Lipocine Announces First Patient Dosed in Phase 3 Study for Oral Testosterone Replacement Therapy

SALT LAKE CITY, Feb. 10, 2014 (GLOBE NEWSWIRE) --Lipocine Inc. (OTCQB:LPCN), a specialty pharmaceutical company, today announced that the first patient has been dosed in its Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study. The trial is designed to evaluate the safety and efficacy of LPCN 1021, an oral testosterone replacement therapy, in hypogonadal men with low testosterone (Low T; www.lowtstudy.com). Approximately 300 patients are expected to be enrolled in multiple sites in the United States. The company expects to report top-line efficacy data for the trial in the second half 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.

"LPCN 1021 represents a differentiated testosterone replacement therapy approach to treating hypogonadism in men that has the potential to improve patient compliance and overcome inadvertent testosterone transference risk of secondary exposure to women and children associated with topicals" said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "The commencement of the Phase III trial is an important milestone for both LPCN 1021 and the company as we move into late-stage testing for our lead product." "We are pleased with the high degree interest in this study shown by both investigators and patients," added Dr. Patel.

About the SOAR Trial

SOAR is a randomized, open-label, parallel-group, Phase 3 clinical study of hypogonadal males with low testosterone (< 300 ng/dl). All subjects will be randomized in 2:1 ratio, such that approximately 200 will be treated with LPCN 1021 for 52 weeks and 100 with Androgel 1.62% (the leading gel product by sales) for 52 weeks.

The co-primary endpoints of the study will be the percentage of subjects achieving 24-hour average total serum testosterone concentration (C_{avg}(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 C_{avg}(0-24).

Secondary endpoints of the study are based on the maximum serum total testosterone concentration (C_{max}) after completion of 13 weeks of treatment and will include:

- percentage of subjects who have a C_{max} below 1500 ng/dL
- percentage of subjects with C_{max} between 1800 and 2500 ng/dL
- percentage of subjects with C_{max} > 2500 ng/dL

Safety of LPCN 1021 will be monitored over the 52 weeks of treatment.

Previously, Lipocine completed a successful Phase II study for LPCN 1021 that produced results consistent with FDA guidelines for approval of testosterone replacement therapies for the starting dose selected for the SOAR trial. The primary and secondary outcomes of the trial were met and there were no significant adverse events.

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 we expect will 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, is Phase III ready 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 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 include all statements that are not historical fact relating to expectations and statements relating to clinical trials and the potential benefits of Lipocine's product candidates, including LPCN 1021, LPCN 1111 and LPCN 1107, and Lipocine's 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, including without limitation its Current Report on Form 8-K as amended, dated July 24, 2013, and in its reports on Form 10-Q and other reports on Form 8-K. Lipocine assumes no obligation to update forward-looking statements contained in this release, except as required by law.

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