First Biopsy Confirmed Nash Patient Dosed In Lipocine LiFT Study Of LPCN 1144

SALT LAKE CITY, Sept. 30, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the first patient has been dosed in its *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic non-alcoholic steatohepatitis ("NASH") subjects.

"The first patient dosing in the *LiFT* study is an important step in the clinical development of LPCN 1144, a differentiated oral treatment with good chronic tolerability, for NASH," stated Mahesh Patel, President and Chief Executive Officer of Lipocine. Patel added, "Reportedly, a majority of biopsy confirmed male NASH patients have low testosterone levels, a significant result given that LPCN 1144 treatment in an earlier clinical study has demonstrated meaningful liver fat reductions in men with low testosterone."

The *LiFT* Phase 2 clinical study is a prospective, multi-center, randomized, double-blind, placebo-controlled multiple-arm study in biopsy-confirmed male NASH subjects with grade F2/F3 fibrosis and a NAFLD Activity Score ("NAS") ≥ 4 with a 36-week treatment period. The *LiFT* clinical study is designed to enroll approximately 75 biopsy confirmed NASH male subjects, randomized into one of three arms (two test arms and one placebo arm) with a 1:1:1 randomization ratio. We currently expect top-line primary end point liver fat reduction data in mid-2020, as measured by MRI-PDFF at 12 weeks, followed by 36-week biopsy data.

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 four development programs TLANDO, LPCN 1144, TLANDO XR (LPCN 1111) and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men and currently under USFDA review for marketing approval. LPCN 1144, an oral product of bioidentical testosterone, 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 is currently in Phase 2 testing. 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 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.

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