

FDA Clears LPCN 1154 IND Application for a Phase 2 Postpartum Depression Study

SALT LAKE CITY, June 14, 2021 /PRNewswire/ -- Lipocine Inc. (Nasdaq: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the U.S. Food and Drug Administration ("FDA") has cleared the Company's Investigational New Drug Application ("IND") to initiate a Phase 2 study to evaluate the therapeutic potential of LPCN 1154, an oral neuro-steroid product candidate, for the treatment of postpartum depression ("PPD") in adults.

A pharmacokinetic ("PK") study to assess dose proportionality is planned to start in July 2021 with top-line results expected in the third quarter of 2021. Following the PK study, a proof-of-concept study to evaluate the safety, tolerability, and efficacy of LPCN 1154 in adult female subjects diagnosed with PPD is expected to occur with the first subject dosed in the fourth quarter of 2021.

PPD, a major depressive disorder that is under diagnosed in US, impacts approximately 1 in 7 women after giving birth. PPD can lead to devastating consequences for a woman, her newborn and her family. Currently, there is no oral therapy approved for the treatment of PPD. The active moiety in LPCN 1154 is an endogenous positive allosteric modulator of [γ-aminobutyric acid](#) ("GABA_A") receptor. LPCN 1154 is expected to be an "at home" treatment with easier treatment access than the current standard of care invasive option that requires hospitalization with significant limitations. Moreover, LPCN 1154 is expected to provide the required level of privacy for a mother, avoiding bonding/breast feeding interruptions due to the required hospitalizations for the current option.

"We are eager to leverage our unique oral-enabling technology platform to embark upon a program in neuroendocrinology for a leading neuropsychiatric indication with a high unmet need," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "We believe LPCN 1154 has the potential to provide a suitable option for all women in need of PPD therapy, including breastfeeding mothers."

About Lipocine

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: TLANDO, LPCN 1144, TLANDO XR, LPCN 1148, LPCN 1154, and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing. In a phase 2 clinical evaluation when administered as once daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. LPCN 1154 is an oral neuro-steroid targeted for the treatment of post-partum depression. 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 Lipocine's product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will not approve any of our products, risks related to our products including LPCN 1154, 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 including the Phase 2 clinical study with LPCN 1154, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, risk related to on-going litigation 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.

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