# Lipocine Announces First Cohort Dosed in Pivotal Study of LPCN 1154

Company anticipates topline results from this crossover pivotal study late in the second quarter of 2024

SALT LAKE CITY, March 25, 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 study enrollment is complete and the first cohort of subjects has been dosed in pivotal pharmacokinetic (PK) study designed to support a New Drug Application (NDA) for LPCN 1154. LPCN 1154, oral brexanolone, is being developed by Lipocine for the treatment of postpartum depression (PPD).

The pivotal PK study is an open label, randomized, crossover study in 24 healthy postmenopausal women utilizing the "to be marketed" formulation of LPCN 1154 and dosing regimen. The primary objective of the study is to compare the pharmacokinetics of a multi-dose regimen of oral LPCN 1154 to IV infusion brexanolone administered per label instructions. During the two treatment visits, each participant will receive the oral and IV brexanolone regimens in a randomized, crossover manner. Safety and tolerability of the multidose regimen of LPCN 1154 will also be evaluated. Consistent with the goal of NDA submission by the end of the fourth quarter of 2024, the company anticipates topline results from this crossover pivotal study late in the second quarter of 2024.

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 being developed to provide rapid relief with robust efficacy.

Recent reports suggest that the market size for PPD is larger than previously estimated. 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. Increasing awareness of PPD among physicians and patients is expected to result in higher diagnosis rates and greater numbers of patients seeking treatment.

Lipocine has 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.

"It is encouraging to see that awareness of this serious condition is growing," 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. 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.

**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.

SOURCE Lipocine Inc.

For further information: Krista Fogarty, Phone: (801) 994-7383, kf@lipocine.com; Investors, PJ Kelleher, Phone: (617) 430-7579, pkelleher@lifesciadvisors.com

---