

Lipocine Reports Topline Safety and Efficacy Results for LPCN 1154 in Patients with Postpartum Depression

- In the Phase 3 study population (N=90) of patients with PPD, LPCN 1154 did not show a statistically significant reduction from baseline in HAM-D17 total score compared to placebo at hour 60 (primary endpoint); the primary endpoint was not met
- In a post hoc analysis of participants (n=54) who had a history of psychiatric conditions, LPCN 1154 demonstrated nominal statistically significant and clinically meaningful reductions in HAM-D scores compared to placebo as early as hour 12 and sustained through day 30
- In the overall population, LPCN 1154 was well tolerated and demonstrated a differentiated safety profile with no reported adverse event, including somnolence or dizziness, occurring in more than 5% of the LPCN 1154-treated participants
- The Company plans to evaluate all available options going forward

SALT LAKE CITY, April 2, 2026 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery, today announced topline results from its Phase 3 placebo-controlled trial evaluating LPCN 1154 (oral brexanolone) for the treatment of postpartum depression (PPD). For more information on the trial design, refer to clinicaltrials.gov: NCT06979544.

LPCN 1154 did not show a statistically significant reduction from baseline in HAM-D total score compared to placebo at hour 60 in the full analysis set and the primary was not met. The results showed LPCN 1154 to be well tolerated and demonstrated a favorable safety profile to support outpatient administration without the need for healthcare provider monitoring. No treatment-related severe or serious adverse events (SAEs) were reported; no cases of excessive sedation or loss of consciousness were observed; and no treatment-related discontinuations were reported.

In a post hoc analysis of participants with a history of psychiatric conditions diagnosed using Mini-International Neuropsychiatric Interview (MINI, a structured diagnostic interview used to screen for and diagnose psychiatric disorders using DSM/ICD criteria), the Company identified signals that could indicate a potential development path for LPCN 1154.

Table: Placebo-Adjusted HAM-D17 Score Change from Baseline

Timepoint	Overall Population N=90		History of Psychiatric Conditions Subset N=54	
	Placebo-Adjusted Difference	Statistical Significance	Placebo-Adjusted Difference	Statistical Significance
Hour 12	-3.9	P < 0.01	-7.2	P < 0.001
Hour 36	-1.7	NSS	-5.0	P < 0.05
Hour 60	-1.3	NSS	-6.1	P < 0.01
Day 7	-1.2	NSS	-4.2	NSS
Day 30	-2.3	NSS	-5.3	P < 0.05

NSS: Not Statistically Significant. Mixed model for repeated measures, least squares means placebo-adjusted difference. P-values are nominal except for Hour 60 Overall Population.

Based on the results of the post hoc analysis of efficacy among participants with a history of psychiatric condition based on the MINI, the Company has applied for breakthrough therapy and fast track designations for LPCN 1154 in patients with PPD. While the Company is waiting for feedback from the FDA on such designations, the Company plans to preserve capital and engage with stakeholders, including investors, regulators, and advisors, to evaluate all options available to the Company going forward. Such options may include, but are not limited to, continued development of LPCN 1154, including the potential submission of a validation study protocol, development of other product candidates, strategic transactions, partnerships, and other opportunities.

The Company intends to complete its full analysis of the trial data in the coming weeks and plans to present the results at upcoming conferences. The Company thanks patients, investigators, and site staff for their contributions.

About LPCN 1154

LPCN 1154 is an oral formulation of brexanolone being developed to provide rapid relief of postpartum depression in a convenient, at-home treatment. It has potential as first line treatment choice for women with PPD. It also has characteristics that could be particularly beneficial to patients with severe PPD (including those with elevated suicide risk) for whom rapid

improvement is a priority. LPCN 1154 is expected to offer a compelling safety profile for breastfeeding mothers.

About Postpartum Depression and Unmet Needs

PPD is a major depressive disorder with onset either during pregnancy or within four weeks of delivery, with symptoms persisting up to 12 months after childbirth. Hormonal changes leading to GABA dysfunction are common in depression and pregnancy. Symptoms of PPD include hallmarks of major depression, including, but not limited to, sadness, depressed mood, loss of interest, change in appetite, insomnia, sleeping too much, fatigue, difficulty thinking/concentrating, excessive crying, fear of harming the baby/oneself, and/or thoughts of death or suicide. Results from a recent survey (Truist Securities Research, January 2024) show that obstetricians believe approximately 20-40% of their patients may suffer from PPD. Further, obstetricians are comfortable making a diagnosis and prescribing antidepressants for PPD. Traditional antidepressants, not approved for PPD, have slow onset of action, side effects such as weight gain, and do not demonstrate adequate remission.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery. Lipocine has drug candidates in development as well as drug candidates for which we are exploring partnerships. Our drug candidates represent enablement of differentiated patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine's development pipeline includes: LPCN 1154 for the treatment of postpartum depression, LPCN 2202 for treatment of treatment resistant depression, LPCN 2101 for the treatment of epilepsy, LPCN 2203 targeted for the management of essential tremor, LPCN 2401 as an aid for improved body composition in obesity management, LPCN 1148 targeted for the management of symptoms associated with liver cirrhosis, and LPCN 1107 our candidate for prevention of preterm birth. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. For more information, please visit www.lipocine.com.

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 development of LPCN 1154 and related efforts with the FDA, the potential uses and benefits of LPCN 1154 on the treatment of PPD, the commercial potential for LPCN 1154, and potential strategic opportunities. 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 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 release, except as required by law.

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