Lipocine Announces Confirmation of Dosing Regimen for Pivotal Study of LPCN 1154

- *Positive clinical study results confirm 48-hour dosing regimen for the pivotal PK study*
- *On track for Q2-24 pivotal study topline results and planned Q4-24 NDA filing*

SALT LAKE CITY, Feb. 6, 2024 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders by leveraging its proprietary platform, today announced that results from a multi-dose clinical study have confirmed the LPCN 1154 48-hour dosing regimen for the upcoming NDA enabling pivotal pharmacokinetic (PK) study. LPCN 1154 is an oral neurosteroid being developed by Lipocine for the treatment of postpartum depression (PPD).

PPD is a major depressive disorder with onset either during pregnancy or within four weeks of delivery, with symptoms persisting for up to 12 months after childbirth. There is an unmet need for an oral fast-acting product with an improved efficacy and safety profile to treat PPD. Oral LPCN 1154 comprising a bioidentical neuroactive steroid with 48-hour outpatient dosing is targeted to provide rapid relief with robust efficacy.

Lipocine has previously confirmed with the U.S. Food and Drug Administration (FDA) acceptance of a proposal for a 505(b)(2) NDA filing based on a single pivotal study comparing exposure of LPCN 1154 with the approved IV infusion of brexanolone. Following a successful meeting with the FDA, Lipocine reached agreement on the use of exposure parameters and criteria to assess comparable exposure to IV infusion brexanolone.

Based on positive results of the 2023 multi-arm crossover pilot PK study, Lipocine recently completed a single arm PK study (N=8) utilizing the "to be marketed" formulation and target dosing regimen. PK exposure results of the "to be marketed" scaled up formulation were consistent with the PK performance of pilot study clinical formulation. Furthermore, the exposure PK parameters observed in this study are comparable to those of IV infusion brexanolone administered per label instructions in the pilot study. There were no serious or severe adverse events observed in this single arm, multi-dose study, and a single report of asymptomatic, moderate decrease of oxygen saturation. Consistent with the goal of NDA submission by the end of the fourth quarter of 2024, the company anticipates top line results late in the second quarter of 2024 from the crossover pivotal study of LPCN 1154 with the reference product IV brexanolone.

"We believe these results support the design of the planned NDA enabling pivotal study," said Dr. Mahesh Patel, President and CEO of Lipocine. "LPCN 1154 is targeted to be a highly effective, oral, fast-acting and short duration treatment option for PPD, a serious and potentially life-threatening condition. We believe a 48-hour oral dosing duration will be important for patients and caregivers. If approved, LPCN 1154 has the potential to be a differentiated preferred treatment option for PPD."

About LPCN 1154

LPCN 1154 is an oral formulation of brexanolone in development targeted for administration resulting in rapid relief of postpartum depression (PPD). Brexanolone is a bioidentical to naturally occurring neuro active 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. Approximately 500,000 women are affected by PPD annually in the United States and, according to the CDC, an estimated 175,000 women suffer from moderate to severe PPD. 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 sexual dysfunction and weight gain, and do not demonstrate adequate remission post-acute treatment. The current approved standard of care is a continuous infusion of intravenous brexanolone which requires inpatient administration and has significant limitations.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products for CNS disorders. Lipocine has drug candidates in development as

well as drug candidates for which we are exploring partnering. 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 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, LPCN1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, and LPCN 1144, our candidate for treatment of non-cirrhotic NASH. 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 development efforts, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the timing and outcome of product studies, our development of and filing of a NDA with the FDA for LPCN 1154, 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, 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.

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