Lipocine Inc. Announces FDA Clearance of IND to Commence Phase 2 Study of LPCN 1144 in Biopsy Confirmed NASH Subjects

SALT LAKE CITY, Feb. 14, 2019 /PRNewswire/ -- Lipocine Inc. (Nasdaq: LPCN), a specialty pharmaceutical company, today announced that the U.S. Food & Drug Administration ("FDA") indicated that the Phase 2 clinical study of LPCN 1144 in non-alcoholic steatohepatitis ("NASH") with biopsy confirmed NASH subjects may proceed in response to the Company's Investigational New Drug ("IND") application. Lipocine's planned Phase 2 clinical study is a prospective, multi-center, randomized, placebo-controlled multiple-arm study in male hypogonadal biopsy-confirmed NASH subjects with grade F2/F3 fibrosis with an expected 36-week treatment period.

"We are pleased with the clearance of our IND to further evaluate LPCN 1144 starting in biopsy confirmed male hypogonadal NASH subjects. This is an important next step in advancing LPCN 1144 for treatment of NASH given the substantial liver fat reductions in the interim analysis observed via MRI-PDFF," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "There are currently no FDA approved products for the treatment of NASH and we believe our unique oral androgen, known to promote anabolism in the musculoskeletal system while generally repressing adiposity, can more effectively address the needs of this patient population with high likelihood of sarcopenia."

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 a proof-of-concept ("POC") liver imaging study. The POC liver imaging study is being conducted to assess liver fat changes in hypogonadal men at risk of developing non-alcoholic steatohepatitis NASH using MRI-PDFF technique. Sixteen-week results from the POC liver imaging study are expected in the first quarter of 2019. 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, with approximately 60% of NASH patients being male. Additionally, it is estimated that there are ~22 million hypogonadal males in U.S. between the ages of 30 and 79. Based on our POC liver imaging study, we estimate that approximately 25% of hypogonadal males have at least 10% liver fat, an indicator of patients at risk for NASH.

LPCN 1144, with up to 52 weeks exposure, exhibited no adverse drug reaction in the Hepatobilliary System Organ Class (e.g., peliosis hepatitis, hepatic neoplasms, cholestatic hepatitis and jaundice), no major adverse cardiac events ("MACE"), no signs of increased skeletal fragility or nephrotoxicity and good gastrointestinal tolerability.

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 current and future clinical trials including the Phase 2 study with LPCN 1144, the timing of completion of clinical trials including the ongoing LPCN 1144 clinical trial, 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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For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, (801) 519-4090, mb@lipocine.com; Investors: Hans Vitzthum , Phone: (617) 535-7743, hans@lifesciadvisors.com

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