Lipocine to Initiate Dosing Validation Study for LPCN 1021, Oral Testosterone Replacement Product Candidate

SALT LAKE CITY, Dec. 05, 2016 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced it plans to initiate a dosing validation study after receiving feedback from the U.S. Food and Drug Administration ("FDA") of its protocol for LPCN 1021. LPCN 1021 is an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.

Based on the assessment received, Lipocine plans to initiate the dosing validation ("DV") study immediately and expects that the first patient will be screened in December 2016. The results of the DV study are expected to validate the dosing regimen for LPCN 1021 and provide critical data required for resubmission. The DV study is an open-label, fixed dose, single treatment arm study of LPCN 1021 in hypogonadal males and is expected to enroll 100 subjects. 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").

"We are pleased with the clarity received from the FDA on the DV study protocol, especially as we continue to advance LPCN 1021 into a position for approval," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "We look forward to the DV study initiation with top-line results from the DV study anticipated in the second quarter of 2017."

About LPCN 1021

LPCN 1021 is a novel twice-a-day 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 so far in 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 twice-daily oral testosterone replacement therapy product candidate, was well tolerated and met the primary efficacy end point in Phase 3 testing, which utilized 24-hour pharmacokinetic data for dose adjustments. LPCN 1111, a novel prodrug of testosterone, originated with and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing and is currently in Phase 2 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 was recently 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 additional clinical trial needed to validate our dosing regimen and the FDA process with respect to our planned SPA, the possible outcome and timing of such clinical trial or FDA review process, the path to approvability by the FDA of LPCN 1021, our commitment to bring LPCN 1021 to market, the results of the Phase 2b clinical study of LPCN 1111, the potential uses and benefits of our product candidates, and our product development efforts. 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, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the receipt of a CRL from the FDA for LPCN 1021, the receipt of regulatory approvals, the results and timing of clinical trials, including the additional clinical trial for LPCN 1021, 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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