Lipocine's Oral Testosterone Well Tolerated in Phase 3 Study

LPCN 1021 was well tolerated during 52 weeks of dosing
No reported hepatic, cardiac or drug-related serious adverse events ("SAEs")
Overall adverse event ("AE") profile for LPCN 1021 was comparable to the active control, Androgel® 1.62%

SALT LAKE CITY, June 29, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced top-line 52-week safety results from its 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 candidate, in hypogonadal men with low testosterone. Overall, LPCN 1021 was well tolerated with no hepatic, cardiac or drug-related SAE's reported. Lipocine announced positive top-line efficacy results from the SOAR study in September 2014. The company still expects to file a New Drug Application ("NDA"') with the U.S. Food and Drug Administration ("FDA") in the second half of 2015.

"We are pleased with the safety profile demonstrated by LPCN 1021. We believe that the efficacy and safety data from the SOAR study reinforces our understanding that LPCN 1021 represents a 'best-in-class' testosterone replacement therapy ("TRT") option with the potential to both improve treatment compliance and overcome inadvertent testosterone transference risk to children and partners," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "We look forward to bringing this important new medicine to patients as we continue to work diligently on filing the NDA."

About SOAR Phase 3 Trial:

SOAR is a randomized, parallel-group, active-controlled, open-label Phase 3 clinical study of oral TRT in hypogonadal males with low testosterone (< 300 ng/dL). In total, 315 subjects at 40 sites were randomized, such that 210 were randomized to LPCN 1021 and 105 were randomized to active control, for 52 weeks of treatment. Efficacy and safety were evaluated during the initial 13 weeks of the study and subjects continued to receive treatment through 52 weeks during a safety extension phase. All subjects randomized to LPCN 1021 were started at 225 mg testosterone undecanoate ("TU") (equivalent to ~ 142 mg of testosterone) twice daily ("BID") and then dose titrated, if needed, up to 300 mg TU BID or down to 150 mg TU BID. Dose titration decisions were based on serum testosterone levels measured during weeks 3 and 7. All doses were to be taken with a standard meal. The safety extension phase of the study provided key safety information about LPCN 1021 and the active control while subjects were on a stable dosing regimen.

Overall, subjects had a mean age of approximately 53 years, average body mass index ("BMI") of 31 kg/m^2, and baseline testosterone of ~ 205 ng/dL. Demographics and baseline characteristics were similar between treatment groups. Study discontinuation rates were comparable across both groups.

Adverse Events:

The safety population, defined as subjects who received at least one dose of study drug, comprised 314 subjects; 210 subjects who received LPCN 1021 and 104 subjects who received the active control. The only AE's occurring in more than 5% of subjects with either LPCN 1021 or the active control were upper respiratory tract infection (5.2% with LPCN 1021 and 5.8% with active control) and fatigue (2.4% with LPCN 1021 and 6.7% with active control). Any SAE and cardiac AE profiles were consistent between treatment groups and none of the observed cardiac AEs occurred in greater than 1.0% of the subjects in the LPCN 1021 arm and none were classified as severe.

Adverse Drug Reactions (ADRs):

ADRs, drug-related AEs, occurring in more than 2% of subjects with either LPCN 1021 or active control were headache (0.5% with LPCN 1021 and 3.9% with active control), acne (2.9% with LPCN 1021 and 2.9% with active control) and patient reported weight increase (2.4% with LPCN 1021 and 0% with active control). The overall mean weight change as compared to baseline was not significantly different between the treatment groups. Weight changes greater than 10% from baseline over 52 weeks occurred in 2.3% of subjects with LPCN 1021 and 3.8% of subjects with the active control. All observed ADRs were classified as mild or moderate in severity and no serious ADRs occurred during the 52-week treatment period. ADRs, such as peripheral edema, polycythemia, and thrombocytopenia, occurred in 1% or fewer subjects with LPCN 1021.

Other Safety Parameters:

There were no significant changes in mean systolic and diastolic blood pressure from baseline in either treatment arm. Mean values for the lipid parameters, except high density lipoprotein levels ("HDL"), were not significantly different from baseline. Mean HDL levels following LPCN 1021 treatment decreased slightly from baseline but were not significantly different from the active control after 52 weeks of exposure. Mean values for cardio biomarkers were not significantly different from baseline. Mean values for liver enzymes remained within the normal range. Mean values for hematocrit, hemoglobin, platelet count, prothrombin time and prostate specific antigen, were not significantly different from baseline. Mean dihydrotestosterone levels increased from baseline following LPCN 1021 treatment, but were comparable to changes seen with the active control.

In summary, LPCN 1021 was well tolerated upon 52-week exposure with no hepatic, cardiac or drug related SAEs.

About LPCN 1021

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. The current testosterone market is dominated by topical products that are associated with FDA "black box" warnings related to inadvertent transfer of testosterone and by injectables.

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 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, product development and commercialization efforts and the projected timing of regulatory filings. 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.
