Lipocine Files IND To Evaluate LPCN 1144 In Biopsy Confirmed NASH Subjects

SALT LAKE CITY, Jan. 24, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced that it has filed an Investigational New Drug application ("IND") with the U.S. Food and Drug Administration ("FDA") to initiate a Phase 2 clinical study of LPCN 1144 in non-alcoholic steatohepatitis ("NASH") with biopsy confirmed NASH subjects.

"This IND filing is an important step forward as we pursue further evaluation of LPCN 1144 in biopsy confirmed NASH patients for the treatment of NASH. There is currently no FDA approved product for the treatment of NASH and we believe our well-tolerated oral LPCN 1144 is well positioned to mechanistically address this disease and provide additional unmet benefits," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

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 liver fat imaging 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.

SOURCE Lipocine Inc.

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