FDA Accepts for Filing Lipocine's New Drug Application for Its Oral Testosterone Replacement Product Candidate, LPCN 1021

SALT LAKE CITY, Oct. 29, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing its New Drug Application ("NDA") 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"). The acceptance by the FDA of the NDA indicates that the application is sufficiently complete to permit a substantive review.

"FDA acceptance of the NDA for LPCN 1021 is a significant milestone for both Lipocine and the millions of patients that could potentially benefit from an oral testosterone replacement therapy option," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We will continue to work with the FDA as they complete their review."

About LPCN 1021

LPCN 1021 is a novel 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 per month has 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. 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, that 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.

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