

Lipocine Announces the Presentation of Clinical Data for LPCN 1021, Its Oral Testosterone Replacement Therapy Product Candidate, at ENDO 2016

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 ENDO 2016 in Boston, MA.

"We are excited to share additional safety and efficacy data on LPCN 1021 with our peers and the clinical endocrinology community at ENDO," said Dr. Mahesh Patel, President and CEO of Lipocine. "This data reinforces our belief that LPCN 1021 represents a best-in-class TRT with the potential to offer significant benefits to men with hypogonadism."

Poster details are as follows:

Title: [Long-term Safety and Tolerability of Oral Testosterone \(LPCN 1021\) in Hypogonadal Men: Results from the 52-Week Phase 3 Study \(SOAR Trial\)](#)
Poster No: SUN 197

Title: [Hypogonadal Men with and without Cardiovascular Disorders Benefit from LPCN-1021 \(Oral Testosterone\) — SOAR \(Study of Androgen Replacement\) Trial](#)
Poster No: SUN 198

Date/Time: Sunday, April 3, 2016, 1:15 — 3:15 p.m. ET

Presenters: Adrian S. Dobs, MD, MHS, Director, Johns Hopkins Clinical Research Network, and Professor of Medicine, Johns Hopkins University

Anthony DelConte, MD, Chief Medical Director, 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, an 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.

CONTACT:

Morgan Brown
Executive Vice President & Chief Financial Officer
Phone: (801) 994-7383
mb@lipocine.com

Investors:
John Woolford

Phone: (443) 213-0500
john.woolford@westwicke.com

Media:
Heather Anderson
Phone: (980) 938-0260
handerson@6degreespr.com

<https://ir.lipocine.com/Lipocine-Announces-the-Presentation-of-Clinical-Data-for-LPCN-1021-Its-Oral-Testosterone-Replacement-Therapy-Product-Candidate-at-ENDO-2016>