

# Lipocine Receives Updated Regulatory Guidance on LPCN 1154

SALT LAKE CITY, Feb. 6, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery, today announced receipt of revised regulatory guidance for LPCN 1154 which the Company is developing for postpartum depression (PPD) treatment. As previously disclosed, the Company was scheduled to meet with the U.S. Food and Drug Administration (FDA or the Division) in Q1 2025 to discuss the NDA submission package of LPCN 1154. Following the meeting, the Company was advised that the Division believes, in addition to the previously completed PK bridge data, an efficacy and safety study of oral LPCN 1154 in the target population will be required for 505(b)(2) NDA submission.

Lipocine remains committed to advancing a rapid relief treatment for postpartum depression. Based on the guidance received and observed comparable exposure of LPCN 1154 and the reference drug in the completed PK bridge study, Lipocine is planning next steps toward the execution of a phase 3 safety and efficacy study.

"The regulatory guidance regarding a safety and efficacy study provides an opportunity to generate safety and depression symptom relief data with LPCN 1154, which we believe will be beneficial for potential inclusion in product labeling and eligibility for clinical investigation exclusivity for a 48-hour, oral treatment option," said Mahesh Patel, CEO of Lipocine. "Furthermore," Dr. Patel added, "the planned study will investigate the potential of oral brexanolone to treat anxiety disorders, representing another attractive commercial opportunity with a high unmet need."

## 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  $\gamma$ -aminobutyric acid (GABA<sub>A</sub>) 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 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. 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 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](http://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 current intention to conduct a safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, the timing of our submission 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, 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](http://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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