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Lipocine Announces Submission of SPA on LPCN 1107, an Oral Alternative for the Prevention of Preterm Birth

SALT LAKE CITY, June 26, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that it has submitted a Special Protocol Assessment ("SPA") request to the U.S. Food and Drug Administration ("FDA"), as part of the ongoing interaction with the FDA on the detailed design of the planned Phase 3 clinical development program for LPCN 1107 for prevention of recurrent preterm birth ("PTB") with history of singleton pregnancy. An SPA is an advanced declaration from the FDA that a planned trial's design, clinical endpoints, and statistical analyses could potentially result in data acceptable for FDA review towards approval for the proposed indication.

The proposed Phase 3 clinical trial has been designed as an adequate and well-controlled non-inferiority trial comparing LPCN 1107 with Makena®, the current standard of care for PTB. Based on prior interactions with the FDA, Lipocine has proposed an efficacy endpoint focusing on the rate of delivery at less than 37 weeks gestation. Success on this gestational age endpoint could lead to Subpart H approval by the FDA. The proposed enrollment population is singleton pregnant women with a history of singleton spontaneous preterm birth. The proposed trial has an adaptive design with an interim analysis.

"We have submitted an SPA request to the FDA with the goal of solidifying the development and regulatory pathway for LPCN 1107, and specifically, the details of our planned Phase 3 clinical trial," said Dr. Mahesh V. Patel, Chairman, President and CEO of Lipocine. "Prevention of PTB is a significant unmet need with approximately 11.7% of all U.S. pregnancies resulting in this outcome (delivery less than 37 weeks). It is a leading cause of neonatal mortality and morbidity."

About LPCN 1107

LPCN 1107 is a novel oral product candidate in development for the prevention of recurrent preterm birth in women with singleton pregnancy. Potential benefits of Lipocine's oral product candidate relative to current injectable products include: the elimination of pain and site reactions associated with weekly injections, elimination of weekly doctor visits or visits from the nurse, and elimination of interference/disruption of personal, family or professional activities associated with weekly visits. LPCN 1107 has received orphan drug designation from the FDA.

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-points in Phase 3 testing with twice daily dosing. 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 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 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 1107, clinical trials related to LPCN 1107, the possible outcome and timing of such clinical trials or FDA review process, the path to approvability by the FDA of LPCN 1107 and other development programs for LPCN 1021 and 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 1107 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.

Makena® is a registered trademark of AMAG Pharmaceuticals, Inc.

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