

Lipocine Announces Completion of Dosing in Pivotal Study of Postpartum Depression Candidate, LPCN 1154

Pivotal study design aligned with FDA on streamlined pathway to NDA submission goal in 2024

Topline results anticipated late in 2Q 2024

SALT LAKE CITY, May 1, 2024 [/PRNewswire/](#) -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company, today announced that dosing of subjects has been completed in the pivotal pharmacokinetic (PK) study designed to support a New Drug Application (NDA) for LPCN 1154. LPCN 1154, oral brexanolone, is being developed as a treatment of postpartum depression (PPD). Lipocine anticipates topline results late in the second quarter of 2024, with the goal of NDA submission by the end of the fourth quarter of 2024.

"We are pleased to complete dosing of participants in this NDA enabling study of LPCN 1154," said Dr. Mahesh Patel, President and CEO of Lipocine. "We look forward to reporting topline results from this 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 enabled by a single pivotal PK study comparing exposure of LPCN 1154 with the approved IV infusion of brexanolone.

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 γ -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 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 combination of anabolic androgen receptor agonist and α -tocopherol, an antioxidant, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in chronic weight management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms

associated with liver cirrhosis including prevention of the recurrence of overt hepatic encephalopathy. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, LPC 2401 for obesity management 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 an 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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