Lipocine Completes Successful Meeting with FDA on LPCN 1154 in Postpartum Depression

- *Lipocine and FDA agreed on the acceptance criteria for the pivotal study which enables advancement of LPCN 1154 for postpartum depression (PPD)*
- *Company on track to initiate dosing in the pivotal study Q1'24*

SALT LAKE CITY, Oct. 26, 2023 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders by leveraging its proprietary platform, today announced the completion of a meeting with the FDA and guidance for the appropriate acceptance criteria for the upcoming LPCN 1154 pivotal study.

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. LPCN 1154 is targeted to be a differentiated oral option with rapid-onset, robust efficacy, and short treatment duration as a mono or add-on therapy for patients with unresolved depression symptoms.

Following positive results from the pilot PK bridge study, Lipocine completed a successful meeting with the U.S. Food and Drug Administration (FDA) on October 18th with agreement on the following:

- Confirmation of Lipocine's 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
- The use of exposure parameters and criteria to assess comparable exposure to IV infusion brexanolone

Consistent with the goal to file a New Drug Application (NDA) in 2024, the company anticipates beginning the pivotal study program in Q1'24 with LPCN 1154 "to be marketed" formulation. Top line results from the study are expected by Q2 '24.

"We are thankful for FDA's guidance and are pleased to reach an agreement on key elements of pivotal study design and other components required for registration," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "PPD is a serious condition, and we are developing LPCN 1154 to be a highly effective, oral, fast-acting and short duration treatment option. We believe rapid relief within 3 days will be important for patients and, 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. 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 products for CNS disorders. Lipocine has candidates in development as well as candidates for which we are exploring partnering. Our candidates represent enablement of patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine 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, an oral prodrug of bioidentical testosterone 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 1148, for the management of decompensated cirrhosis, LPCN

1144, our candidate for treatment of non-cirrhotic NASH, and LPCN 1111, a once-a-day therapy candidate for testosterone replacement therapy (TRT). 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, our strategic plans for developing products to treat CNS disorders, our ability to monetize non-core product candidates, including through entering into partnering arrangements, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, 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 to treat CNS disorders, 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, 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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