

Lipocine Announces LPCN 1144 Clinical Trial Results Selected for Late-Breaker Presentation at The Liver Meeting® 2018

SALT LAKE CITY, Oct. 11, 2018 /PRNewswire/ -- [Lipocine Inc.](#) (NASDAQ: LPCN), a specialty pharmaceutical company, announced today that it has been selected to present LPCN 1144 results as part of the late-breaker session of The Liver Meeting® 2018. The presentation will highlight data from multiple clinical trials of LPCN 1144 in potential non-alcoholic fatty liver disease ("NAFLD") / non-alcoholic steatohepatitis ("NASH") patients. The Liver Meeting® 2018, which is the annual meeting of the American Association for the Study of Liver Diseases ("AASLD"), is being held November 9th – 13th in San Francisco, CA.

Presentation

Details

Title: Oral Testosterone Undecanoate Normalizes Liver Function Measures and Serum Triglycerides in Subjects At-Risk for Non-Alcoholic Fatty Liver Disease ("NAFLD")

Publication Number: LB-37

Date: Monday, November 12th

Location: Moscone Center North/South Building, Hall C

Time: Monday, November 12: 8:00 am – 5:30 pm;
Presenters Available: 12:30 pm–2:00 pm

LPCN 1144 is an oral androgen targeting androgen signaling pathways. The clinical studies to be presented include a randomized active-controlled clinical study designed to evaluate the efficacy, safety and tolerability of oral androgen therapy in patients having testosterone deficiency and a randomized placebo-controlled clinical study.

"We look forward to sharing the results from our clinical trials with our well-tolerated, safe, oral androgen, LPCN 1144, as part of the late-breaker poster session at The Liver Meeting," stated Mahesh Patel, Ph.D., Lipocine's Chairman, President and Chief Executive Officer. "The observed reduction in serum liver enzymes and lipids highlight the promise of LPCN 1144 as a potential therapy for NASH. Our proposed unique mechanism targets the full spectrum of NASH pathogenesis with collateral health benefits associated with treating liver diseases."

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 1111, LPCN 1107 and LPCN 1144. 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 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. LPCN 1144, an oral androgen, is being developed as a treatment of non-alcoholic steatohepatitis ("NASH") and is currently being studied in two proof-of-concept clinical studies. 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 and the FDA review process relating to its product candidates, the path to approvability by the FDA of Lipocine's development programs, the potential uses and benefits of our product candidates, including LPCN 1144, 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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