FDA Clears LPCN 1148 IND Application for Phase 2 Cirrhosis Trial

SALT LAKE CITY, May 5, 2020 /PRNewswire/ -- Lipocine Inc. (Nasdaq: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the U.S. Food & Drug Administration ("FDA") has accepted the Company's Investigational New Drug application ("IND") to initiate a Phase 2 proof-of-concept study to evaluate the therapeutic potential of LPCN 1148, an oral prodrug of bioidentical testosterone, for the treatment of liver cirrhosis in adult male cirrhotic patients. The planned Phase 2 clinical study is a prospective, multi-center, randomized, placebo-controlled 52-week study in male cirrhotic patients that are on the liver transplant list. Contingent upon available funding, Lipocine projects study initiation in the fourth quarter of 2020 or the first quarter of 2021.

Liver cirrhosis is estimated to affect in excess of 600,000 Americans, with men affected at twice the rate of women, and results in approximately 45,000 deaths every year. Due to a lack of available organs, only a third of waitlisted patients receive liver transplants, and patients who do receive a transplant are increasingly being described as frail. Low testosterone affects up to 90% of cirrhotic men, and is a predictor of mortality and increased adverse events including ascites, hepatic encephalopathy, and clinically significant portal hypertension.

"We are excited the FDA has accepted the LPCN 1148 Phase 2 clinical protocol to test our potential treatment in cirrhotic patients," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "We believe LPCN 1148 has the potential to improve survivability and quality of life for cirrhotic 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 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 pre-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 NASH 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. 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 including LPCN 1148, 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 including the Phase 2 clinical study with LPCN 1148, 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.

SOURCE Lipocine Inc.

For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, (801) 519-4090, mb@lipocine.com; Investors, Hans Vitzhum, Phone: (617) 535-7743, hans@lifesciadvisors.com

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