Lipocine's NASH Therapy Candidate Achieves Meaningful Liver Fat Reduction Based on Interim Results

SALT LAKE CITY, Jan. 17, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced approximately eight-week top-line interim results from an ongoing sixteen-week Liver Fat Imaging study ("Liver Fat Study") with LPCN 1144. The Liver Fat Study is designed to assess the therapy potential of LPCN 1144 in non-alcoholic steatohepatitis ("NASH") with liver fat changes assessed using magnetic resonance imaging, proton density fat fraction ("MRI-PDFF") technique, a non-invasive quantitative biomarker of liver fat content. NASH is an advanced form of non-alcoholic fatty liver disease ("NAFLD") and occurs when fat accumulates in liver cells due to causes other than excessive alcohol use and a patient has hepatitis (inflammation of the liver) and liver cell damage. Currently there are no approved treatments for NASH. NASH is a silent killer that affects ~30 million Americans.

The ongoing Liver Fat Study is an open-label, multi-center, single arm study evaluating LPCN 1144 treatment in a cohort of 36 hypogonadal males. Subjects with at least 10% baseline liver fat were evaluated which is indicative of subjects with NAFLD with the potential to have NASH. Interim results of seven of the nine subjects in the Liver Fat Study with baseline liver fat of at least 10% are presented as two subjects were unable to schedule an eight-week MRI-PDFF visit. Baseline mean liver fat of these seven subjects was 21.0%.

Treatment results showed an absolute mean reduction from baseline of 7.6% liver fat and demonstrated a 38% relative mean liver fat reduction from baseline. Moreover, there was an 86% responder rate in which subjects experienced at least a 4.1% absolute reduction in liver fat from baseline and a 71% responder rate in which subjects experienced at least a 29% reduction in liver fat from baseline.

A recent publication in *Therapeutic Advances in Gastroenterology* (Patel et al., *Therapeutic Advances in Gastroenterol*. 2016 Sep; 9(5): 692–701) quantified the magnitude of MRI-PDFF reduction corresponding to a histologic response in NASH in a clinical setting with paired liver biopsy. The results concluded that histologic responders had a statistically significant reduction in MRI-PDFF of -4.1% with a mean relative percent change of -29.3%.

"Hypogonadism is an underappreciated condition in NAFLD/NASH," said Dr. Stephen Harrison, Medical Director, Pinnacle Clinical Research and Visiting Professor of Hepatology, Radcliffe Department of Medicine, Oxford University. Dr. Harrison further stated, "The interim results strongly suggest the potential benefit of LPCN 1144 therapy for patients with NAFLD and support further study to validate a histopathologic benefit in patients with NASH. Additionally, testosterone therapy has additional known benefits, including improved bone density and muscle mass."

Based on multiple clinical studies with up to 52-week exposure, LPCN 1144 is well tolerated with no adverse liver enzyme signals, no deaths or MACE events, and no drug related SAEs. Moreover, LPCN 1144 has shown good gastrointestinal tolerability with no signs of skeletal fragility or nephrotoxicity. LPCN 1144 was well tolerated in the Liver Fat Study.

"We are very encouraged by these results especially as the observed liver fat reductions are the largest of any well-tolerated oral product candidate within approximately eight weeks. We look forward to the sixteen-week results later this quarter," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "We believe LPCN 1144 can offer additional unmet benefits such as

improvement in cardiovascular disease, sarcopenia, and sexual dysfunction."

About Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH)

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.

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. 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 from the FDA on May 8, 2018. 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 a proof-of-concept clinical study. 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 including the Liver Fat Study, the timing of completion of clinical trials including the ongoing LPCN 1144 clinical trials, 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, (801) 994-

7383, mb@lipocine.com; or Investors, Hans Vitzthum, (617) 535-7743, hans@lifesciadvisors.com

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