Lipocine Announces First Patient Dosed in Phase 2B Clinical Study for LPCN 1111, a Novel Testosterone Replacement Therapy

SALT LAKE CITY, Jan. 04, 2016 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that the first patient has been dosed in its Phase 2b clinical study for LPCN 1111, a novel testosterone replacement therapy ("TRT") product candidate. The primary objectives of the study will be to determine the optimal dose of LPCN 1111 along with the safety and tolerability of LPCN 1111 and its metabolites following oral administration of single and multiple doses of LPCN 1111 in hypogonadal males.

"We are pleased to initiate a Phase 2b study for LPCN 1111, our candidate for once daily oral testosterone replacement therapy," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Progress with this product builds on our leadership position in oral testosterone replacement therapy."

About LPCN 1111

The current testosterone market is dominated by topical products that are associated with poor patient compliance and FDA "black box" warnings related to inadvertent transfer of testosterone. LPCN 1111 is a novel ester prodrug of testosterone, being developed as a next-generation testosterone replacement therapy product candidate with potential for increased compliance with once daily dosing. LPCN is a follow-on product candidate to LPCN 1021, a twice-daily oral testosterone product candidate which is currently under regulatory review with a FDA PDUFA goal date of June 28, 2016. LPCN 1111 uses the Company's proprietary solubilization technology to improve systemic absorption to give effective testosterone levels upon once daily dosing.

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 demonstrated positive efficacy and safety results in Phase 3 testing, is targeted for testosterone replacement therapy and has a NDA under review with the FDA. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone replacement therapy product with once daily dosing, that is currently in Phase 2 testing, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth with orphan drug designation, that is currently in Phase 1 testing.

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 the Lipocine's common stock and preferred stock, the FDA review process relating to our product candidates and the outcome of such process, clinical trials, the potential uses and benefits of the Lipocine's 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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