

Lipocine Announces Regulatory Path Forward for TLANDO™ Resubmission

SALT LAKE CITY, Feb. 24, 2020 /PRNewswire/ -- Lipocine Inc. (LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced the results of its Post Action meeting with the U.S. Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA") for TLANDO™, the Company's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. Based on the Post Action meeting and written feedback, the FDA indicated Lipocine's approach to addressing the single remaining deficiency through the reanalysis of existing data in accordance with FDA feedback appears to be a reasonable path forward. The FDA requested that the information generated by the reanalysis be submitted as part of an NDA resubmission with a six-month Prescription Drug User Fee Act ("PDUFA") clock.

"We are committed to working closely with the FDA towards the goal of achieving approval of TLANDO, our fixed-dose oral TRT," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We plan to submit the TLANDO NDA in the first quarter of 2020."

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 1111"), LPCN 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. Lipocine received a complete response letter from the FDA related to TLANDO on November 8, 2019. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of pre-cirrhotic NASH. 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 NASH cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate, with end of phase 2 meeting completed, indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. 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 and related clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, our product development efforts, or plan to submit the TLANDO NDA in the first quarter of 2020, and future discussions and potential future actions by the FDA related to TLANDO. 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, 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, 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.

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