

Lipocine Announces Open Label Extension to Ongoing LPCN 1144 LiFT Study

SALT LAKE CITY, Dec. 30, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that it is enrolling patients into an open label extension to the ongoing LPCN 1144 Phase 2 *LiFT* study based on investigator and patient interest in continuing treatment. The *LiFT* ("**L**iver **F**at intervention with oral **T**estosterone") clinical study is a paired-biopsy study investigating LPCN 1144 in confirmed non-cirrhotic non-alcoholic steatohepatitis ("NASH") subjects.

In the initial, double-blind part of the *LiFT* study, patients were randomized to receive one of two treatments of LPCN 1144 or placebo over 36 weeks. Patients who complete this portion will now have the option to enter the 36-week open label extension study, which is designed to evaluate the long-term safety and tolerability of LPCN 1144 treatment. There is no placebo arm in the open label extension study, and all patients will be treated with LPCN 1144.

"This extension to our ongoing *LiFT* clinical study will allow us to collect additional data on LPCN 1144 for up to a total of 72 weeks of therapy," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "Patients who may have received placebo during the initial, randomized part of the trial now have the opportunity to receive active drug."

For more information on *LiFT*, refer to NCT04134091. For more information on this open label extension study, refer to NCT04685993.

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, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. 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 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 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.

SOURCE Lipocine Inc.

For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, Phone: (801) 994-7383, mb@lipocine.com; Investors: Hans Vitzthum, Phone: (617) 430-7875, hans@lifesciadvisors.com

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