Lipocine Announces Completion of Enrollment in its SOAR Phase 3 Study for Oral Testosterone Replacement Therapy

Top-line Efficacy Data Expected in 3Q14
NDA filing expected in 2H15

SALT LAKE CITY, April 29, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced that the Company has completed enrollment of its Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300). The trial is designed to evaluate the safety and efficacy of LPCN 1021, oral testosterone undecanoate ("TU"), in hypogonadal men with low testosterone ("Low T"). The Company expects top-line efficacy data for the trial to be available in the third quarter of 2014, with a New Drug Application ("NDA") filing with the U.S. Food and Drug Administration ("FDA") anticipated in the second half of 2015.

"We were highly pleased with the pace of enrollment for this pivotal trial," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "We believe the high degree of interest and participation in the study speaks to the potential demand that exists for a convenient, orally available testosterone replacement therapy. We look forward to reporting top-line efficacy results and making continued progress towards an NDA filing next year."

About the Phase 3 SOAR Trial

SOAR is a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of oral testosterone in hypogonadal males with low testosterone (< 300 ng/dl). In total, 315 subjects were randomized at 40 active sites in 2:1 ratio, such that 210 are being treated with LPCN 1021 and 105 with Androgel 1.62% (the leading gel product by sales) for 52 weeks. LPCN 1021 subjects are being dosed at 225 mg TU (equivalent to ~ 142 mg of T) twice daily (BID) and then titrated up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone as measured during weeks 3 and 7.

The primary endpoints of the study include the percentage of subjects achieving 24-hour average total serum testosterone concentration (Cavg(0-24)) within the normal range of 300-1140 ng/dL after completion of 13 weeks of treatment, as well as a measure of the lower bound of the 95% confidence interval for Cavg(0-24).

Secondary endpoints of the study are based on the maximum serum total testosterone concentration (Cmax) after completion of 13 weeks of treatment and include:

- percentage of subjects who have a Cmax below 1500 ng/dL
- percentage of subjects with Cmax between 1800 and 2500 ng/dL
- percentage of subjects with Cmax > 2500 ng/dL

Safety of LPCN 1021 will be monitored over the 52 weeks of treatment. Additional parameters that will be assessed after 52 weeks of treatment include:

- change from baseline in patient-reported outcomes for LPCN 1021
- change from baseline in safety laboratory parameters
- number of subjects with adverse events

Previous Phase 2 Data

Previously, Lipocine completed a successful Phase 2 study for LPCN 1021 that produced results after steady-state consistent with typical FDA targets for approval of testosterone replacement therapies for the starting dose of 225 mg TU BID, that was selected as the starting dose for the SOAR trial. The primary and secondary outcomes of the Phase 2 trial were met and there were no significant adverse events.

The Phase 2 study for LPCN 1021 enrolled 84 hypogonadal men across five parallel groups; 81 subjects completed the treatment. Four doses were used, starting at 75 mg TU and increasing to 150 mg TU, 225 mg TU, and then 300 mg TU to determine an effective dose for producing serum testosterone levels in a normally occurring range. Groups I through III received 75 mg TU, 150 mg TU, and 225 mg TU doses twice daily, respectively. The study duration was 15 days and doses were administered twice daily, 30 minutes after breakfast and dinner. Groups IV and V received 300 mg TU and 225 mg TU doses respectively and the study duration was 29 days. In these two groups the doses were also administered twice daily 30 minutes after breakfast and dinner.

Primary endpoints included Cavg (0-24) testosterone levels between 300 and 1140 ng/dL in at least 75% of patients and the lower bound of the 95% confidence interval is at least 65%. Secondary endpoints included a maximum serum testosterone level less than 1500 ng/dL in at least 85% of patients, maximum serum (Cmax) testosterone level between 1800 to 2500 ng/dL in less than or equal to 5% of patients, and no patients who experience maximum serum testosterone greater than 2500 ng/dL.

The combined 225 mg twice-a-day groups III and V (total of 24 subjects) met or exceeded the primary and secondary endpoint targets on day 15. There were no deaths or serious adverse events in the trial and no subject had liver enzymes above the upper limit of normal during the trial. The other key safety parameters, the ratio of dihydrotestosterone, or DHT, to T, and changes in estradiol, low-density lipoprotein, or LDL, high-density lipoprotein, or HDL, and prostate-specific antigen, or PSA, were within the range experienced with other approved testosterone replacement therapies.

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 with low gastro-intestinal drug exposure that we expect

will overcome the major shortcomings of existing products with a more patient/ physician friendly label that includes three simple dosing options and faster time to maintenance dose in most patients, which is expected to improve patient compliance. Unlike a selective estrogen receptor modulator ("SERM"), LPCN 1021 is not designed to interact with estrogen receptors and is targeted to address an unmet oral option needed in the established testosterone replacement market for chronic use.

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, currently in Phase 3 and is targeted to treat symptoms of low testosterone for men in need of testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth.

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, 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'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 Form 8-K, 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.

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