Lipocine Announces Positive Phase 1b Top-Line Results With LPCN 1107 in Pregnant Women

First demonstration of relevant hydroxyprogesterone caproate levels following oral administration in pregnant women
Projected dose between 400 and 800 mg twice a day is expected to be comparable to marketed 250 mg weekly IM product
Relative bioavailabilities similar between pregnant and non-pregnant women

SALT LAKE CITY, Jan. 12, 2015 (GLOBE NEWSWIRE) --Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced successful top-line results of a Phase 1b study of LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate. The primary objectives of the study were to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an intramuscular ("IM") HPC, as well as safety and tolerability in pregnant women.

"With positive pharmacokinetic data and the ability to achieve meaningful drug levels shown in pregnant women, we continue to believe that LPCN 1107 has the potential to become the first oral product for prevention of preterm birth," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "Given the known progestogenic activity of HPC and results from this study, we believe that LPCN 1107 may have market opportunities beyond prevention of preterm birth."

This Phase 1b open-label study enrolled eight healthy, pregnant women at 16 to 18 weeks gestation. All subjects received three treatments in sequence. In period one, subjects received two doses of 400 mg oral LPCN 1107, administered 12 hours apart. In period two, subjects received two doses of 800 mg oral LPCN 1107, administered 12 hours apart. In period three, subjects were given 250 mg of HPC via intramuscular injection (marketed product Makena®). Blood samples were collected periodically over 24 hours following oral dosing and over 28 days following the IM dose.

The maximum concentration ("Cmax") and the area under the curve ("AUC") for the oral treatments with LPCN 1107 are shown in Table 1.

Table 1: Single Dose Pharmacokinetic Parameters

Dosing Regimen (BID) (N=7*)	C_{max} (ng/ml) [range]	AUC_{0-24} (ng.h/ml) [range]
400mg	21.3	156
	[11.5 - 36.2]	[81 - 234]
800 mg	63.2	577
	[37.8 - 144]	[323 - 1365]

* one subject data analysis pending

Results from this study demonstrate significant HPC absorption following oral administration in healthy pregnant women. Additionally, there was a more than dose proportional increase in exposure with the 800 mg dose.

Steady state pharmacokinetic parameters for oral and IM dosing regimens were simulated based on single dose data and the Cmax and AUC values are shown in Table 2.

Table 2: Simulated Steady State Pharmacokinetic Parameters

Products / Dosing Regimen (N=7*)	$C_{ss,max}$ (ng/ml) [range]	AUC_{SS} (ng.h/ml)# [range]
LPCN 1107 / 400mg BID	21.6	1074
	[12.1 - 36.2]	[82 - 229]
LPCN 1107 / 800mg BID	71.1	4058
	[43.8 - 144.1]	[311 - 1100]
Intramuscular injection / 250mg weekly	13.0	1817
	[6.5 - 29.4]	[805 - 3904]

* one subject data analysis pending

AUCss calculated for post steady state 1 week duration

Based on the results shown in Table 2, LPCN 1107 dosing between 400 and 800 mg twice a day is expected to be comparable to the marketed 250 mg weekly IM product.

The simulated steady state PK parameters for oral and IM dosing from this study (LPCN 1107-14-003) were compared to

simulated steady state data from previously reported results from Phase 1a study (LPCN 1107-14-001) in non-pregnant women (see Table 3).

Table 3: Bioavailability in pregnant and non-pregnant women

	AUC $_{SS}$ (ng.h/ml)[#]		Relative bioavailability
Study population (N)	**LPCN 1107/ 400 mg BID Oral**	**Intramuscular Injection / 250 mg weekly**	**[oral / IM]**
Pregnant women (7*)	1074	1817	59 %
Non-pregnant women (10)	1348	2468	55 %

* one subject data analysis pending

AUCss calculated for post steady state 1 week duration

Based on the results shown in Table 3, relative bioavailability of oral to IM dosing was similar between pregnant and non-pregnant women.

In this study, LPCN 1107 was well tolerated with no serious adverse events observed. Lipocine plans to review the development plan with FDA before deciding next steps in the program.

About LPCN 1107

LPCN 1107 has the potential to become the first oral HPC product for the prevention of preterm birth in women with a prior history of at least one preterm birth. Potential benefits of our 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.

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 lead product candidate, LPCN 1021, demonstrated positive top-line efficacy results in Phase 3 testing and is targeted for testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product with once daily dosing, that is currently in Phase 2 testing, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, and is currently in Phase 1 testing.

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 expectations regarding clinical trials, the potential uses and benefits of Lipocine's product candidates, and product development and commercialization efforts. 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, the receipt of regulatory approvals, the results 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 U.S. Securities and Exchange Commission (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 Company's website at www.lipocine.com or 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.
