

# Lipocine to Present Preclinical Data on Therapeutic Potential of LPCN 1144 in Hepatic Fibrosis and NASH at The Liver Meeting Digital Experience™

SALT LAKE CITY, Nov. 5, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced it will present a poster with results from a preclinical study investigating LPCN 1144 treatment on hepatic fibrosis and non-alcoholic steatohepatitis ("NASH") features at [The Liver Meeting Digital Experience™](#), hosted by the American Association for the Study of Liver Diseases ("AASLD"). The poster will be available virtually on Friday, November 13, 2020, Room 1970 between 6:00 AM - 11:55 PM ET.

"It has been shown that low testosterone levels in men are independently associated with the presence and severity of NASH," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "These preclinical data add to our understanding of the effects of oral testosterone on the liver, showing that LPCN 1144 improved high fat diet induced hepatic fibrosis and NASH features."

Lipocine recently announced completion of enrollment in its *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study, a paired-biopsy study investigating LPCN 1144 in confirmed NASH subjects. The Company 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.

## **LPCN 1144 Treatment Potential Assessment in a High Fat Diet Induced Rabbit Model of Hepatic Fibrosis and NASH** (Kilyoung Kim et al)

The goal of this study was to evaluate the treatment potential of daily LPCN 1144 on histological and biochemical features of NASH and fibrosis using a high fat diet ("HFD")-induced NASH model. Male rabbits were randomly assigned to 5 groups: regular diet ("RD"), HFD, HFD+LPCN 1144 vehicle ("VEH"), HFD+LPCN 1144, and HFD+LPCN 1144+a-tocopherol ("LPCN 1144+AT"). The study duration was 12 weeks.

Both the LPCN 1144 and LPCN 1144+AT arms improved mean histological scores of NASH with fibrosis compared to HFD arm. Importantly, the fibrosis percentage (in sampled liver tissue area) was significantly improved in both the LPCN 1144 ( $p<0.05$ ) and LPCN 1144+AT ( $p=0.05$ ) treatment arms vs the HFD arm. Both LPCN 1144 and LPCN 1144+AT arms also reduced HFD-induced elevated liver mRNA inflammation and fibrosis markers. Furthermore, LPCN 1144 concomitant treatment improved insulin resistance, visceral adiposity, and low testosterone (metabolic dysfunctions) induced by HFD.

## **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. 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, 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](http://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 timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, 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](http://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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