Lipocine Announces First Patient Dosed in Phase 2a Study of LPCN 1111, a Novel Testosterone Ester for Oral Testosterone Replacement Therapy

SALT LAKE CITY, May 27, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced that the first patient has been dosed in a Phase 2a clinical study of LPCN 1111, a novel ester prodrug of testosterone, in hypogonadal males. The primary objectives of the study will be to determine safety, tolerability, single and steady state pharmacokinetics of testosterone following oral administration of LPCN 1111.

"Based on Phase 1 clinical data, we believe that LPCN 1111 has the potential to be a once a day oral testosterone replacement therapy or provide high average testosterone levels while limiting supraphysiological levels with a twice a day dosing regimen," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "We look forward to reporting top-line results from this study in the second half of 2014 which would become the basis for our Phase 2b study in hypogonadal males."

This 12 patient open-label pharmacokinetic study includes a single ascending dose followed by a fixed dose steady state arm in males between the age of 18 and 80, with documented onset of hypogonadism prior to age 65. These subjects must have serum total testosterone < 300 ng/dL based on two blood draws on two separate days. Subjects will receive three escalating single doses of LPCN 1111 followed by a 28 day multiple dose selected based on single dose results. Serum testosterone, dihydrotestosterone, parent ester and dihydrometabolite of the parent ester are analyzed using LC/MS method. Hematology, clinical chemistry, urinalysis, echocardiogram, prostate specific antigen and adverse events are monitored as part of safety assessment.

LPCN 1111 is a next-generation, novel ester prodrug of testosterone, being developed as a possible testosterone replacement treatment. LPCN 1111 uses the Company's Lip'ral technology to enhance solubility and improve systemic absorption. Previous clinical data suggested feasibility of either once or twice daily dosing.

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 expectations, clinical trials, 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.
