Lipocine Announces FDA Grants Fast Track Designation to LPCN 1144 for Treatment of Non-Cirrhotic NASH

SALT LAKE CITY, Nov. 4, 2021 /PRNewswire/ -- Lipocine Inc. (LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track Designation to LPCN 1144 as a treatment for non-cirrhotic non-alcoholic steatohepatitis ("NASH"). LPCN 1144, an oral prodrug of bioidentical testosterone, was recently studied in the Liver Fat intervention with oral Testosterone ("*LiFT*") Phase 2 paired biopsy clinical study in patients with confirmed NASH. Treatments with LPCN 1144 in the *LiFT* clinical study resulted in robust liver fat reduction, assessed by magnetic resonance imaging, proton density fat fraction ("MRI-PDFF") technique, and showed improvement of liver injury markers with no observed tolerability issues. Additionally, key secondary endpoint results after 36 weeks of treatment in the *LiFT* clinical study demonstrated that treatments with LPCN 1144 met the NASH resolution regulatory endpoint, showed positive effects in appendicular lean mass and whole-body fat mass and continued to show substantial reductions in markers of liver injury compared to placebo.

"The granting of Fast Track Designation represents an important recognition by the FDA of LPCN 1144's potential to address a significant unmet need in the treatment of NASH," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We believe the Fast Track Designation will enable us to work closely with the FDA on our development program for NASH, including the design of the Phase 3 program."

The Fast Track program is designed to accelerate the development and expedite the review of products, such as LPCN 1144, which are intended to treat serious diseases and for which there is an unmet medical need. Fast Track designation lends eligibility for some, or all, of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed

About NASH
NASH is a more advanced state of non-alcoholic fatty liver disease ("NAFLD") and can progress to a cirrhotic liver and eventually hepatocellular carcinoma/liver cancer. Twenty-five to thirty percent of the U.S. population is estimated to suffer from NAFLD. NASH afflicts three to twelve percent of the U.S. population, which is a substantially large population that lacks effective therapy. Currently, there are no FDA approved treatments for NASH. Approximately 50% of NASH patients are in adult males and the number of NASH cases is projected to increase 63% from 16.5 million cases in 2015 to 27.0 million cases in 2030. NAFLD/NASH is becoming more common due to its strong correlation with obesity and metabolic syndrome, including components of metabolic syndrome such as diabetes, cardiovascular disease and high blood pressure. In men, especially with comorbidities associated with NAFLD/NASH, testosterone deficiency has been associated with an increased accumulation of visceral adipose tissue and insulin resistance, which could be factors contributing to NAFLD/NASH.

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, LPCN 1154, 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 prodrug of bioidentical testosterone, recently completed a Phase 2 clinical study demonstrating the potential utility in the treatment of non-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 cirrhosis. LPCN 1154 is an oral neuro-steroid targeted for the treatment of post-partum depression. 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 and completion of additional clinical trials and studies, the potential uses and benefits of LPCN 1144 for the treatment of NASH, the timing of additional data, our ability to take advantage of the benefits of Fast Track Designation for LPCN 1144,whether LPCN 1144 will receive accelerated approval from the FDA for LPCN 1144, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risk 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.

SOURCE Lipocine Inc.

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