Lipocine Announces First Subject Dosed in Multi-Dose PK Study for Its Oral Product Candidate for the Prevention of Pre-Term Birth

SALT LAKE CITY, Sept. 28, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced the first subject dosed in its multi-dose PK dose finding clinical study for LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate, being developed as a potential therapy for the prevention of pre-term birth ("PTB"). The primary objective of the study will be study pharmacokinetics over an extended period of time with multiple dose strengths of oral administration of LPCN 1107 in pregnant women.

"We are pleased to initiate this study following recent feedback we received from theU.S. Food and Drug Administration," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Pre-term birth continues to be a significant unmet medical need, and LPCN 1107 as potentially the first oral product, may offer patients with an important new treatment option."

About LPCN 1107

LPCN 1107 has received orphan drug designation and has the potential to become the first oral HPC product for the prevention of pre-term birth in women with a prior history of at least one pre-term 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 pre-term birth with orphan drug designation, 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, product development and commercialization efforts and the projected timing of regulatory filings. 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 ofLipocine's products, and other risks detailed in Lipocine's filings 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.
