Lipocine Announces Completion of Enrollment in LPCN 1144 Liver Imaging Study in Subjects At-Risk for NASH

SALT LAKE CITY, Nov. 5, 2018 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced the completion of enrollment in the proof-of-concept clinical study with LPCN 1144 to assess liver fat changes in hypogonadal men at risk of developing non-alcoholic steatohepatitis ("NASH") using magnetic resonance imaging, proton density fat fraction ("MRI-PDFF") technique. LPCN 1144 is the Company's oral product candidate for the treatment of NASH comprising a prodrug of bioidentical testosterone. The study enrolled 36 subjects and results are expected in the first quarter of 2019.

"Assessing the impact of LPCN 1144 treatment on liver fat changes in hypogonadal men with confirmed fatty liver would enable us to understand the underappreciated association between hypogonadism and non-alcoholic fatty liver disease ("NAFLD"). Additionally, the outcome from this clinical study will be an important foundation for designing future clinical studies of LPCN 1144 for the treatment for NAFLD/NASH," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel added, "We are excited about LPCN 1144's potential differentiating mechanisms of action that may provide additional collateral health benefits to patients with impaired liver function."

About LPCN 1144

LPCN 1144, an oral prodrug of bioidentical testosterone, is being developed as a treatment of NASH and is currently being studied in two proof-of-concept ("POC") clinical studies. LPCN 1144 is being studied in a proof-of-concept study in a biopsy-confirmed NASH in-vivo pre-clinical model as well as in a POC clinical study to assess liver fat changes in hypogonadal men at risk of developing non-alcoholic steatohepatitis NASH using MRI-PDFF technique. Results from the biopsy-confirmed in-vivo POC study and the POC liver imaging study are expected in the first quarter of 2019. Additionally, LPCN 1144 results have been selected to be a part of the late-breaker session of The Liver Meeting® 2018. The presentation will highlight data from multiple clinical trials of LPCN 1144 in potential NAFLD/NASH patients.

NASH is a more advanced state of NAFLD and can progress to a cirrhotic liver and eventually hepatocellular carcinoma or liver cancer. Twenty to thirty percent of the U.S. population is estimated to suffer from NAFLD and fifteen to twenty percent of this group progress to NASH, which is a substantially large population that lacks effective therapy. 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 are factors contributing to NAFLD/NASH.

Preclinical and clinical studies in the literature have shown the prevalence of testosterone deficiency across the NAFLD/NASH histological spectrum wherein low testosterone was independently associated with NAFLD/NASH with an inverse relationship between testosterone and NAFLD/NASH.

Post hoc analyses of existing clinical trials in subjects with comorbidities typically associated with NASH indicate that oral testosterone therapy significantly and consistently reduces elevated levels of key serum biomarkers (liver function enzymes and serum triglyceride) generally associated with NAFLD/NASH.

About Lipocine

Lipocine Inc. is a specialty pharmaceutical company developing innovative pharmaceutical products for use in men's and women's health using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes four development programs TLANDO, LPCN 1144, LPCN 1111, and LPCN 1107 and. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. TLANDO received a Complete Response Letter ("CRL") from the FDA on May 8, 2018 and is currently being evaluated in two on-going clinical studies that address deficiencies identified in the CRL. LPCN 1144, an oral prodrug of bioidentical testosterone, is being developed as a treatment of non-alcoholic steatohepatitis ("NASH") and is currently being studied in two proof-of-concept clinical studies. LPCN 1111, 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 and is currently in Phase 2 testing. 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. An End of Phase 2 meeting with the FDA has been completed. 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 and the FDA review process relating to its product candidates, the timing of completion of clinical trials including the ABPM study for TLANDO, the path to approvability by the FDA of Lipocine's development programs, 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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