Lipocine Announces Positive Top-Line Results in Phase 2a Study of LPCN 1111

Single daily oral dose provides testosterone levels in the eugonadal range
Demonstrated good dose response
Steady state achieved by day 14
No subject exceeded peak serum testosterone concentration of 1500 ng/dL on multi-dose exposure
Consistent inter-day performance
Well tolerated and no SAEs

SALT LAKE CITY, Oct. 13, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced positive top-line results from a Phase 2a clinical study of LPCN 1111, a novel testosterone replacement therapy ("TRT") candidate, in hypogonadal males. The primary objective of the study was to determine the feasibility of once daily dosing of LPCN 1111 in hypogonadal males.

"We are pleased that the results in the hypogonadal subject population confirmed our Phase 1 findings that LPCN 1111 is a candidate for once daily oral testosterone replacement therapy," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Additionally, these results, along with our positive top-line efficacy Phase 3 results for our lead asset, LPCN 1021, a twice-a-day oral TRT, are particularly important in establishing Lipocine'sleadership in providing "best in class" patient friendly oral TRT options. We believe that oral TRT will significantly increase patient compliance and overcome many of the inconvenience and transference issues associated with today's marketed TRT products."

This open-label, dose-escalating single and multiple dose study enrolled 12 males. These subjects had serum total testosterone < 300 ng/dL based on two blood draws on two separate days. Subjects received doses of LPCN 1111 as a single dose of 330 mg, 550 mg, 770 mg, followed by once daily administration of 550 mg for 28 days in 10 subjects, and once daily administration of 770 mg for 28 days in eight subjects.

Results from this study demonstrated the feasibility of a once daily dosing with LPCN 1111 in hypogonadal men and a good dose response. Additionally, the clinical study confirmed that steady state is achieved by day 14 with consistent inter-day performance observed on day 14, 21 and 28. No subjects exceeded peak serum testosterone concentration ("Cmax") of 1500 ng/dL at any time during the 28 day dosing period on multi-dose exposure. Overall, LPCN 1111 was well tolerated with no serious adverse events.

Responder analysis for average 24 hour serum testosterone concentration ("Cavg") and Cmax from this study for the 550 mg dose and the 770 mg dose at day 28 are shown below:

Responder analysis (Cavg and Cmax)

Measure	550mg QD	770mg QD	*Typical FDA targets for approval of TRT*
% subjects with C_{avg} within normal range	67%	88%	≥ 75%
% of subjects with C_{max} ≤1500ng/dL	100%	100%	≥ 85%
% of subjects with C_{max} between 1800ng/dL and 2500mg/dl	0%	0%	≤ 5%
% of subjects with C_{max} > 2500ng/dL	0%	0%	0%

Based on these positive results, a Phase 2b study is planned to begin in the first quarter of 2015 with the objective of determining the optimal once daily dosing regimen of LPCN 1111.

About LPCN 1111

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 1111 is a novel ester prodrug of testosterone, being developed as a next-generation testosterone replacement therapy product candidate. LPCN 1111 uses the Company's proprietary solubilization technology to improve systemic absorption to give effective testosterone levels upon once daily dosing.

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, 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 includes 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 efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to the receipt of regulatory approvals, the results of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine'sproducts, 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.
