Lipocine Announces Results From Pre-NDA Meeting for LPCN 1021, an Oral Testosterone Product Candidate

SALT LAKE CITY, March 24, 2015 (GLOBE NEWSWIRE) --Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced that it has completed its pre-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration ("FDA") related to LPCN 1021, its Oral Testosterone product for hypogonadal men with low testosterone. The purpose of the meeting was to discuss and obtain concurrence regarding adequacy for submission of the proposed NDA package for LPCN 1021 and to receive guidance on the 505(b) (2) filing and approval.

Based on the FDA's preliminary response, Lipocine does not expect to conduct any additional clinical studies other than the on-going labeling "food effect" study which has always been required for the expected submission of the NDA. Lipocine is conducting the labeling "food effect" study per the FDA requirement and plans to submit preliminary results from this study to the FDA in the second quarter of 2015 for review and comment prior to submitting the NDA.

The labeling "food effect" study is an open-label, randomized, four period, four treatment, crossover, single dose study evaluating bioavailability and pharmacokinetics of LPCN 1021 as a function of food fat content in hypogonadal males. The study is being conducted at a single site and will enroll 16 hypogonadal males with ages ranging between 18 and 80.

Based on our meeting with the FDA, we do not expect to be required to conduct a heart attack and stroke risk study or any additional safety studies prior to filing the NDA for LPCN 1021. As a result of our meeting, there is no change in our previous guidance with respect to our projected NDA filing for LPCN 1021 in the second half of 2015.

"We are pleased with a very productive pre-NDA meeting with the FDA that enabled us to get detailed guidance regarding our planned NDA filing. This meeting represents the completion of another important milestone for Lipocine. LPCN 1021 has the potential to be the 'best-in-class' testosterone replacement option, with respect to both improved patient compliance and elimination of the inadvertent testosterone transference risk," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "We look forward to the announcement of the one-year safety data from the pivotal Phase 3 study by mid-year as well as the NDA filing in the second half of this year."

LPCN has previously announced positive efficacy and safety 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. The study demonstrated positive results with respect to the trial's primary efficacy endpoint with no serious adverse events to date classified as drug related or cardiovascular in nature.

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, 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, 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, and product development and commercialization efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, planned regulatory filings and expected regulatory requirements, the timing of results from clinical trials, 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.
