Lipocine Receives FDA Orphan Drug Designation for LPCN 1107, an Oral Product Candidate for the Prevention of Preterm Birth

SALT LAKE CITY, June 2, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced the U.S. Food and Drug Administration ("FDA") has granted orphan drug designation to LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate, a potential treatment for the prevention of preterm birth ("PTB"). There are approximately 180,000 pregnancies annually in the United States in women with a prior history of at least one preterm birth. Lipocine previously announced positive Phase 1b top-line results with LPCN 1107 in pregnant women.

"We are pleased to receive orphan designation for LPCN 1107, as PTB represents a significant unmet medical need and we believe that LPCN 1107 has the potential to be the first oral product of the only approved drug for this significant opportunity," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We expect to announce our clinical development plan for the program in the near future."

The orphan drug designation is based on a plausible hypothesis that LPCN 1107 may be clinically superior to the same drug that is already approved for the same orphan indication. In order to obtain orphan drug exclusivity upon approval, LPCN 1107 will need to demonstrate that it is clinically superior to this already approved drug.

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

Orphan designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated.

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.
