Lipocine Announces Development Plans for LPCN 1107

SALT LAKE CITY, June 8, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced its development plans for LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate. Recently the company received a Type C written response from the U.S. Food and Drug Administration ("FDA") that outlined next steps in the development of the product as a potential treatment for the prevention of preterm birth ("PTB").

Based on the FDA feedback, Lipocine intends to complete formulation optimization on LPCN 1107 and then to conduct a multiple-dose pharmacokinetic ("PK") dose selection study in pregnant women. The PK dose selection study is planned to commence in the fourth quarter of 2015 or first quarter of 2016. At the completion of the PK selection study, Lipocine plans to schedule an End-of-Phase 2 meeting with the FDA to obtain agreement on a Phase 3 development plan.

Lipocine previously announced that LPCN 1107 has been granted orphan drug designation ("ODD") by the FDA. To obtain orphan drug exclusivity upon approval, LPCN 1107 will need to demonstrate clinical superiority to the same drug already approved for the same orphan indication. Demonstrating clinical superiority can be achieved through establishing that the product offers a "major contribution to patient care" among other things.

"We are encouraged with the FDA feedback on LPCN 1107 and look forward to beginning the next steps of this program," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "PTB represents a significant unmet medical need and we believe that LPCN 1107 has the potential to be the first oral product for this significant market opportunity."

About LPCN 1107

LPCN 1107 has the potential to become the first oral HPC product for the prevention of preterm birth in women with a prior history of at least one preterm birth. Potential benefits of our oral product candidate relative to current injectable products include 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.

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 lead product candidate, LPCN 1021, demonstrated positive top-line efficacy results in Phase 3 testing and is targeted for testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone 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, and 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 expectations regarding clinical trials, the potential uses and benefits of Lipocine's product candidates, and product development and commercialization efforts. 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, the receipt of regulatory approvals, the results of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine'sfilings with the U.S. Securities and Exchange Commission (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 Company's website at www.lipocine.com or 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.
