Lipocine Announces Completion of Enrollment in the LPCN 1144 LiFT Study

Phase 2 Clinical Study Investigating LPCN 1144 in Biopsy-Confirmed Non-Cirrhotic NASH Subjects

SALT LAKE CITY, Sept. 21, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the last patient has been enrolled in its *LiFT* ("***Li***ver ***F***at intervention with oral ***T***estosterone") Phase 2 clinical study, a paired-biopsy study investigating LPCN 1144 in confirmed non-cirrhotic non-alcoholic steatohepatitis ("NASH") subjects. LPCN 1144 is an oral prodrug of endogenous testosterone. To date LPCN 1144 therapy has shown meaningful reductions of liver fat in our proof of concept liver fat imaging study in hypogonadal males and has demonstrated treatment potential in a pre-clinical NASH and hepatic fibrosis rabbit model. Moreover, no notable tolerability issues have been seen in 700+ hypogonadal subjects with up to 52-week exposure.

There is a growing body of preclinical and clinical evidence supporting the relationship between testosterone deficiency and NAFLD/NASH. The majority of biopsy-confirmed NASH male patients reportedly have low testosterone and the levels of free T decrease significantly with increased fibrosis.

The *LiFT* Phase 2 clinical study is a 38-week, prospective, multi-center, randomized, double-blind, placebo-controlled, three-arm study of LPCN 1144 in biopsy-confirmed male NASH subjects (based on NAFLD activity score) with grade F1-F3 fibrosis. The study randomized 56 subjects 1:1:1 to two test arms and one placebo arm. Lipocine expects to report top-line change in liver fat data measured by MRI-PDFF (primary endpoint), in January 2021. Subsequently, 36-week biopsy and MRI-PDFF data are expected mid-2021. For more information, refer to NCT04134091.

"We are pleased to have completed enrollment in the *LiFT* trial, especially during the current COVID-19 crisis, and look forward to sharing primary endpoint results," stated Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "Considering the possible benefit to risk profile, we are excited to investigate LPCN 1144 for the treatment of biopsy-confirmed NASH patients."

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 it is currently under review. 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. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, a novel oral prodrug of testosterone, originated and 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 standard TRT primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of liver 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, including the *LIFT* clinical study, 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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