Lipocine Receives Complete Response Letter (CRL) for LPCN 1021 From U.S. Food and Drug Administration

SALT LAKE CITY, June 29, 2016 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that it has received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") regarding 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, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.

The CRL identified deficiencies related to the dosing algorithm for the label. Specifically, the proposed titration scheme for clinical practice was significantly different from the titration scheme used in the Phase 3 trial leading to discordance in titration decisions between the Phase 3 trial and real-world clinical practice.

The next step will be to request a meeting with the FDA to understand more fully the issues raised and to agree on a path forward to achieve approval of LPCN 1021.

"We are evaluating the content of the CRL, including the FDA recommended actions to bring our NDA in a position for approval, and will work closely with the FDA to determine the appropriate next steps for the NDA. We remain committed to bringing LPCN 1021 to patients who will benefit from its intended use," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine. "We continue to believe that LPCN 1021 has the potential 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 that exist with topical gels.

About LPCN 1021

LPCN 1021 is a novel twice-a-day oral testosterone replacement therapy product candidate 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. According to the IMS Health database, an average of half a million prescriptions a month have been dispensed so far in 2016 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, an oral testosterone replacement therapy product candidate, demonstrated positive efficacy and safety results in Phase 3 testing. LPCN 1111, a next-generation oral testosterone replacement therapy product with once-daily dosing, is currently in Phase 2 testing. LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, is currently in Phase 1 testing and has been granted orphan drug designation by the FDA. 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 relating to Lipocine's FDA review process relating to LPCN 1021 and the possible outcome of such process, clinical trials, the regulatory process for our other product candidates, the potential uses and benefits of our product candidates, the TRT market, product development and commercialization efforts and the projected timing and outcome of regulatory filings and actions. 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, the risks related to market conditions for Lipocine's common stock 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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