Lipocine Receives FDA Clearance for Clinical Testing its NASH Candidate, LPCN 1144, in Expanded Target Population

SALT LAKE CITY, July 23, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that it has received clearance from the U.S. Food and Drug Administration ("FDA") to clinically investigate LPCN 1144 in an expanded target population of adult male non-alcoholic steatohepatitis ("NASH") patients. Specifically, the FDA has waived the limitation of only testing in NASH subjects with total testosterone levels below 300 ng/dL (threshold for hypogonadism). LPCN 1144 is a differentiated oral treatment with a postulated multi-dimensional mechanism of action across the full NASH disease spectrum and has demonstrated meaningful liver fat reductions with good clinical tolerability for chronic use.

NASH is an advanced form of non-alcoholic fatty liver disease ("NAFLD") and occurs when fat accumulates in liver cells without excessive alcohol use and a patient has hepatitis (inflammation of the liver) and liver cell damage. 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 (Estes et al. Hepatology, 2018). A recent National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK") report (Sarkar et al. Gastroenterology 2019) suggests that 75% of biopsy confirmed NASH subjects have less than 372 ng/dL of total testosterone and that the degree of fibrosis severity is inversely related to free testosterone levels; thus, providing a good rationale for testing LPCN 1144 in adult NASH patients regardless of their hypogonadal status.

LPCN 1144 is currently being studied in the *LiFT* ("Liver Fat intervention with oral Testosterone") Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects. The *LiFT* clinical study is a prospective, multi-center, randomized, placebo-controlled multiple-arm study in biopsy-confirmed male NASH subjects with grade F2/F3 fibrosis and a NAFLD Activity Score ("NAS") ≥ 4 with a 36-week treatment period.

"We are excited about receiving FDA clearance to expand our target patient population in adult NASH males regardless of their hypogonadal status," said Dr. Mahesh Patel, President, Chief Executive Officer and Chairman of the Board of Lipocine. Dr. Patel further stated, "Besides the larger potential market opportunity for LPCN 1144, we believe testing in the expanded cleared patient population will be a pioneering and differentiated potential indication for LPCN 1144."

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 four development programs TLANDO, LPCN 1144, TLANDO XR (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. 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. TLANDO XR (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, the potential patient population for our product candidates, 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.

SOURCE Lipocine Inc.

For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, Phone: (801) 994-7383, mb@lipocine.com; Investors: Hans Vitzthum, Phone: (617) 535-7743, hans@lifesciadvisors.com

---