Lipocine Submits New Drug Application to FDA for Its Oral Testosterone Replacement Product Candidate, LPCN 1021

SALT LAKE CITY, Aug. 31, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that it has submitted a 505(b)(2) New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for LPCN 1021, an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone ("hypogonadism").

"Filing of the NDA for LPCN 1021 is a significant achievement for Lipocine and a major milestone toward bringing this potential testosterone replacement therapy option to patients. LPCN 1021 has the potential both to improve the ease of use compared to the available formulations, including topical gels and injections, and to overcome inadvertent testosterone transference risk to children and partners," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We look forward to working closely with the FDA during the review process."

The NDA filing is supported by results from Lipocine's Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021 in hypogonadal men with low testosterone. The study met its primary efficacy endpoint by successfully restoring testosterone levels to the normal range in 88% of the subjects. In addition, 85% of the subjects reached their final dose with no more than one dose titration. LPCN 1021 treatment was well tolerated with no hepatic, cardiac, gastrointestinal or drug related serious adverse events.

About LPCN 1021

LPCN 1021 is a twice-a-day, oral testosterone replacement therapy product candidate with three simple oral dosing options that Lipocine expects will overcome the major shortcomings of existing products. The current testosterone market is dominated by topical products that carry FDA "black box" warnings related to inadvertent transfer of testosterone and by injectable products. The IMS Health database shows that an average of half a million prescriptions a month have been dispensed so far in 2015 for TRT.

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. A New Drug Application was filed with the FDA for Lipocine's lead product candidate, LPCN 1021. LPCN 1021 demonstrated positive - efficacy and safety results in Phase 3 testing and is targeted for testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone replacement 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 with orphan drug designation, 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 the FDA review process relating to our NDA for LPCN 1021 and the outcome of such process, clinical trials, the potential uses and benefits of Lipocine's product candidates, product development and commercialization efforts and the projected timing and outcome 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, risks related to the FDA's review of our NDA for LPCN 1021, 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.
