

Lipocine Announces the Presentation of Clinical Data for LPCN 1021, Its Oral Testosterone Replacement Therapy Product Candidate, at the American Society of Andrology 41st Annual Conference

SALT LAKE CITY, March 28, 2016 (GLOBE NEWSWIRE) -- [Lipocine Inc.](#) (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that clinical data for LPCN 1021, an oral testosterone replacement therapy ("TRT") product candidate being developed for adult males with conditions associated with a deficiency or absence of endogenous testosterone, also known as hypogonadism, will be presented at the American Society of Andrology 41st Annual Meeting in New Orleans, LA.

Poster details are as follows:

Title: [Effect of LPCN 1021 \(Oral Testosterone\) in Hypogonadal Men Reporting Psychosocial Symptoms at Baseline — Subgroup Analysis of SOAR \(Study of Androgen Replacement\) Trial](#)

Poster No: 85

Title: [Hypogonadal Men with Sexual Dysfunction Benefit from LPCN 1021 \(Oral Testosterone\) — SOAR \(Study of Androgen Replacement\) Trial](#)

Poster No: 122

Date/Time: Monday, April 4, 2016, 11:15 a.m. — 12:30 p.m. CT

Presenter: Nachiappan (Chidu) Chidambaram, Ph.D.
Vice President of Product Development, Lipocine Inc.

About LPCN 1021

LPCN 1021 is a novel twice-a-day oral testosterone replacement therapy product candidate that is designed to help restore normal testosterone levels in hypogonadal men. The safety and efficacy of LPCN 1021 is currently under FDA review. Lipocine expects LPCN 1021 will help fulfill an unmet need in the treatment of hypogonadism. The current testosterone market primarily uses short-acting injectable products as well as topical products that carry an FDA "black box" warning related to inadvertent transfer of testosterone to others. According to the IMS Health database, an average of half a million prescriptions a month have been dispensed so far in 2016 for TRT.

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. LPCN 1021, an oral testosterone replacement therapy product candidate, demonstrated positive efficacy and safety results in Phase 3 testing and has a New Drug Application under review with the FDA. LPCN 1111, a next-generation oral testosterone replacement therapy product with once-daily dosing, is currently in Phase 2 testing. LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, is currently in Phase 1 testing and has been granted orphan drug designation by the FDA. 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 relating to Lipocine's common stock, the FDA review process relating to our product candidates and the possible outcome of such process, clinical trials, the potential uses and benefits of our product candidates, product development and commercialization efforts and the projected timing and outcome of regulatory filings and actions. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to our products, expected product benefits, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the FDA's review of our NDA for LPCN 1021, the receipt of regulatory approvals, the results of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, the risks related to market conditions for Lipocine's common stock 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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<https://ir.lipocine.com/Lipocine-Announces-the-Presentation-of-Clinical-Data-for-LPCN-1021-Its-Oral-Testosterone-Replacement-Therapy-Product-Candidate-at-the-American-Society-of-Andrology-41st-Annual-Conference>