Treatment Potential of LPCN 1144 Demonstrated in a Pre-Clinical NASH and Hepatic Fibrosis Model

SALT LAKE CITY, May 13, 2020 /PRNewswire/ -- Lipocine Inc. (LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced the results of a pre-clinical study of LPCN 1144. LPCN 1144 is an oral prodrug of bioidentical testosterone ("testosterone undecanoate" or "TU"). The pharmacological effect of LPCN 1144 was investigated in a non-genomic, five arm, 12-week high fat diet ("HFD")-induced, rabbit animal model of NASH and hepatic fibrosis.

In the pre-clinical study, the HFD induced histological NASH features with fibrosis, altered key biomarkers, and lowered serum testosterone levels. Expectedly, treatment with LPCN 1144 increased testosterone levels in rabbits with HFD-induced low testosterone. Histological and biomarker analyses also demonstrate that LPCN 1144 improved HFD-induced NASH features and hepatic fibrosis. LPCN 1144 treatment reduced HFD-induced visceral fat increase and insulin resistance. LPCN 1144 treatment-related reduction in key liver inflammation and fibrosis markers was comparable to that reported for obeticholic acid ("OCA") under a similar pre-clinical methodology (Vignozzi et al., Mol Cell Endocrinol, 2014). Lipocine plans to present the results at an upcoming scientific conference.

LPCN 1144 is currently being studied in the *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 paired biopsy clinical study in patients with confirmed non-cirrhotic NASH.

"We are encouraged by these pre-clinical study results," said Dr.Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "Pending confirmation in the on-going *LiFT* clinical trial, these findings suggest therapeutic potential of LPCN 1144 in the treatment of NASH and hepatic fibrosis," Dr. Patel added.

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 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 has resubmitted its NDA to the FDA for TLANDO and has a PDUFA date of August 28, 2020. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-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 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 pre-clinical and clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, the use and benefits of LPCN 1144 in the treatment of NASH and hepatic fibrosis, our product development efforts, and future discussions and potential future actions by the FDA related to TLANDO including the PDUFA date. 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, pre-clinical, 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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