FDA Confirms Lipocine's Previously-Agreed Clinical Development Plan for LPCN 1021

SALT LAKE CITY, Dec. 15, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced that it has received confirmation from the U.S. Food and Drug Administration ("FDA") that the design of its ongoing pivotal Study of Oral Androgen Replacement ("SOAR") Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021 in hypogonadal men with low testosterone ("Low T") is currently acceptable for filing a New Drug Application ("NDA") for the class testosterone replacement therapy ("TRT") labeling. The FDA reiterated the primary efficacy endpoint required for approval being 75% of subjects with a Cavg for serum testosterone in the normal range with the lower bound of the two-sided 95% confidence interval being > 65%. Lipocine remains confident that our efficacy results are in line with approval requirements.

The FDA did not identify any additional clinical studies that would be required for NDA filing, but did state that should any safety signal become apparent during analysis of our SOAR Phase 3 study results or during the course of their review, it is possible that additional data may be required. Based on the response received, Lipocine does not anticipate the need to conduct additional studies above those previously agreed to with the FDAfor NDA filing. The FDA also acknowledged that they are still internally discussing the advice and recommendations from the FDA Advisory Committee held on September 17, 2014.

"We are pleased that the FDA confirmed that our SOAR Phase 3 clinical study design is sufficient for filing our NDA with LPCN 1021 for the class TRT labeling. We continue to target the second half of 2015 for filing the NDA upon completion of the ongoing safety extension," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "We continue to believe that LPCN 1021 represents a 'best-in-class' TRT option with the potential to both improve patient compliance and overcome inadvertent testosterone transference risk."

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 statements by the FDA, Lipocine's expected NDA filing and completion of the safety extension of Lipocine's SOAR Phase 3 clinical study, clinical trials, the potential uses and benefits of Lipocine'sproduct 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'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.
