Lipocine's LPCN 1144 for NASH Demonstrates Substantial Fatty Liver Resolution and Meaningful Liver Fat Reduction in NAFLD Population

SALT LAKE CITY, March 12, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company focused on endocrine and metabolic disorders, today announced top-line results from the 16-week Liver Fat Imaging Study ("Liver Fat Study") with LPCN 1144. Previously, we announced eight-week top-line interim results on January 17, 2019. The Liver Fat Study was designed to assess the therapeutic potential of LPCN 1144 in non-alcoholic *steatohepatitis* ("NASH") with l*iver 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 Liver Fat Study was an open-label, multi-center, single arm study evaluating 16-week LPCN 1144 treatment in a cohort of 36 hypogonadal males. There were 34 evaluable subjects that had at least one post-baseline MRI-PDFF visit. Sixty-two percent (62%) of the of the evaluated subjects had NAFLD, defined as baseline liver fat of at least 5%.

Treatment results at End of Study ("EOS") with LPCN 1144 demonstrated that 48% of the treated NAFLD subjects had NAFLD resolution, defined as liver fat <5% post treatment, an improvement over the 28% percent observed after ~8 weeks of treatment. Additionally, 100% subjects experiencing NAFLD resolution had at least a 35% relative liver fat reduction from baseline with a relative mean liver fat reduction of 55% in this group. NAFLD resolution results are as follows:

Baseline Liver Fat %, n	NAFLD Resolution*		Relative Reductions Among Patients with NAFLD Resolution at EOS
	8-Weeks, %	EOS, %	Mean %, n=10
At least 5%, n=21	28	48	55

*Liver fat <5% post treatment

Results from the Liver Fat Study at 16 weeks, EOS, are shown below:

Baseline Liver Fat Category, n	Mean Liver Fat % at Baseline	Relative Reductions at EOS		Responder Rate** at EOS, %
		Mean %	Median %	
At least 10%, n=8	20.5	40	39	75
At least 8%, n=10	18.3	42	42	80
At least 5%, n=21	12.1	33	41	71

**Based on subjects who experienced at least a 30% reduction in liver fat from baseline.

LPCN 1144 was well tolerated in the Liver Fat Study.

"The results from the Liver Fat Study are striking because both the proportion and degree of improvement in steatosis rivals or exceeds those seen with other drugs currently in development. Furthermore, the extent of NAFLD resolution provides a strong rationale for additional studies in both hypogonadal males with NASH as well as more unselected populations of men with NASH," said Dr. Arun Sanyal, Professor in the Virginia Commonwealth University (VCU) Department of Internal Medicine and Education Core Director in the VCU Center for Clinical and Translational Research.

Reportedly, sarcopenia, skeletal fragility, sexual/mood disorder, and anemia, all symptoms of low testosterone, are strongly associated with liver disease, likely due to compromised androgen signaling. Testosterone deficiency is also known to further exacerbate liver disease symptoms.

"We are encouraged by the Liver Fat Study results, especially the extent of the observed NAFLD resolution which improved over eight-week interim results with potential for further improvement upon longer treatment," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "We look forward to conducting further clinical testing with LPCN 1144, in biopsy confirmed NASH subjects."

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 LPCN 1144
LPCN 1144 is a product targeted for treatment of pre-cirrhotic NASH comprising an oral prodrug of bioidentical testosterone, an androgen receptor agonist. Based on the multiple clinical studies with up to 52-week exposure, LPCN 1144 is well tolerated, exhibited no adverse drug reaction in the Hepatobilliary System Organ Class (e.g., peliosis hepatitis, hepatic neoplasms, cholestatic hepatitis and jaundice), exhibited no observed increase in mean LDL, exhibited no increase in mean serum hormone binding globulin ("SHBG"), exhibited no deaths or MACE events, and exhibited no drug related SAEs. Moreover, LPCN 1144 has shown good gastrointestinal tolerability with no signs of skeletal fragility (adverse muscle mass or bone density effects) or nephrotoxicity. LPCN 1144 recently completed a proof-of-concept clinical study demonstrating the potential utility in treatment of NASH. The U.S. Food & Drug Administration ("FDA") has indicated that a Phase 2 clinical study of LPCN 1144 in NASH with biopsy confirmed NASH subjects may proceed.

About Lipocine
Lipocine Inc. is a specialty pharmaceutical company developing innovative pharmaceutical products for use in endocrine and metabolic disorders 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 through lymphatic delivery of the active TLANDO received a Complete Response Letter from the FDA on May 8, 2018. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility the in treatment of NASH. 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, 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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