulresso's established efficacy data.

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}
1. ZULRESSO® label

LPCN 1154 – Phase 3 Safety and Efficacy Study Design

Utilized same dose and regimen as the PK dose confirmation study

Study design

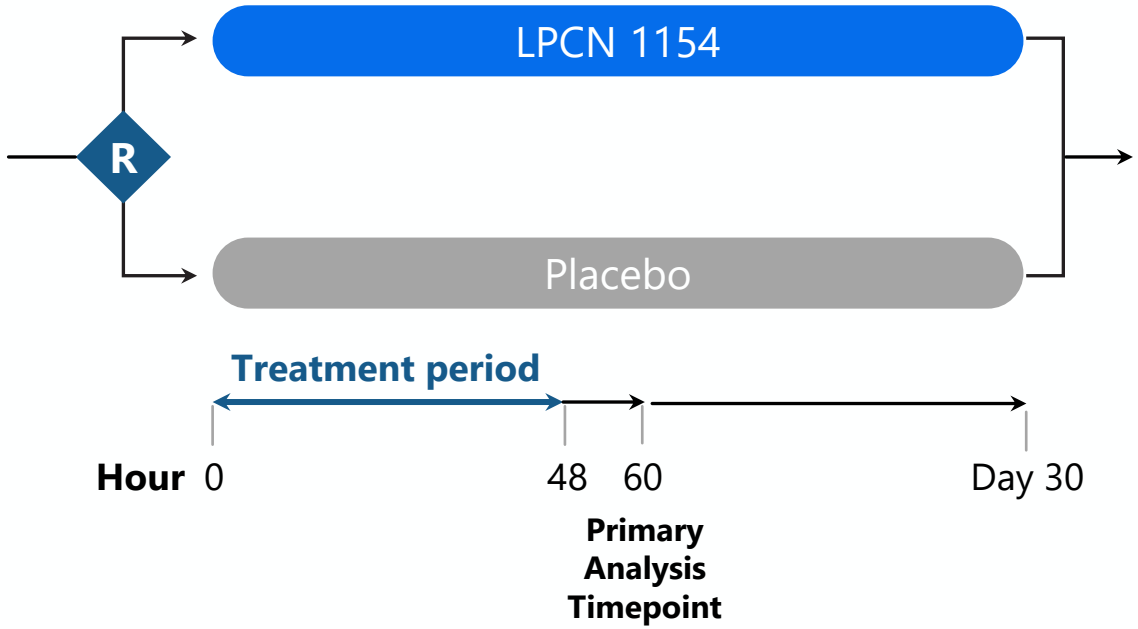
- Two arm, outpatient, randomized, blinded, placebo-controlled trial in women with postpartum depression at home administration with no required medical monitoring

Inclusion criteria

Severe PPD (HAM-D ≥26)

Age ≥15 yrs

N= 90 women



Endpoints

Rating Scales:
Administered at baseline, 12h, 36h, 60h, Day 7 and Day 30

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

https://clinicaltrials.gov/study/NCT06979544

Full Analysis Set

Baseline demographics

Characteristics	LPCN 1154	Placebo	Overall
N	45	45	90
Age (years) (Mean, SD)	30.7 (5.41)	30.8 (6.52)	30.8 (5.96)
BMI (kg/m^2) (Mean, SD)	30.0 (5.96)	29.6 (6.06)	29.8 (5.98)
Ethnicity (HISP; %)	64.4	60.0	62.2
Race (White; %)	62.2	66.7	64.4
Antidepressant use at baseline (%)	8.9	8.9	8.9
History of psychiatric diagnosis# (N, %)	24 (53.3%)	30 (66.7%)	54 (60.0%)
HAM-D at baseline (Mean, SD)	28.3 (2.8)	28.2 (3.1)	28.3 (2.9)

- 15 sites randomized participants

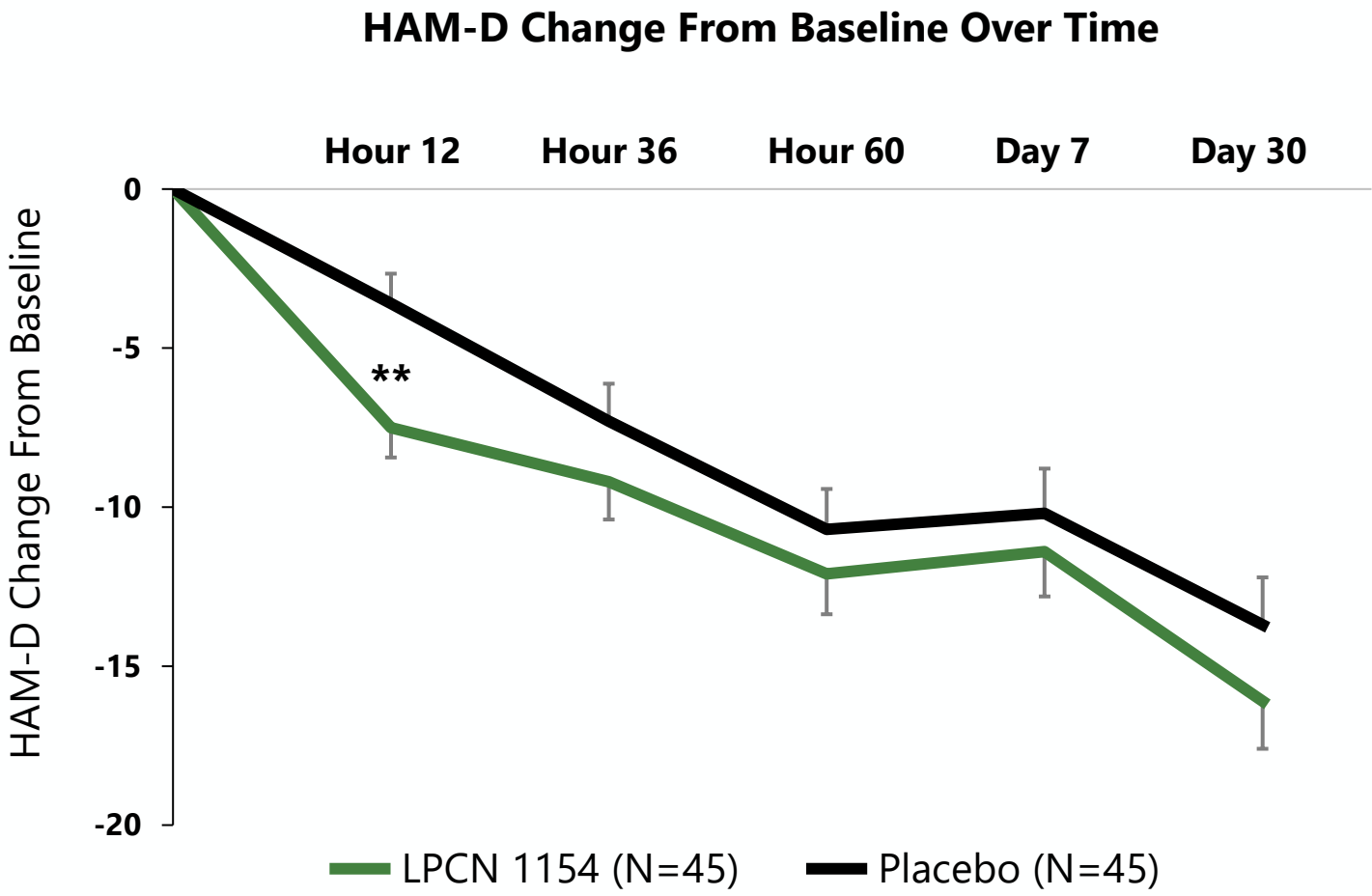
Based on MINI (Mini-International Neuropsychiatric Interview)

Full Analysis Set – HAM-D Change From Baseline

Primary endpoint not met

Parameter	LPCN 1154	Placebo
CFB at 60 hours [LSM (SE)]	-12.0 (1.27)	-10.7 (1.27)
LSM difference (SE)	-1.3 (1.80)	
P-value	NS (>0.05)	

- Numerically superior at all timepoints, with nominal statistical significance at Hour 12



** p<0.01, nominal p-value
Mixed model for repeated measures. Data graphed as LSM, SE
CFB: Change From Baseline; LSM: Least Squares Mean; SE: Standard Error.

Full Analysis Set: Safety

LPCN 1154 was well tolerated

Parameter	LPCN 1154 N=45 n (%)	Placebo N=45 n (%)
Any TEAE	8 (17.8)	8 (17.8)
Any treatment-related TEAE	5 (11.1)	3 (6.7)
Any severe TEAE	2 (4.4)	0 (0.0)
Any serious TEAE	1 (2.2)	0 (0.0)
TEAEs in ≥ 2 participants in LPCN 1154 arm		
Headache	2 (4.4)	3 (6.7)
Dizziness	2 (4.4)	0 (0.0)
Somnolence	2 (4.4)	0 (0.0)
Nausea	2 (4.4)	0 (0.0)

- 100% of participants completed dosing period
- No treatment-related severe or serious TEAEs
- All dizziness, somnolence, and nausea were mild-moderate and resolved without intervention

TEAE: Treatment-emergent adverse event (any AE that occurred after first dose of study drug)

LPCN 1154 - Strong and Coherent Efficacy with Exclusion of Outlier Site

Subgroup Analysis*

Subgroup Analyses

- Anomalies raise substantive questions about data validity for **one site (1 out of 15 total)**
  - 39% of LPCN 1154-treated participants had no evidence of study drug in their system
  - Different phenotype: high rates of 'de novo' PPD
  - Extreme placebo response: 80-90% remission and response rates

- **Exclusion of outlier site data** signals LPCN 1154's true treatment effect suggesting rapid, sustained, and clinically meaningful efficacy in PPD
  - Consistent trends across multiple outcomes and scales support rapid-acting antidepressant and anxiolytic effects of LPCN 1154
  - LPCN 1154 efficacy aligns with proven effects of brexanolone (IV) for the treatment of PPD

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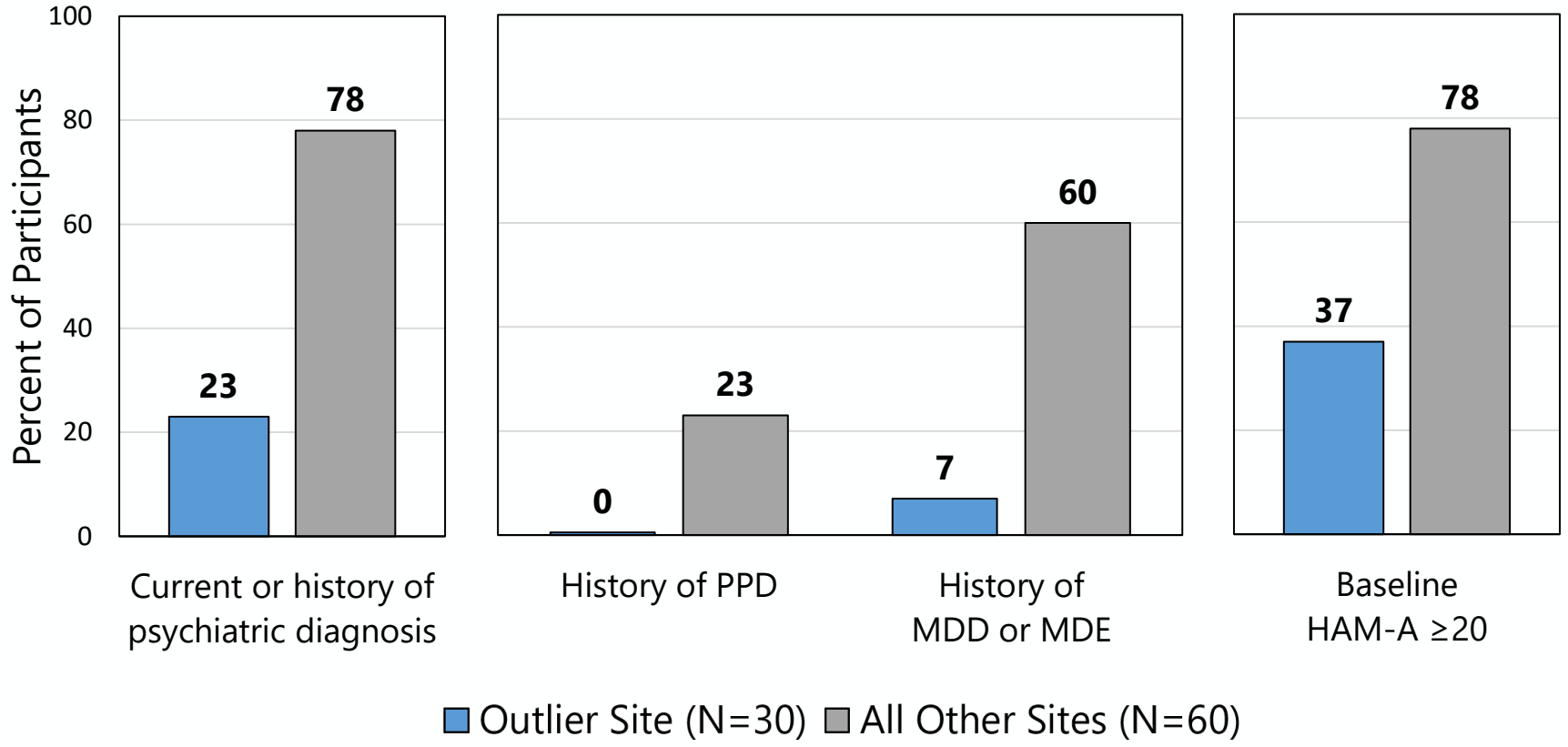
Bech's Depression Subscale (BDI-6) is a validated 6-item measure that assesses the core severity of depressive symptoms with minimal somatic confounding
De novo PPD is defined as the current PPD episode being the participant's first and only psychiatric diagnosis (determined by MINI)
*Post-hoc

Comparison Between Outlier Site and Other Sites

Outlier subgroup: low percentage of patients with prior or current psychiatric diagnosis



Outlier site had significantly lower rates of psychiatric diagnoses compared to all other sites, prior PPD studies, and estimated real-world prevalence

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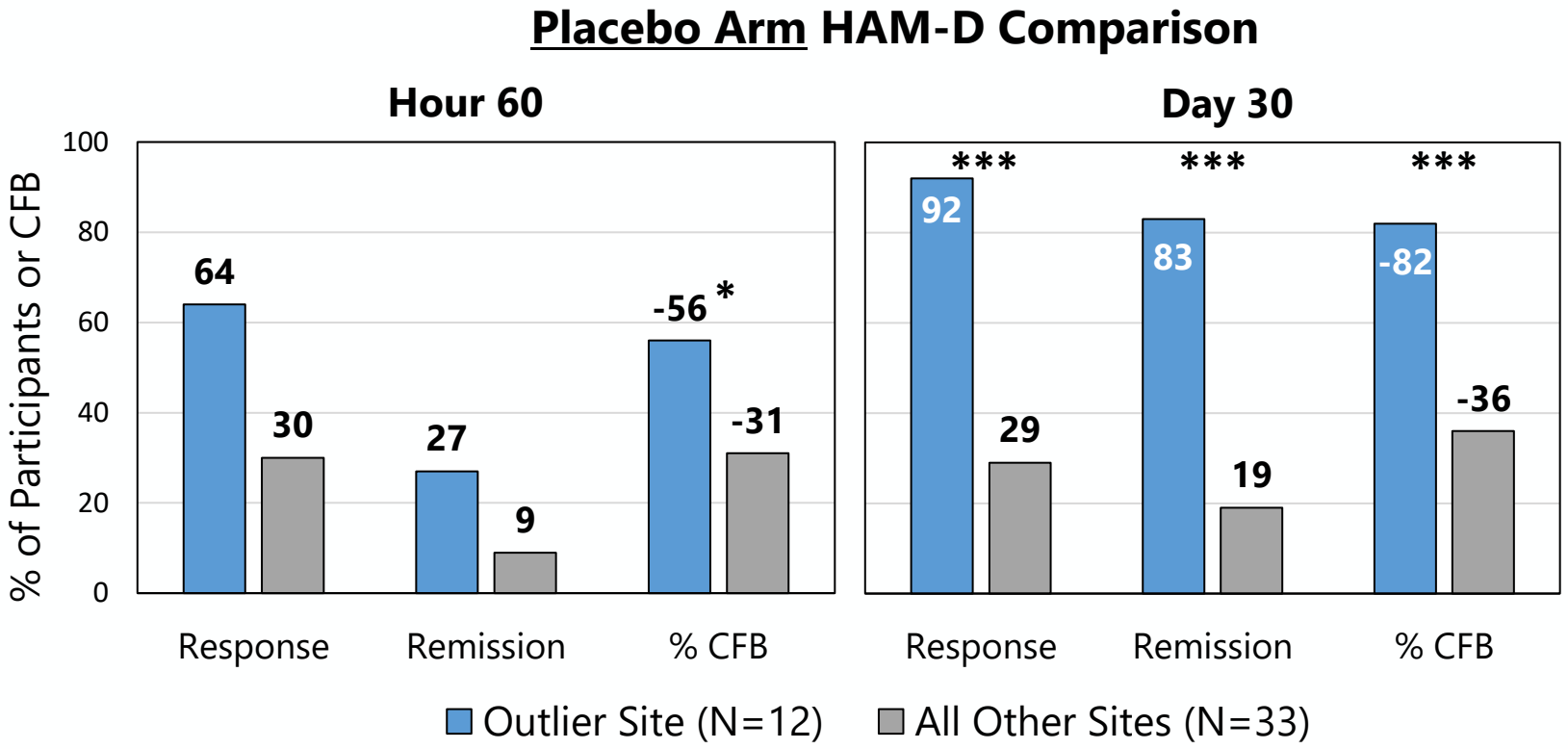
HAM-A, Hamilton Anxiety Rating Scale; MDD, major depressive disorder; MDE, major depressive episode; PPD, postpartum depression
HAM-A ≥20 indicates moderate to severe anxiety
*De novo PPD is defined as the current PPD episode being the participant's first and only psychiatric diagnosis (determined by MINI)

Comparison Between Outlier Site and Other Sites

Outlier subgroup: Placebo effect - high rates of HAM-D response, remission, and change from baseline



- Day 30 HAM-D change from baseline was **-23** at outlier site
- Site was identified as an outlier by treatment-by-site interaction analysis (p=0.01)

Response: ≥50% reduction in HAM-D total score; Remission: HAM-D total score ≤7. CFB: Change from baseline.
* p<0.05; ** p<0.01; *** p<0.001. Continuous data: MMRM; dichotomous data: Fisher exact

Baseline Demographics

Subgroup Analysis: Non-Outlier Sites

Characteristics	LPCN 1154	Placebo	Total
N	27	33	60
Age (years)	30.0 (5.9)	31.7 (6.6)	30.9 (6.3)
BMI (kg/m^2)	31.9 (6.4)	30.5 (6.4)	31.1 (6.4)
Ethnicity (HISP; %)	40.7	45.5	43.3
Race (White; %)	55.6	54.5	55.0
Antidepressant use at baseline (%)	11.1	12.1	11.7
History of psychiatric diagnosis* (N; %)	22 (81.5)	25 (75.8)	47 (78.3)
HAM-D at baseline (Mean, SD)	28.8 (3.3)	28.5 (3.4)	28.6 (3.3)

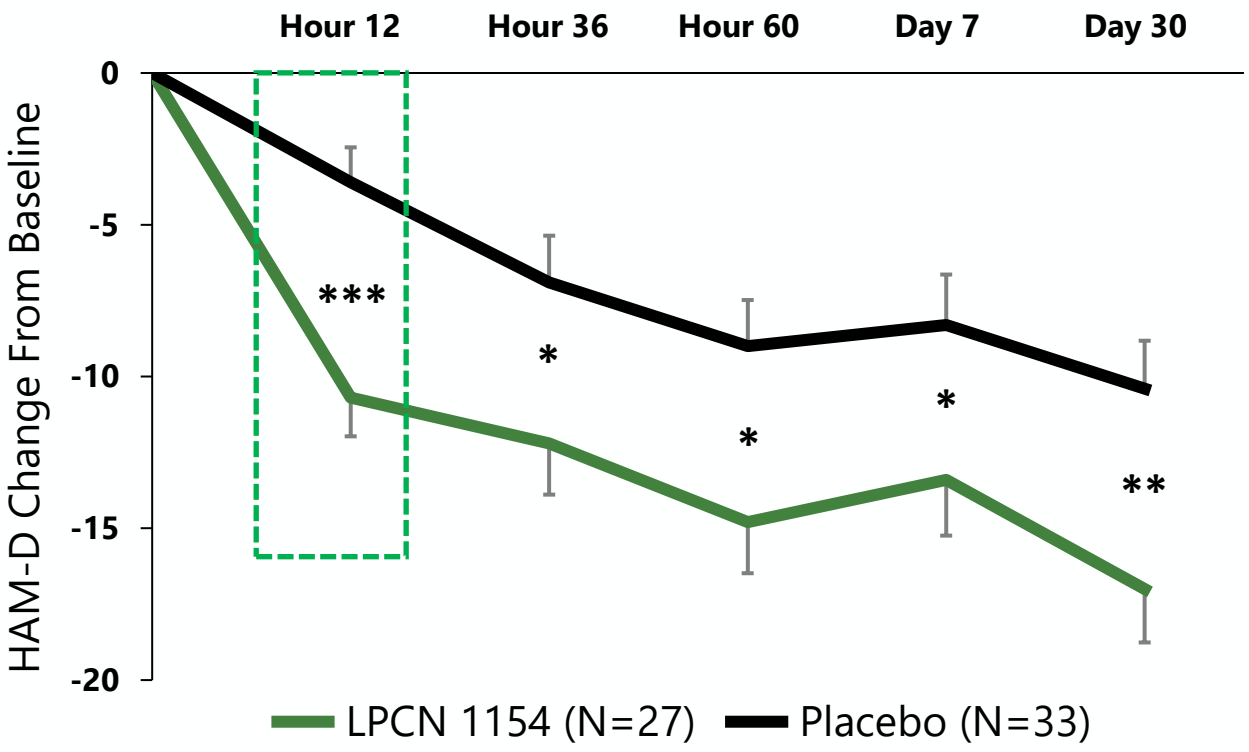
Upon outlier site exclusion, the study population is consistent with PPD epidemiology (~20% de novo PPD)

*Based on MINI (Mini-International Neuropsychiatric Interview)

Rapid, Durable, & Meaningful Improvement Across All Timepoints

Subgroup Analysis: Non-Outlier Sites

HAM-D Change From Baseline Over Time



Time	Placebo-adjusted Difference	Statistical Significance	Cohen's d
Hour 12	-7.1	P < 0.001	-1.09
Hour 36	-5.3	P < 0.05	-0.64
Hour 60	-5.8	P < 0.05	-0.68
Day 7	-5.2	P < 0.05	-0.54
Day 30	-6.6	P < 0.01	-0.76

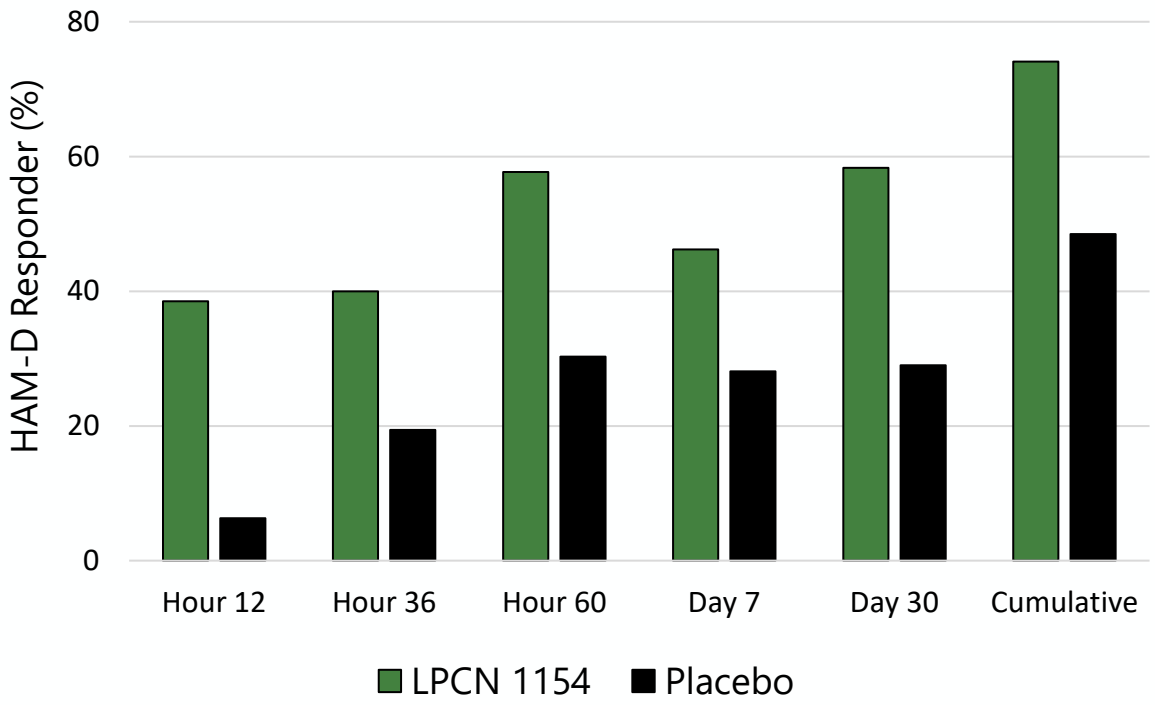
* p<0.05; ** p<0.01; *** p<0.001.

Mixed model for repeated measures, least squares means placebo-adjusted difference. P-values are nominal
Post-hoc analyses

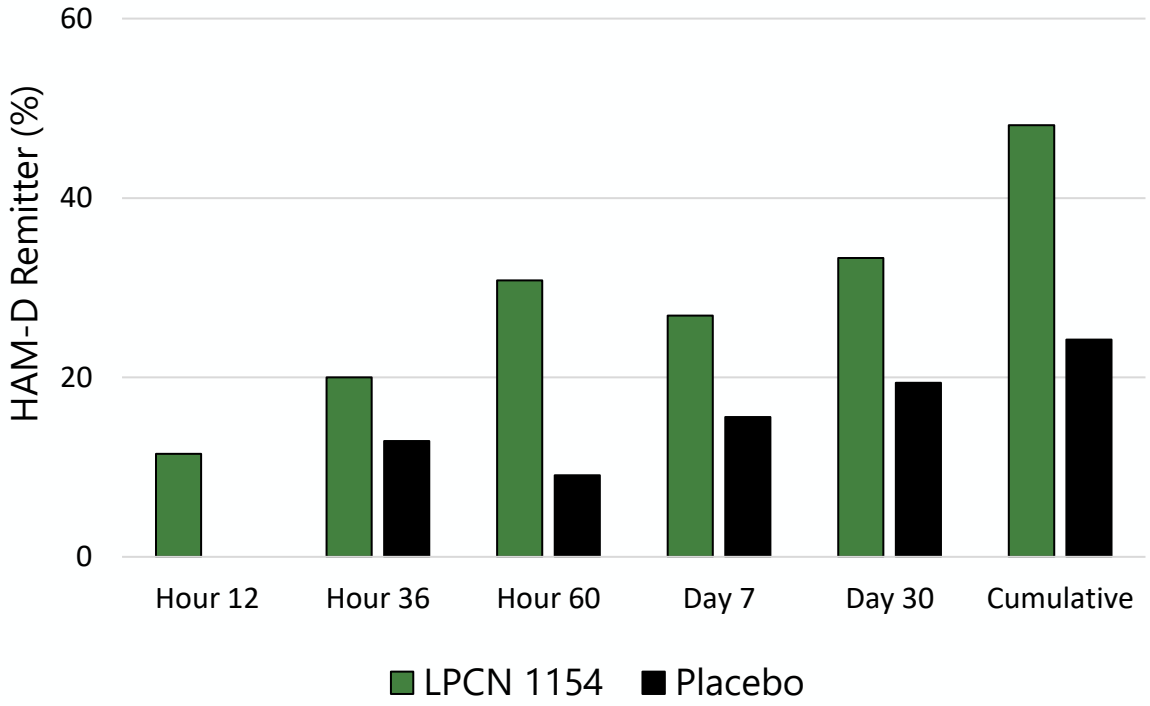
Responder & Remitter Results Corroborate Strong Treatment Effect

Subgroup Analysis: Non-Outlier Sites

Percent of Participants with HAM-D Response



Percent of Participants with HAM-D Remission



Response: ≥ 50% reduction in HAM-D score; Remission: HAM-D score ≤ 7
Nominal statistical significance is not shown
Post-hoc analyses

LPCN 1154 – Fastest Observed Onset in PPD; Clinically Meaningful Relief at 12 Hours

Subgroup Analysis: Non-Outlier Sites

At 12 Hours	Excluding Outlier Site (N=60)
HAM-D17[1]	**-7.1** *** (Cohen's d = -1.10)
HAM-A[1]	-6.3 ** (Cohen's d = -0.86)
HAM-D17 Response[2] (Active vs Placebo)	**38.5%** vs 6.3% **
HAM-D6[1]	-2.8 ** (Cohen's d = -0.77)

* p<0.05; ** p<0.01; *** p<0.001.

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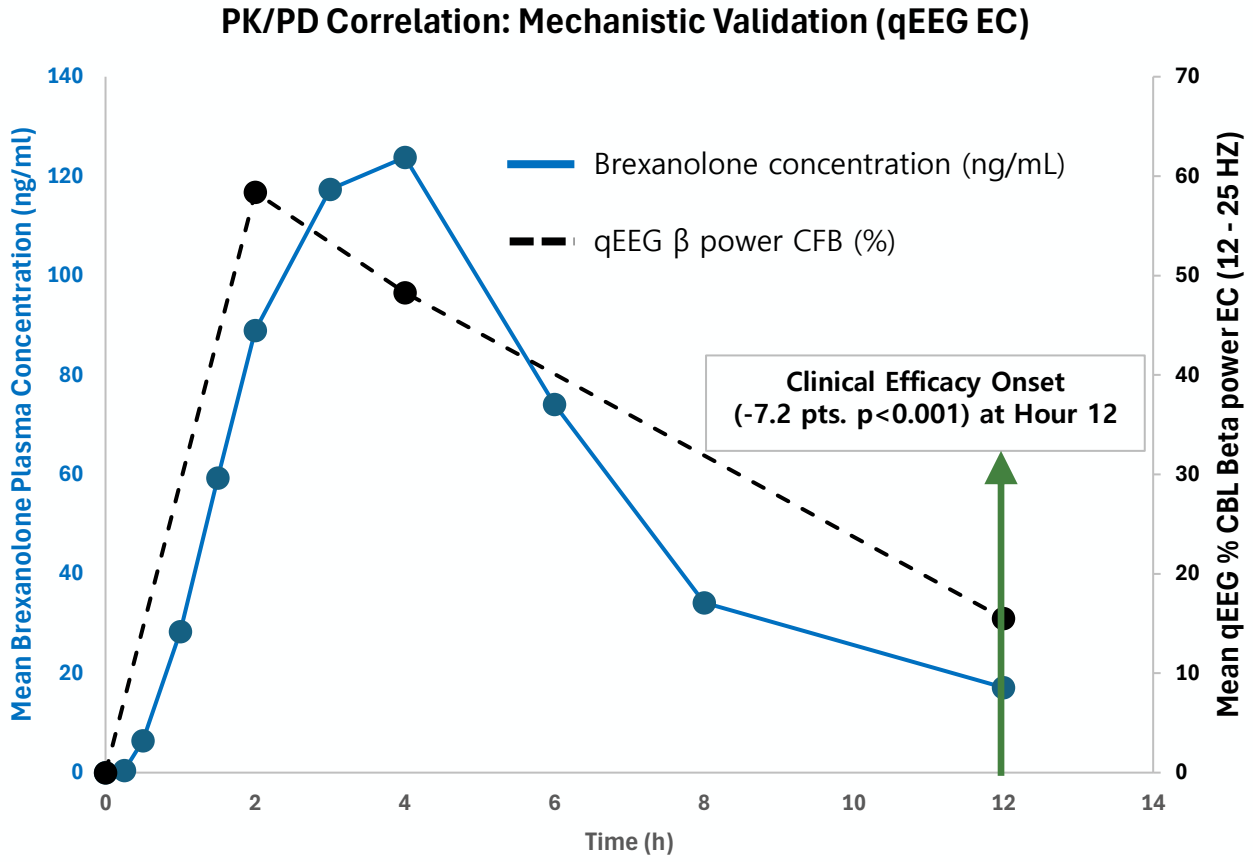
[1]Placebo adjusted CBL
[2]Response: ≥ 50% reduction in HAM-D score
Post-hoc analyses

Rapid and Sustained Target Engagement

LPCN 1154 – PK/PD correlation

- β band qEEG activity is a validated, objective biomarker of $GABA_A$ receptor modulation

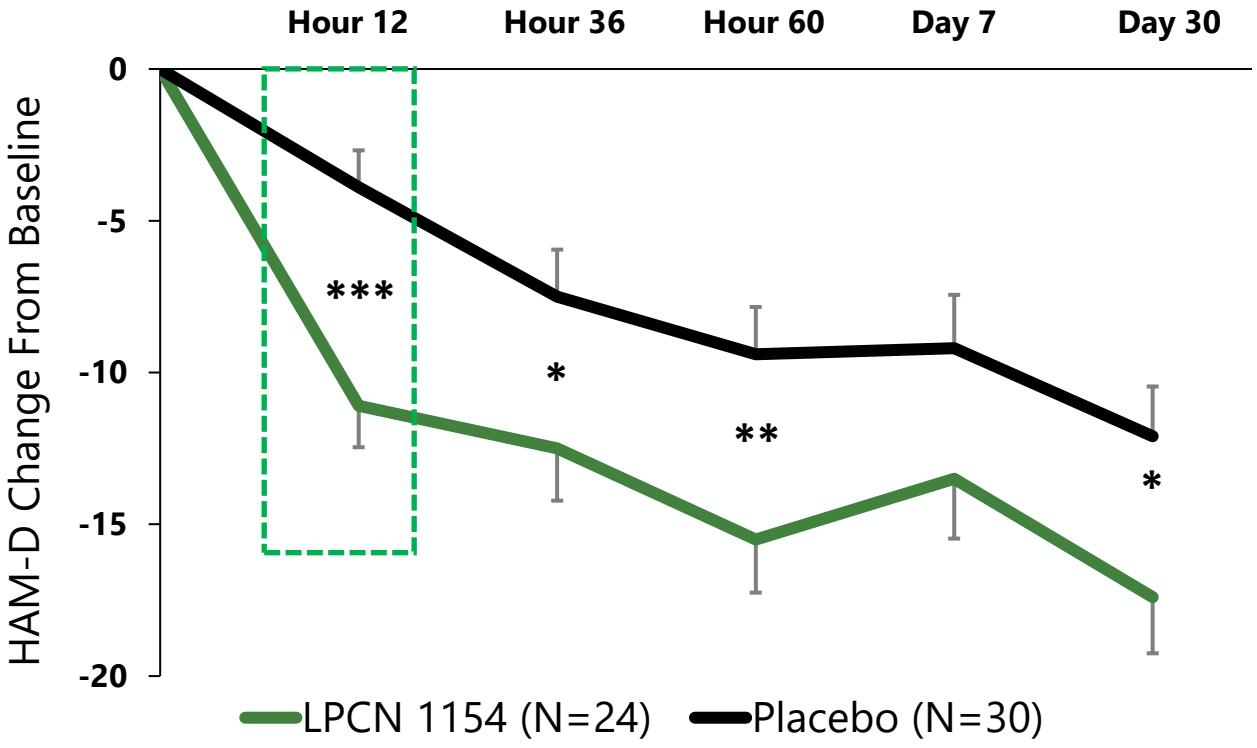
- Significant increase in β band amplitude
  - Confirms target engagement (GABA-A receptor)
  - Early (2h) and sustained (12h) effects
  - Consistent results in eyes open and eyes closed conditions



Rapid, Durable, & Statistically Significant Improvement Across Multiple Timepoints

Subgroup Analysis: PPD with History of Psychiatric Diagnosis

HAM-D Change From Baseline Overtime



* p<0.05; ** p<0.01; *** p<0.001.

Time	Placebo-adjusted Difference	Statistical Significance	Cohen's d
Hour 12	-7.2	P < 0.001	-1.10
Hour 36	-5.0	P < 0.05	-0.60
Hour 60	-6.1	P < 0.01	-0.73
Day 7	-4.2	NSS	-0.46
Day 30	-5.3	P < 0.05	-0.60

Mixed model for repeated measures, least squares means placebo-adjusted difference. P-values are nominal
Post-hoc analyses

LPCN 1154 Summary and Conclusions

Subgroup analyses

- **HAM-D data support rapid and durable treatment effect in two subgroups**
  - Excluding outlier site
  - PPD with history of psychiatric condition

- **Clinically meaningful efficacy as early as 12 hours (HAM-D CFB ~ -11, Cohen's d > 1)**
  - Median time to first response: **2.6 days** with LPCN 1154 vs **~30 days** with placebo
  - Results for additional HAM-D analyses **(response, remission, Bech depression subscale), MADRS, and HAM-A** were at least numerically superior for LPCN 1154 at all timepoints

- **Well-tolerated, with no drug-related severe or serious AEs**
  - 18% of participants reported an adverse event
  - Low rates of CNS AEs

- **Potential for differentiated profile**
  - Rapid and sustained relief with short treatment duration, at-home administration

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Time to first response: time at which 50% of participants are HAM-D responders

Dr. Jain (MD, MPH) is a clinical professor in the Department of Psychiatry at the Texas Tech University Health Sciences Center School of Medicine - Permian Basin in Midland. He is also in private practice in Austin, TX. Dr. Jain attended medical school at the University of Calcutta in India. He then attended graduate school at The University of Texas Health Science Center at Houston (UTHealth Houston) School of Public Health, where he was awarded a National Institute/Center for Disease Control Competitive Traineeship. He graduated from the School of Public Health in 1987 with a masters of public health degree. He served a 3-year residency in psychiatry in the Department of Psychiatry and Behavioral Sciences at UTHealth Houston McGovern Medical School. He followed that by obtaining further specialty training, by undergoing a 2-year fellowship in child and adolescent psychiatry. In addition, Dr. Jain completed a postdoctoral fellowship in research psychiatry at The University of Texas Mental Sciences Institute in Houston. He was awarded the National Research Service Award for the support of this postdoctoral fellowship. Dr. Jain has been involved with more than 100 research projects studying the effects of medications on the short- and long-term treatment of depression, anxiety, pain/mood overlap disorders, attention-deficit/hyperactivity disorder, and psychosis in adult and child/adolescent populations. He is the author of 55 articles published in various journals and magazines, such as the Journal of Psychiatric Research and The Journal of Clinical Psychiatry, among others, and he has presented more than 25 original research posters at meetings for various professional societies, including the American Psychological Association, the American College of Neuropsychopharmacology, the American Academy of Child and Adolescent Psychiatry, and the Psych Congress. He has also coauthored 6 books that range from patient education to cutting-edge neurobiologic findings in psychiatry and mental health. He serves on several advisory boards that focus on drug development and disease state education. He also recently served as chair of the Psych Congress, held in Las Vegas, NV, and has served as a member of the Steering Committee for the Psych Congress for several years.

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Recent LPCN 1154 Clinical Data: Clinical Interpretation and Relevance to Practice

Dr. Rakesh Jain

Comments on Observed Safety of LPCN 1154 (Full Analysis Set)

LPCN 1154 was self-administered at-home

Parameter	LPCN 1154 N=45 n (%)	Placebo N=45 n (%)
Any TEAE	8 (17.8)	8 (17.8)
Any treatment-related TEAE	5 (11.1)	3 (6.7)
Any severe TEAE	2 (4.4)	0 (0.0)
Any serious TEAE	1 (2.2)	0 (0.0)
TEAEs in ≥ 2 participants in LPCN 1154 arm		
Headache	2 (4.4)	3 (6.7)
Dizziness	2 (4.4)	0 (0.0)
Somnolence	2 (4.4)	0 (0.0)
Nausea	2 (4.4)	0 (0.0)

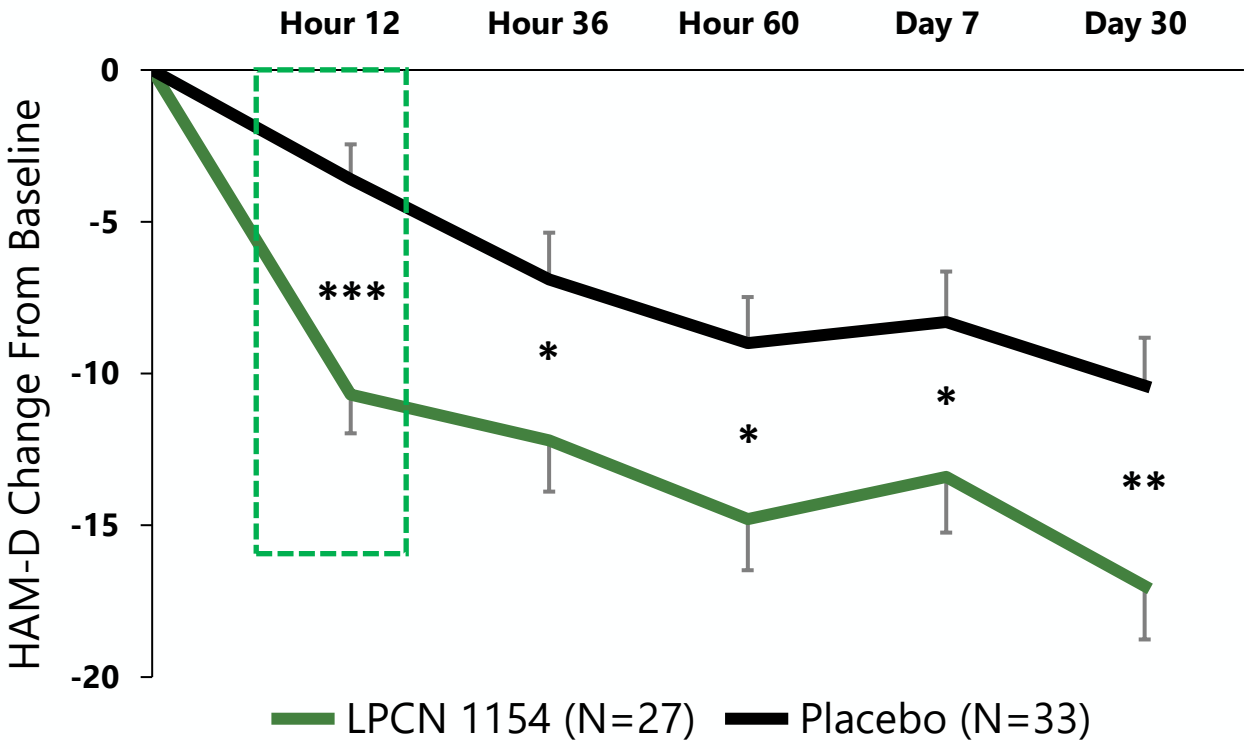
- 100% of participants completed dosing period
- No treatment-related severe or serious TEAEs
- All dizziness, somnolence, and nausea were mild-moderate and resolved without intervention

TEAE: Treatment-emergent adverse event (any AE that occurred after first dose of study drug)

Rapid, Durable, & Meaningful Improvement Across All Timepoints

Subgroup Analysis: Non-Outlier Sites

HAM-D Change From Baseline Over Time



Time	Placebo-adjusted Difference	Statistical Significance	Cohen's d
Hour 12	-7.1	P < 0.001	-1.09
Hour 36	-5.3	P < 0.05	-0.64
Hour 60	-5.8	P < 0.05	-0.68
Day 7	-5.2	P < 0.05	-0.54
Day 30	-6.6	P < 0.01	-0.76

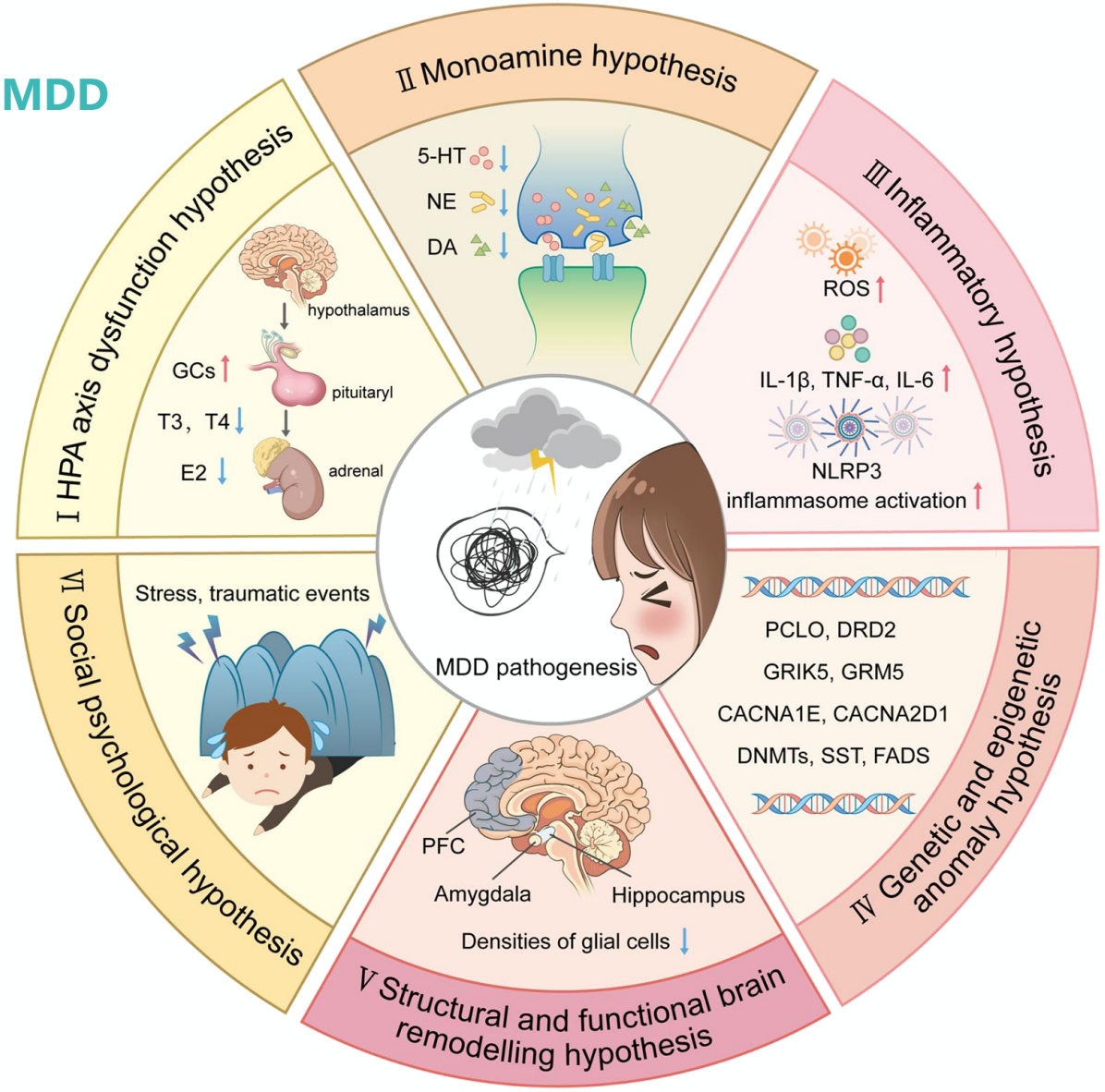
* p<0.05; ** p<0.01; *** p<0.001.

Mixed model for repeated measures, least squares means placebo-adjusted difference. P-values are nominal
Post-hoc analyses

Major Depressive Disorder

Multiple pathophysiological pathways contribute to MDD

- 9.2% of Americans aged ≥12 years experienced MDD in the past-year,[1] resulting in an economic cost >$380 billion in 2023[2]
- Landscape of pharmacologic treatment is rapidly evolving, including NMDA receptor modulation, $GABA_A$ receptor potentiation, and multimodal serotonergic activity
- Brexanolone targets mechanisms associated with MDD pathophysiology, including deficits in GABAergic neurotransmission, stress-system dysregulation (HPA), inflammation, and impaired synaptic plasticity

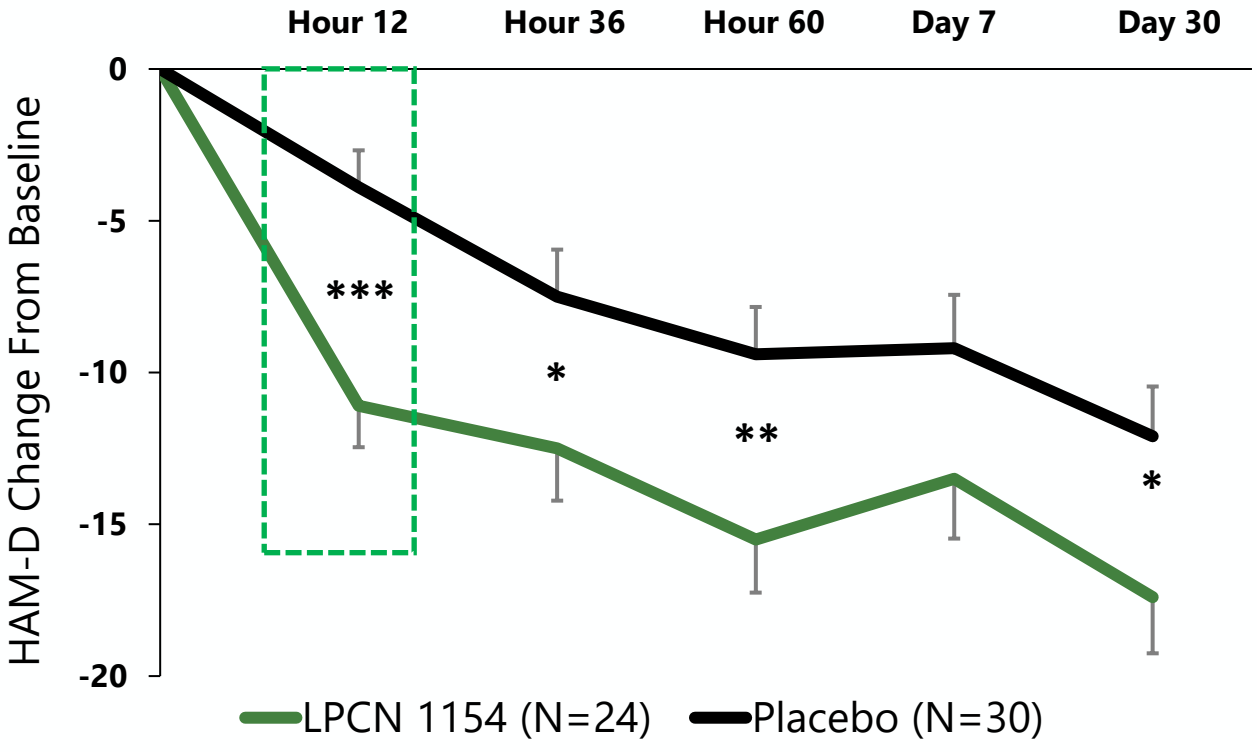


1. Goodwin et al., Am J Prev Med (2022);63(5):726–733
2. Greenberg et al., Adv Ther (2023); 40:4460–4479
3. Image from Cui et al. *Sig Transduct Target Ther* **9**, 30 (2024).

Rapid, Durable, & Statistically Significant Improvement Across Multiple Timepoints

Subgroup Analysis: PPD with History of Psychiatric Diagnosis

HAM-D Change From Baseline Overtime



* p<0.05; ** p<0.01; *** p<0.001.

Time	Placebo-adjusted Difference	Statistical Significance	Cohen's d
Hour 12	-7.2	P < 0.001	-1.10
Hour 36	-5.0	P < 0.05	-0.60
Hour 60	-6.1	P < 0.01	-0.73
Day 7	-4.2	NSS	-0.46
Day 30	-5.3	P < 0.05	-0.60

Mixed model for repeated measures, least squares means placebo-adjusted difference. P-values are nominal
Post-hoc analyses

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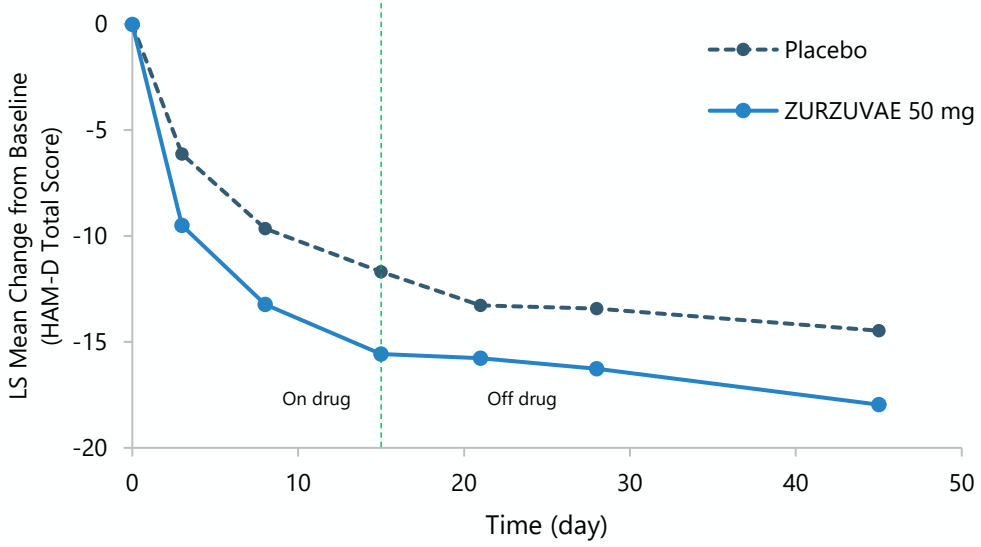
Recent LPCN 1154 Clinical Data: Clinical Interpretation and Relevance to Practice

Dr. Kristina Deligiannidis

LPCN 1154 Demonstrated Differentiated Efficacy Signal

Zurzuvae

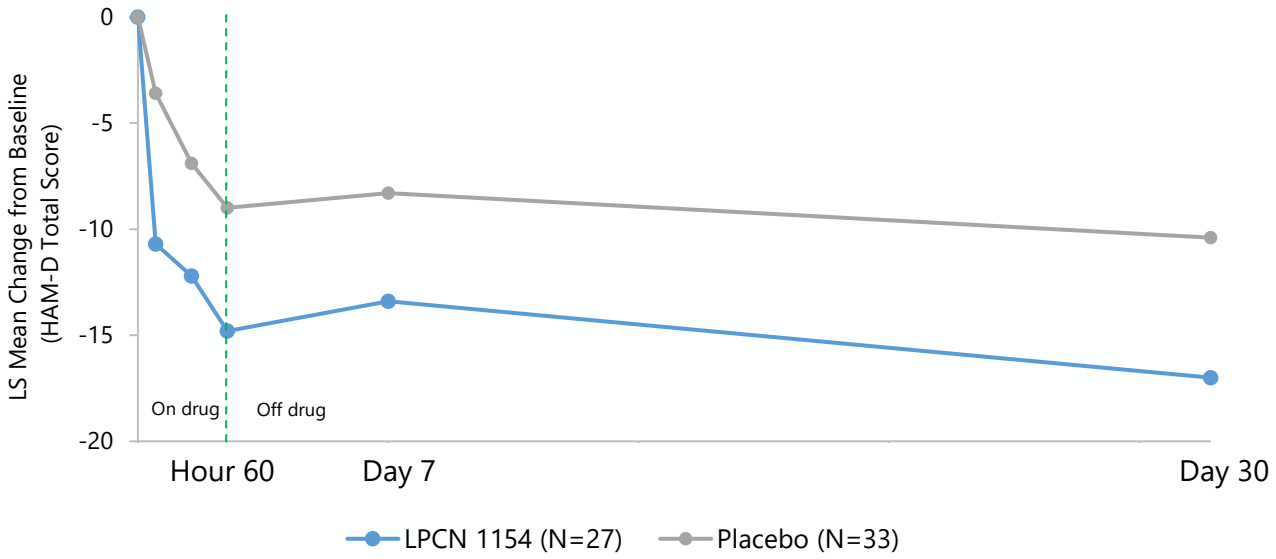
LS Mean CBL in HAM-D Total Score Over Time in Study[1]



Timepoint	Study Name	Day 3	Day 8	Day 15	Day 28	Day 45
LSMD (95% CI)	Skylark[1]	**-3.4** (-5.4, -1.4)	**-3.7** (-5.8, -1.6)	**-4.0** (-6.3, -1.7)	**-2.9** (-5.4, -0.5)	**-3.5** (-6.0, -1.0)

LPCN 1154 – Including Non-Outlier Sites

LS Mean CBL in HAM-D Total Score Over Time



Timepoint	Hour 12	Hour 36	Hour 60	Day 7	Day 30
LSMD (95% CI)	**-7.1** (-10.5, -3.8)	**-5.3** (-9.8, -0.8)	**-5.8** (-10.3, -1.4)	**-5.2** (-10.0, -0.3)	**-6.6** (-11.2, -1.9)

LSMD, Least squares mean difference versus placebo; CI, confidence interval; CBL, change from baseline

No head-to-head clinical trials have been conducted. **Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations.**

1. Study PPD-301 (50 mg), SKYLARK; FDA Integrated Review (MDR), NDA 217369Orig2s000, 2023.
2. Study PPD-201B (30 mg), ROBIN; FDA Integrated Review (MDR), NDA 217369Orig2s000, 2023.

PPD Therapy Overview – LPCN 1154 and Existing Options

LPCN 1154 (Brlizio) is expected to provide rapid relief of PPD with a short (48-hour) treatment

Zuranolone (ZURZUVAE®) treatment is associated with frequent CNS depressant effects such as somnolence, dizziness, and sedation

SSRIs / SNRIs have slow onset, longer treatment duration, and lower response rates. Additionally side effects such as sexual dysfunction, changes in sleep pattern and weight gain are common

	Oral Brexanolone *(LPCN 1154)*	**Zuranolone** *(ZURZUVAE®)*	***SSRIs/SNRIs*** *Off-Label Use*
Description	**Bioidentical NAS**	Synthetic NAS derivative	Synthetic SSRI/SNRI
Median Time to Response* Onset	**2.6 days****	9 days[1]	weeks
CNS depressant AEs	**Low[3]**	High[2]	Moderate[4]
Onset of Action	**Hours**	Days	Weeks
Treatment Duration	**48 hours**	14 days	Months

No head-to-head clinical trials have been conducted. Data are derived from published reports of different clinical trials at different points in time, with differences in trial design, size, and patient populations.

1. Deligiannidis et al., Am J Psychiatry 180:9, September 2023
2. Zurzuvae label; Somnolence (36%), dizziness (13%), dose Reduction (14%), and discontinuation (2%),
3. Defined as less than 5% with no drug discontinuations, drug-related SAEs, loss of consciousness, or excessive sedation
4. https://www.uptodate.com/contents/image?imageKey=PSYCH%2F143603

*Median time to response is defined as time to 50% of participants experiencing response (≥50% reduction in HAM-D)
**internal data based on data from both subgroup analyses

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Why LPCN 1154 Matters Now, Next Steps, and Concluding Remarks

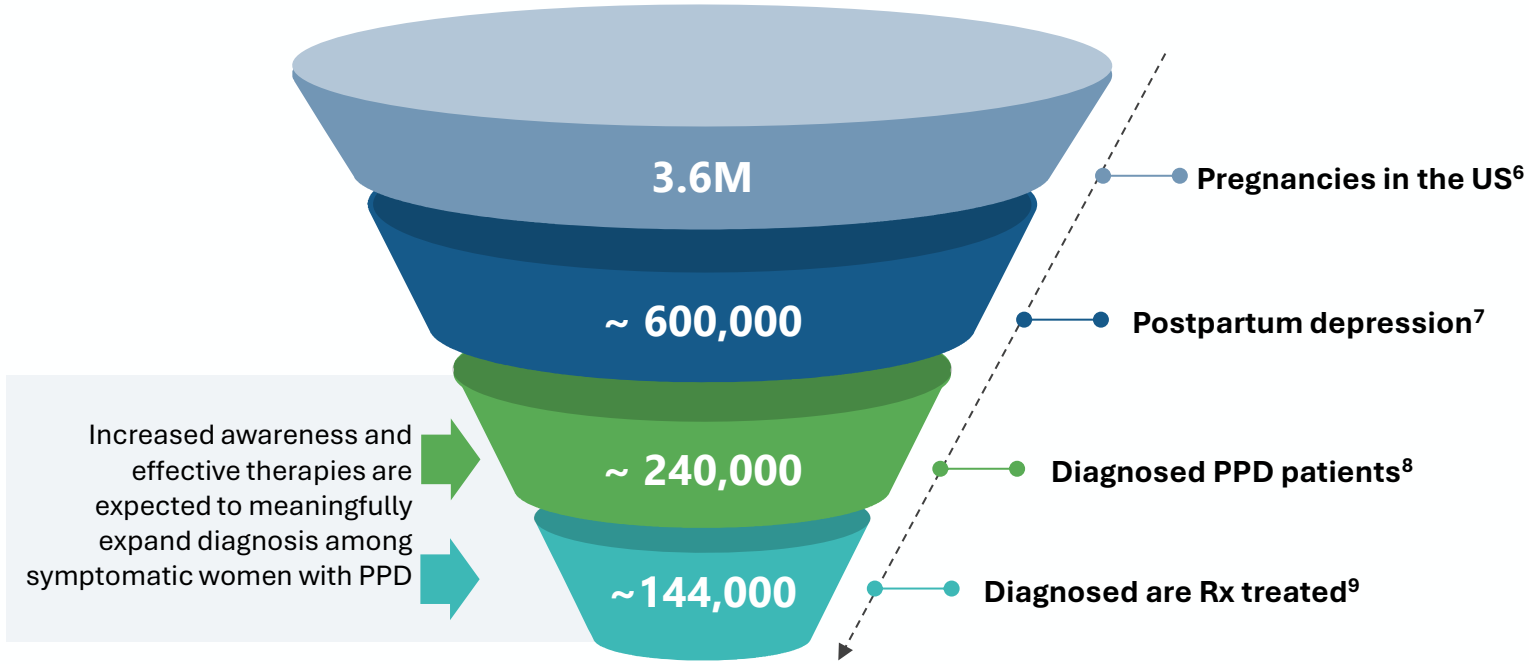
Dr. Mahesh Patel,
President and CEO Lipocine

PPD – An Expanding Market Opportunity

Awareness drives diagnosis - empowering women with PPD through effective therapies

- High clinical and economic burden with consequences beyond the mother
- Treatment goal is rapid symptom relief to improve outcomes for mother and child
- Meaningful negative impact on family stability, child development, and society
- PPD commonly presents with psychiatric comorbidity; 64% report anxiety symptoms[1]
- Mental health disorders are the leading cause of maternal mortality in the United States[2]
  - Up to 30% of women with PPD report suicidal ideation[3]
- Compelling pharmacoeconomic rationale for early, effective intervention[4]

Estimated patients in the U.S. with PPD[5]



ZURZUVAE® Rx price: $16,377

ZURZUVAE revenue $66M Q4-25[10]

Projected peak ZURZUVAE® sales of ~$1B[11]

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

1. Farr et al. J Womens Health (Larchmt). 2013 Oct 26;23(2):120–128
2. Reis, J Midwifery Womens Health. 2025;70(1):13–16
3. Mauri et al. Arch Womens Ment Health. 2012; 15(1): 39-47
4. Leerink Center for Pharmacoeconomics, 2025 MEDACorp LLC
5. Foster Rosenblatt market research 2023 (Lipocine internal data)
6. National Vital Statistics Report vol 72, num 1, 2023; Vital Statistics Rapid Release, report 26, 2023
7. Van Niel et al. Cleveland Clinic J of Medicine. 2020;87(5):273-277
8. Cox et al. J Clin Psychiatry. 2016;77:9, Beck. AJN. 2006;106:5
9. Sage/Biogen HEOR Claims Analysis
10. Biogen 4th Quarter 2025 Financial Results
11. Sage May 2025 Management Projection

Differentiated Target Attributes as a Rapid-Acting PPD treatment*

Strong candidate to meet FDA RAAD criteria

FDA Criteria for Rapid-Acting Anti-Depressants (RAAD)

For rapid-acting antidepressants, the timing of effect considerations include the following:

- Efficacy generally should be demonstrated within 1 week for a rapid-acting antidepressant. Some novel antidepressants are thought to be effective within hours or days. In such cases, an earlier primary efficacy endpoint would be appropriate.
- Durability of effect beyond the initial response should be characterized. To demonstrate both early onset of action and durability of effect, a primary efficacy endpoint early in the course of treatment would be chosen, with continued observation of drug–placebo differences over time.

Efficacy demonstrated within 1 week

Rapid relief as early as **12 hr**

Median Time to Response* Onset: **2.6 days**

Durability of effect beyond the initial response

Effect lasts ~1 month post treatment

Superior tolerability

Bioidentical, **low** CNS depressant effect (<5%), and devoid of psychotomimetic effects

Low to no infant breast feeding sedation risk

Ultrashort treatment duration

48-hour treatment

At home access

Ease of use

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/major-depressive-disorder-developing-drugs-treatment

*Based on subgroup based hypothesis generating results

LPCN 1154 Next Regulatory Steps

FDA meeting to align on clinical data package and confirm NDA submission pathway

Submit Validation study protocol

Applied for Breakthrough Therapy and Fast Track Designations with FDA

LPCN 1154 – Potential "Game Changer" for Fast Acting Depression Therapy

Key takeaways

- Large, attractive market opportunity
- Differentiated product profile addressing unmet needs
- Streamlined path to NDA submission
- Issued and pending patent protection globally
- Platform potential for expansion into additional depressive indications

LPCN 1154

Rapid & Durable Relief

Superior Tolerability

At Home 48-hour Treatment

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Q&A