Lipocine Reports Positive Results of Multi-Dose Pharmacokinetic Study of LPCN 1107 for the Prevention of Preterm Birth in Pregnant Women

Relevant hydroxyprogesterone caproate levels achieved following oral administration
Amenable to dose adjustment while on therapy
Well tolerated with no serious adverse events or adverse drug reactions

SALT LAKE CITY, Feb. 16, 2016 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced top-line results from its multi-dose pharmacokinetic ("PK") dose finding clinical study of LPCN 1107, its oral hydroxyprogesterone caproate ("HPC") product candidate for the prevention of preterm birth.

The study was an open-label, four-period, four-treatment, randomized, single and multiple dose, PK study in pregnant women of three dose levels of LPCN 1107 and injectable HPC (Makena®). The study enrolled 12 healthy pregnant women (average age of 27 years) with a gestational age of approximately 16 to 19 weeks. Subjects received three dose levels of LPCN 1107 (400 mg BID, 600 mg BID, or 800 mg BID) in a randomized, crossover manner during the first three treatment periods and then received five weekly injections of HPC during the fourth treatment period. During each of the LPCN 1107 treatment periods, subjects received a single dose of LPCN 1107 on Day 1 followed by twice daily administration from Day 2 to Day 8. Following completion of the three LPCN 1107 treatment periods and a washout period, all subjects received five weekly injections of HPC.

Average steady state HPC levels (C_{avg}0-24) were comparable or higher for all three LPCN 1107 doses than for injectable HPC. HPC levels as a function of daily dose were linear for the three LPCN 1107 doses. Unlike the injectable HPC, steady state exposure was achieved for all three LPCN 1107 doses within seven days. The approved HPC injectable product is a single fixed dose product that does not allow for dose adjustments.

A previous literature study of 250 mg injectable HPC in pregnant women reported that the lowest preterm birth rates were seen when median HPC concentrations exceeded 6.4 ng/mL and that the plasma concentrations of HPC ranged between 3.7 to 56 ng/mL with the injectable HPC.[1] With all three LPCN 1107 doses tested, HPC exposure (C_{avg}0-24) did not fall below 6.4 ng/ml in any study subject.

LPCN 1107 was well tolerated across the three dose levels. No adverse drug reactions, serious adverse events, or deaths were reported during the study.

"We are pleased that the dose linearity and short duration to steady state demonstrated in this study could potentially allow dose adjustments of LPCN 1107 during the course of therapy to optimize the clinical outcome," said Dr. Mahesh Patel, President and CEO of Lipocine. "Given these encouraging data, we plan to request a meeting with the U.S. Food and Drug Administration ("FDA") to obtain agreement on a Phase 3 development plan."

About LPCN 1107

LPCN 1107 is a novel oral product candidate in development for the prevention of preterm birth in women with singleton pregnancy. Potential benefits of Lipocine's oral product candidate relative to current injectable products include: customized dosing for patients and the elimination of pain and site reactions associated with weekly injections, elimination of weekly doctor visits or visits from the nurse, and elimination of interference/disruption of personal, family or professional activities associated with weekly visits. LPCN 1107 has received orphan drug designation from the U.S. Food and Drug Administration.

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. 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 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 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.

[1]Caritis SN, Venkataramanan R, Thom E, et al. Relationship between 17-alpha hydroxyprogesterone caproate concentration and spontaneous

preterm birth. Am J Obstet Gynecol 2014;210(2):128.

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https://ir.lipocine.com/Lipocine-Reports-Positive-Results-of-Multi-Dose-Pharmacokinetic-Study-of-LPCN-1107-for-the-Prevention-of-Preterm-Birth-in-Pregnant-Women