Lipocine Announces Successful Completion of Food Effect Study for LPCN 1021, an Oral Testosterone Product Candidate

Consistent and predictable therapeutic levels of testosterone when administered with a meal
No significant sensitivity to meal fat content

SALT LAKE CITY, June 15, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced the successful completion of its labeling "food effect study" for LPCN 1021, its Oral Testosterone product for hypogonadal men with low testosterone. Lipocine conducted the study per the U.S. Food and Drug Administration ("FDA") requirement for submitting the New Drug Application ("NDA") for LPCN 1021.

"Successful completion of the food effect study is another significant milestone towards both the filing of our NDA for LPCN 1021and potentially bringing this important new convenient therapeutic option to patients," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "Importantly, we remain on track to announce one-year safety data from the pivotal Phase 3 study by the end of June, as well as file the NDA in the second half of the year."

The labeling "food effect" study was an open-label, randomized, four-period, four-treatment, crossover, single-dose study evaluating bioavailability and pharmacokinetics of LPCN 1021 as a function of meal and meal fat content in hypogonadal males. Subjects received a single LPCN 1021 dose of 225 mg testosterone undecanoate (the starting dose in the completed Phase 3 clinical study) under fasted conditions and under the following fed conditions (approximately 30 minutes following an 800 to 1000 calorie meal): 15% of calories from fat ("low fat meal"), 30% calories from fat ("standard fat meal"), and 50% calories from fat ("high fat meal"). The study enrolled 14 hypogonadal males with 13 subjects completing the study.

Topline results from the labeling "food effect" study indicate that bioavailability of testosterone from LPCN 1021 is not affected by changes in meal fat content. The results demonstrate comparable testosterone levels between the standard fat meal (similar to the meal instruction provided in the Phase 3 clinical study) and both the low and high fat meals. Testosterone levels were also comparable between the low fat and high fat meals. Based on the comparative analysis of testosterone exposure in this study, LPCN 1021 bioavailability is not sensitive to low, standard, or high fat meal content. Preliminary data for the pharmacokinetic parameters of maximum observed serum concentration ("Cmax") and area under the curve ("AUC") for testosterone following administration of LPCN 1021 under fed conditions with meals of varying fat content are presented in Table 1.

Table 1: Comparative Pharmacokinetic Analysis for Testosterone Exposure following Administration of LPCN 1021 under Fed Conditions with Meals of Varying Fat Content (Study LPCN 1021-14-001, N = 13)

Parameter	Low Fat (~16.5 g) Meal[2]	Standard Fat (~30.1 g) Meal[1] (Reference)	High Fat (~53.5 g) Meal[3]
Cmax (ng/dL)			
Mean (% CV)	1570 (35%)	1560 (31%)	1680 (44%)
[Range]	[844 - 2610]	[746 - 2700]	[692 - 2910]
Point Estimate (90% CI bounds)	98.26 (82.18-117.48)	100	102.72 (85.92-122.82)
AUC 0-24h (ng*h/dL)			
Mean (%CV)	10429 (19%)	10421 (16%)	11974 (18%)
[Range]	[7529 - 14083]	[7817 - 14394]	[8729 - 15184]
Point Estimate (90% CI bounds)	98.86 (90.99-107.42)	100	114.06 (104.98-123.93)

Abbreviations: AUC =area under the curve; CI = confidence interval; Cmax = maximum observed serum concentration; CV = coefficient of variation

[1]30% total calories derived from fat content in the meal consistent with Phase 3 recommended meal

[2]15% total calories derived from fat content in the meal

[3]50% total calories derived from fat content in the meal

Administration of LPCN 1021 under fasted conditions resulted in a significant reduction in bioavailability as presented in Table 2.

Table 2: Pharmacokinetic Parameters for Serum Total Testosterone following LPCN 1021 Administration under Fasted vs Fed Conditions in Hypogonadal Men

Parameter	Fasted (N = 14)	Fed[1] (N = 13)
Cmax (ng/dL)		
Mean (% CV)	562 (26%)	1680 (44%)
[Range]	[342 - 880]	[692 - 2910]
AUC 0-24h (ng*h/dL)		
Mean (% CV)	7423 (19%)	11974 (18%)

[Range]		[5597 - 10787]	[8729 - 15184]

Abbreviations: AUC =area under the curve; Cmax = maximum observed serum concentration; CV = coefficient of variation

[1] 50% total calories derived from fat content in the meal

About LPCN 1021

The current testosterone market is dominated by topical products that are associated with poor patient compliance and FDA "black box" warnings related to inadvertent transfer of testosterone. LPCN 1021 is a twice-a-day, oral product candidate with three simple oral dosing options that we expect will overcome the major shortcomings of existing 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 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 with an orphan drug designation, 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'sfilings 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.
