Lipocine Announces Initiation of Outpatient Phase 3 Postpartum Depression Trial of LPCN 1154

- **48 hour at-home dosing**
- **Patient dosing expected in Q2/2025**

SALT LAKE CITY, March 26, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to enable effective oral delivery of therapeutics, today announced the initiation of a Phase 3 trial for LPCN 1154 (oral brexanolone) which is in development for the treatment of postpartum depression (PPD).

Based on observed comparable exposure of LPCN 1154 and the reference drug established in the pharmacokinetic (PK) bridge study, the company is initiating a phase 3 safety and efficacy study with expected first patient dosed in the second quarter of 2025. This randomized, blinded, placebo controlled study is designed to evaluate safety and efficacy of LPCN 1154 in women with PPD. This outpatient trial is expected to support a global registration package for LPCN 1154 in PPD.

"We are excited to initiate this registration-enabling Phase 3 trial," saidMahesh Patel, CEO of Lipocine. "Importantly, based on FDA protocol feedback, patients will self-administer LPCN 1154 at home. We believe that LPCN 1154 has the potential to be the first line option for rapid symptom relief in women with PPD."

Trial Design

The trial is a two-arm, randomized, blinded study comparing LPCN 1154 to placebo in women aged 15 years and older, diagnosed with severe postpartum depression (PPD). The treatment regimen involves a 48-hour dosing period, consistent with the dosing in Lipocine's PK bridge study.

The primary endpoint is the change from baseline in the Hamilton Depression Rating Scale (HAM-D), a widely recognized clinical measure of depression severity. Additional secondary endpoints include the change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) and the Hamilton Anxiety Rating Scale (HAM-A) to assess anxiety symptoms, as well as key safety and tolerability measures. The trial size is powered based on the treatment effect observed with the FDA approved injectable brexanolone.

About LPCN 1154

LPCN 1154 is an oral formulation of brexanolone in development targeted for administration resulting in rapid relief of PPD. Brexanolone is a bioidentical to naturally occurring neuroactive steroid, allopregnanolone, a positive allosteric modulator of y-aminobutyric acid (GABA) receptor. LPCN 1154 is expected to have characteristics that could be particularly appealing to patients with severe 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. In addition, 64% of women with PPD reported comorbid anxiety symptoms. 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 post-acute treatment.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to enable effective oral delivery of therapeutics. 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 clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy, LPCN 2203 an oral candidate targeted for the management of essential tremor, LPCN 2401 an oral proprietary anabolic androgen receptor agonist, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in obesity management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring

partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 2401 for obesity management, LPCN 1148, for the management of decompensated cirrhosis, and LPCN 1144, our candidate for treatment of metabolic dysfunction-associated steatohepatitis (MASH). 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 P3 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. 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 release, except as required by law.

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