Lipocine Receives FDA Guidance on the Phase 3 Program for LPCN 1107, an Oral Alternative for the Prevention of Preterm Birth

Critical Phase 3 study design input received from U.S. Food and Drug Administration ("FDA"):

- Agreed to a randomized open-label, two-arm clinical study to include a LPCN 1107 arm and a comparator intramuscular ("IM") arm with treatment up to 23 weeks
- Provided positive feedback on the proposed 800 mg BID Phase 3 dose and dosing regimen
- Confirmed the use of a surrogate primary endpoint focusing on rate of delivery less than 37 weeks gestation rather than on clinical infant outcomes
- Acknowledged that the use of a gestational age endpoint would likely lead to Subpart H approval as opposed to full approval
- Recommended a non-inferiority study margin of 7% with interim analyses

SALT LAKE CITY, Jan. 09, 2017 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced receipt of additional guidance from the U.S. Food and Drug Administration ("FDA") on the LPCN 1107 pivotal Phase 3 clinical study design. LPCN 1107, a novel oral hydroxyprogesterone caproate ("HPC") product candidate that has been granted orphan drug designation by the FDA, is in development for the proposed indication of reducing the risk of preterm birth ("PTB") in women with singleton pregnancy who have a history of singleton spontaneous PTB. Prevention of PTB is a significant unmet need as ~11.7% of all U.S. pregnancies result in PTB (delivery less than 37 weeks), a leading cause of neonatal mortality and morbidity.

The recent guidance received is in addition to feedback provided at the End of Phase 2 meeting with the FDA which occurred in August 2016. During the End of Phase 2 meeting and subsequent guidance meetings, the FDA agreed to a randomized, open-label, two-arm clinical study to include a LPCN 1107 arm and a comparator IM arm with treatment up to 23 weeks. The FDA also provided feedback on other critical Phase 3 study design considerations including: positive feedback on the proposed 800 mg BID Phase 3 dose and dosing regimen; confirmation of the use of a surrogate primary endpoint focusing on rate of delivery less than 37 weeks gestation rather on clinical infant outcomes; acknowledged that the use of a gestational age endpoint would likely lead to Subpart H approval as opposed to a full approval; and, recommended a non-inferiority study margin of 7% with interim analyses. Lipocine plans to submit the LPCN 1107 Phase 3 protocol to the FDA via a Special Protocol Assessment ("SPA") in the first half of 2017.

"We are appreciative of the clarity received from the FDA on the critical clinical and regulatory requirements needed to advance LPCN 1107 towards initiating the pivotal registration study," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine.

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, 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 1107, clinical trials related to LPCN 1107 and the related FDA review process for 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.

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