Lipocine Highlights Promising Interim Safety Profile in Phase 3 Trial of LPCN 1154 in Postpartum Depression (PPD)

- Per the Drug Safety Monitoring Board (DSMB) meeting evaluating one-third of planned participants, study to continue as planned
- More than half of planned participants have completed dosing with no dose reductions, discontinuations, drug-related SAEs, loss of consciousness, or excessive sedation reported
- Topline results are on track for the second quarter of 2026

SALT LAKE CITY, Nov. 18, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery, today announced the completion of a scheduled independent Data Safety Monitoring Board review of its ongoing Phase 3 clinical trial evaluating LPCN 1154 (oral brexanolone) for the rapid relief treatment of PPD. This was the first of two DSMB reviews planned during the study and conducted after approximately one-third of planned 80 participants completed at least the day seven follow-up visit (n=30). The DSMB recommended that the trial continue as planned without modification.

47 participants have completed dosing to date and there have been no treatment discontinuations or dose reductions required, and no reports of drug-related serious adverse events. No cases of excessive sedation or loss of consciousness have been reported to date in the development of LPCN 1154.

"We are encouraged by the safety profile observed in our clinical experience to date with our oral product candidate comprising GABAA positive allosteric modulating neuroactive steroid with low sedation," said Mahesh Patel, CEO of Lipocine. "Target attributes of LPCN 1154, including superior tolerability, rapid relief, and a 48-hour treatment duration, could be a game changer in the treatment of PPD, a debilitating and life-threatening condition. We look forward to LPCN 1154 Phase 3 study results, expected in the second quarter of 2026."

About the Phase 3 Study

The pivotal, randomized, double-blind study is evaluating LPCN 1154 compared to placebo in women aged 15 years and older diagnosed with severe PPD. Following constructive feedback from the U.S. Food and Drug Administration (FDA), the trial is being conducted entirely in an outpatient setting and does not require medical monitoring by a healthcare provider. Nineteen clinical sites across the United States are participating. The readout from the second interim DSMB meeting and the safety update is targeted for early in the first quarter of 2026. Data from this Phase 3 trial are expected to support a 505(b)(2) NDA submission for LPCN 1154 in 2026. For more information, refer to clinicaltrials.gov: NCT06979544.

About LPCN 1154

LPCN 1154 is an oral formulation of brexanolone in development targeted for administration resulting in rapid relief of PPD. While it is expected that LPCN 1154 could be the first line treatment choice for women with PPD, it may have characteristics that could be particularly appealing to patients with PPD, acutely elevated suicide risk, and in whom rapid improvement is a priority while presenting no significant risk of adverse reactions to breastfed infants from exposure to brexanolone.

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 product candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 1154, our Phase 3 safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, potential partnering of our product candidates with third parties, and the potential uses and benefits of our product candidates, including the impact of LPCN 1154 on the treatment of PPD. 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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