First Subject Dosed in the Clinical Bridge Study with Lipocine Depression Candidate, LPCN 1154

- LPCN 1154 is an oral formulation of brexanolone in development for the rapid relief of postpartum depression (PPD)
- Topline study results expected in H1 2023

SALT LAKE CITY, April 3, 2023 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders by leveraging its proprietary platform to develop differentiated products, today announced that the first participant has been dosed in a pilot clinical bridge study of LPCN 1154 (oral brexanolone) and approved injectable brexanolone. The U.S. Food and Drug Administration (FDA) has agreed with Lipocine's proposal for establishing the efficacy and safety of LPCN 1154 in women with PPD through a clinical (pharmacokinetic) bridge to an approved IV infusion of brexanolone via a 505(b)(2) NDA filing. Lipocine plans to conduct a pivotal study designed to support NDA filing pending results from the pilot clinical bridge study.

LPCN 1154 is targeted to be a rapid onset "at home" oral treatment option for PPD with improved treatment access and ease of use without disrupting bonding/breast feeding interactions compared to the current, approved PPD standard of care with its significant limitations.

The pilot clinical bridge study is an open label, randomized, partial crossover study. The primary objective of the study is to compare the exposures of multidose regimens of orally administered LPCN 1154 and a continuous IV infusion of brexanolone in healthy postmenopausal women and to inform the dose selection for the pivotal study. The secondary objective is to evaluate the safety and tolerability of multidose regimens of oral LPCN 1154. The study is expected to enroll a total of 12 participants and is being conducted at a single center in the US. Results are expected in the first half of 2023.

"We are excited about our development progress for LPCN 1154," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "The days and weeks after childbirth are critical time periods for the care of both mother and newborn, with urgent relief a high priority for patients with depression," continued Dr. Patel. "We believe that, if approved, LPCN 1154, comprising a bioidentical active, has the potential to be a differentiated treatment for PPD, providing a convenient oral treatment option for administration in outpatient settings that would be less burdensome on patients, caregivers, and providers."

About LPCN 1154

LPCN 1154 is an oral formulation of the neuroactive steroid brexanolone for self-administration in development for the treatment of PPD. The active moiety in LPCN 1154 is a bioidentical positive allosteric modulator of y-aminobutyric acid (GABA) receptor.

About Postpartum Depression

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. 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, and 10-15% of PPD patients have severe depression. The current approved standard of care is continuous infusion of intravenous brexanolone which requires inpatient administration with frequent monitoring.

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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