Lipocine Completes Enrollment in the LPCN 1021 Fixed Dose Clinical Trials

Top-line data from the studies expected in June 2017

SALT LAKE CITY, April 24, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced the completion of enrollment for both its dosing validation ("DV") study and its dosing flexibility ("DF") study for LPCN 1021. LPCN 1021 is an oral testosterone product candidate for testosterone replacement therapy in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.

"We are pleased to complete enrollment for the DV and DF studies which do not require any dose titration; thereby addressing the cited deficiency in the U.S. Food and Drug Administration's ("FDA") Complete Response Letter," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "We look forward to announcing the top-line results from these studies in June 2017, an important milestone toward the resubmission of LPCN 1021."

The DV study will assess LPCN 1021 in hypogonadal males on a fixed daily dose of 450 mg divided into two equal doses. The DV study is an open-label, fixed dose, no titration single treatment arm study of LPCN 1021. Efficacy will be assessed via responder analysis at the end of the dosing period which is 24 days. The pre-specified primary endpoint is the percentage of subjects with an average 24-hour serum testosterone concentration ("Cavg") within the normal range, with secondary endpoints based on maximum serum testosterone concentrations ("Cmax").

The DF study will assess LPCN 1021 in hypogonadal males on a fixed daily dose of 450 mg divided into three equal doses. The DF study is an open-label, fixed dose, no titration, single treatment arm study of LPCN 1021. Efficacy will be assessed via responder analysis at the end of the dosing period which is 24 days. The pre-specified primary endpoint is Cavg within the normal range, with secondary endpoints based on Cmax.

About LPCN 1021

LPCN 1021 is an oral testosterone replacement therapy product candidate containing Testosterone Undecanoate that is designed to help restore normal testosterone levels in hypogonadal men. Lipocine expects LPCN 1021 will help fulfill an unmet need in the treatment of hypogonadism. The current testosterone market primarily uses short-acting injectable products as well as topical products that carry an FDA "black box" warning related to inadvertent transfer of testosterone to others. Per the IMS Health database, an average of 540,000 prescriptions a month have been dispensed from January 2016 through December 2016 for testosterone products.

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 clinical development pipeline includes three development programs LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a novel oral prodrug of testosterone containing Testosterone Undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1021, was well tolerated and met the primary efficacy end-point in Phase 3 testing, which utilized 24-hour pharmacokinetic data for dose adjustments, and is currently being studied in two additional Phase 3 clinical trials. LPCN 1111, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing and is currently in pre-Phase 3 testing. LPCN 1107, the potentially first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth, has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA has been completed. For more information, please visit www.lipocine.com.

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 regarding Lipocine's FDA review process relating to LPCN 1021, the DV and DF studies, the possible outcome and timing of the DV and DF studies, the path to approvability by the FDA of LPCN 1021 and other development programs for LPCN 1111 and LPCN 1107. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will not approve LPCN 1021 or any of our other products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the FDA approval process, the receipt of regulatory approvals, the results and timing 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 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 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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