Lipocine Receives Complete Response Letter for TLANDO™ from U.S. FDA

SALT LAKE CITY, Nov. 11, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company, announced today that it has received a Complete Response Letter ("CRL") from the United States 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. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.

The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations ("Cmax"). The CRL does not identify any specific issues relating to the chemistry, manufacturing and controls ("CMC") of TLANDO.

"We are disappointed by the FDA's decision and intend to request a meeting with the FDA as soon as possible to discuss a potential path forward for the approval of TLANDO," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

We continue to actively enroll in our ongoing LPCN 1144*LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic non-alcoholic steatohepatitis ("NASH") subjects, as the endpoints in the *LiFT* study are based on liver fat reduction via MRI-PDFF and liver biopsy.

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 development programs. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men and received a Complete Response Letter from the U.S. Food and Drug Administration on November 8, 2019. LPCN 1144, a differentiated oral product of bioidentical testosterone, is currently undergoing Phase 2 clinical testing in biopsy confirmed NASH patients and recently completed a proof-of-concept clinical study demonstrating the potential utility the in treatment of NASH. TLANDO XR (LPCN 1111), 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 and has completed Phase 2 testing. LPCN 1148 is a unique oral testosterone product targeted to treat NASH 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. An End of Phase 2 meeting with the FDA has been completed. 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 expectation that it will continue the *LiFT* Phase 2 clinical study, future discussions and actions with the FDA related to TLANDO, Lipocine's product candidates and related clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, and our product development efforts. 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, 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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