Lipocine Announces Positive Top-Line Results in Its Phase 3 Study of LPCN 1021 for Oral Testosterone Replacement Therapy

Met primary efficacy endpoint by successfully restoring testosterone levels to the normal range in 88% of the subjects
Lower limit of the 95% confidence interval was 82%
85% of the subjects reached final dose with no more than one dose titration
Majority of subjects ended on 225 mg BID
Proportion of subjects with maximum serum concentrations generally met FDA pre-specified targets
LPCN 1021 treatment was well tolerated with no drug related serious adverse events

SALT LAKE CITY, Sept. 24, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced positive top-line efficacy results from its ongoing Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021, an Oral Testosterone product, in hypogonadal men with low testosterone ("Low T"). Overall, the study demonstrated positive results with respect to the trial's primary efficacy endpoint with no serious adverse events. Lipocine continues to expect to file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") in the second half of 2015.

"We are extremely pleased with the robustness of the top-line results from this study which are consistent with the existing regulatory paradigm for Testosterone Replacement Therapy ("TRT") product approvals. We believe that LPCN 1021 represents a differentiated TRT for treating hypogonadism in men with the potential to both improve patient compliance and overcome inadvertent testosterone transference risk," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "We look forward to reporting additional safety results from this ongoing study."

About SOAR Phase 3 Trial:

SOAR is a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of oral TRT in hypogonadal males with low testosterone (< 300 ng/dL). In total, 315 subjects at 40 active sites were assigned, such that 210 were randomized to LPCN 1021 and 105 were randomized to the active control, for 52 weeks of treatment. The active control is included for safety assessment. LPCN 1021 subjects were started at 225 mg Testosterone Undecanoate ("TU") (equivalent to ~ 142 mg of T) twice daily ("BID") with a standard meal and then dose titrated, if needed, up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone measured during weeks 3 and 7. The mean age of the subjects in the trial is ~53 yrs with ~91% of the patients < 65 yrs of age.

Results:

Primary statistical analysis was conducted using the Efficacy Population Set ("EPS"). The EPS is defined as subjects randomized into the study with at least one PK profile and no significant protocol deviations and includes imputed missing data by last observation carried forward, N=152. Further analysis was performed using the safety set ("SS") (any subject that was randomized into the study and took at least one dose, includes imputed missing data by last observation carried forward and as treatment failures if no pharmacokinetic data available, N=210).

Efficacy

The primary efficacy end point is the percentage of subjects with an average 24 hour serum testosterone concentration ("Cavg") within the normal range, which is defined as 300-1140 ng/dL, after 13 weeks of treatment. The FDA guidelines for primary efficacy success is that at least 75% of the subjects on active treatment achieve a testosterone Cavg within the normal range; and the lower bound of the 95% confidence interval ("CI") must be greater than 65%.

LPCN 1021 successfully met the FDA primary efficacy guideline. In the EPS analysis, 88% of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82%. Additionally, sensitivity analysis using the SS reaffirmed the finding that LPCN 1021 successfully met the FDA primary efficacy guideline as 80% of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 74%.

Other highlights from the efficacy results include:

- Mean Cavg was 447 ng/dL with coefficient of variance of 37%
- Less than 12% of the subjects were outside the testosterone Cavg normal range at final dose
- 85% of subjects arrived at final dose with no more than one titration
- 51% of subjects were on final dose of 225 mg BID

Safety

Although the safety component of the SOAR trial is on-going, LPCN 1021 treatment has been well tolerated.

LPCN 1021 safety highlights include:

- 3% of the subjects reported a serious adverse event ("SAE"), with none of the SAEs being drug related
- All the drug related adverse events were either mild or moderate in intensity (none were severe)
- Hematocrit ("Hct") and prostate specific antigen ("PSA") increases were noted and consistent with other TRT products with one subject discontinued for elevated Hct exceeding pre-specified limits and one subject discontinued for elevated PSA exceeding pre-specified limits

In the EPS analysis, Cmax ≤1500 ng/dL was 83%, Cmax between 1800 and 2500 ng/dL was 4.6% and Cmax > 2500 ng/dL was 2%. Three

patients had a Cmax > 2500 ng/dL which were transient, isolated and sporadic. Moreover, none of these subjects reported any AEs. Results were generally consistent with those of approved TRT products.

The safety extension phase of the SOAR trial is on-going. The safety extension phase is designed to assess safety information such as metabolites, biomarkers, laboratory values, SAEs and AEs, with subjects on their stable dose regimen in both the treatment arm and the active control arm.

Conference Call and Webcast Details

Conference call details:
Date: September 24, 2014
Time: 8:45 a.m. US Eastern time
Dial-in number: 1 (877) 407-9708

Replay details:
Dates: September 24, 2014 until December 31, 2014
Dial-in number: 1 (877) 660-6853 / 1 (201) 612-7415
Conference ID: 13591771

Webcast details (live broadcast):
URL: https://event.webcasts.com/starthere.jsp?ei=1044036

A replay of the webcast will be available at the Company's web site, www.lipocine.com, in the "Investor Relations" section.

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, is currently in Phase 3 and is targeted for testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product with potential for once a day dosing, that is currently in Phase 2a 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 (i) the receipt of regulatory approvals, (ii) the results of clinical trials, (iii) patient acceptance of Lipocine's products, (iv) the manufacturing and commercialization of Lipocine's products, and (v) 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 10-Q and 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.
