Lipocine Announces First Patient Dosed in Phase 1 Study in Pregnant Women of LPCN 1107, Potentially the First Oral Product for the Prevention of Preterm Birth

SALT LAKE CITY, Sept. 8, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced the first patient was dosed in a Phase 1 study in pregnant women of LPCN 1107, the company's oral hydroxyprogesterone caproate (HPC) product candidate. The primary objectives of the study will be to determine safety, tolerability and pharmacokinetics of oral administration of LPCN 1107 in pregnant subjects.

"Based on previous clinical testing, we believe that LPCN 1107 has the potential to become the first oral product for prevention of preterm birth. HPC is the only drug approved for prevention of recurrent preterm birth, a leading cause of peri-natal mortality and morbidity worldwide, but it is currently only available in an inconvenient injectable form that may cause pain at the site of injection and requires several visits to the physician during the course of treatment," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "We look forward to presenting top-line results from this study in 2015."

This Phase 1, open-label study will enroll up to eight healthy, pregnant female subjects of child bearing age with a normal pregnancy of 16 to 18 weeks. In period one, subjects will receive two doses of 400 mg oral LPCN 1107, administered 12 hours apart. In period two, subjects will receive two doses of 800 mg oral LPCN 1107, administered 12 hours apart. In period three, subjects will be given 250 mg of HPC via intramuscular injection. There will be a washout period of at least three days between each period. Blood samples will be taken and used to determine the pharmacokinetics for each period.

Previously in Phase 1 clinical testing, LPCN 1107 was well tolerated and achieved meaningful drug levels after oral administration in healthy, non-pregnant women.

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, currently in Phase 3 and is targeted to treat symptoms of low testosterone for men in need of testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth.

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 includes statements that are not historical facts relating to the potential uses and benefits of Lipocine's product candidates and product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to 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's filings with the U.S. Securities and Exchange Commission (the "SEC"), including, without limitation, its Form 10-K and other reports on Form 8-K, 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.
