Lipocine Announces Positive Top-Line Phase 2b Study Results for LPCN 1111, a Next Generation Oral Testosterone Replacement Therapy

Once-daily dose identified for the pivotal Phase 3 study
Well tolerated with no drug-related severe or serious adverse events reported

SALT LAKE CITY, Sept. 26, 2016 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today reported positive top-line results from a Phase 2b clinical study of LPCN 1111, a novel oral testosterone replacement therapy ("TRT") product candidate. The primary objectives of the study were to determine the Phase 3 dose of LPCN 1111 along with the safety and tolerability of LPCN 1111 and its metabolites following oral administration of single and multiple doses in hypogonadal males.

The Phase 2b clinical trial was a randomized, open label, two-period, multi-dose PK study that enrolled hypogonadal males into five treatment groups. Each of the 12 subjects in a group received treatment for 14 days. Results of the Phase 2b study suggest that the primary objectives were met, including identifying the dose expected to be tested in a Phase 3 study. Good dose-response relationship was observed over the tested dose range in the Phase 2b study. The target Phase 3 dose met primary and secondary end points. LPCN 1111 was well tolerated with no drug-related severe or serious adverse events reported.

"We are pleased to report these positive top-line results, as these results reinforce our belief that LPCN 1111 represents a promising product candidate for once daily administration of testosterone," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Based on this progress, we plan to meet with the United States Food and Drug Administration to discuss Phase 3 development plans."

About LPCN 1111

LPCN 1111, a novel prodrug of testosterone, originated with and is being developed by Lipocine as a next-generation oral testosterone product with potential for once daily dosing. LPCN 1111 comprises a novel prodrug different from the testosterone ester in LPCN 1021 and it uses Lipocine's proprietary solubilization technology to improve systemic absorption to give effective testosterone levels.

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 clinical development pipeline includes three development programs LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a twice-daily oral testosterone replacement therapy product candidate, was well tolerated and met primary efficacy end point in Phase 3 testing which utilized 24-hour pharmacokinetic data for dose adjustments. LPCN 1111, a novel prodrug of testosterone, originated with and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing and is currently in Phase 2 testing. LPCN 1107, the potentially first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth, has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA was recently completed. For more information, please visit www.lipocine.com.

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 the potential uses and benefits of LPCN 1111 and the potential uses and benefits of our other product candidates. 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 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 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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https://ir.lipocine.com/Lipocine-Announces-Positive-Top-Line-Phase-2b-Study-Results-for-LPCN-1111-a-Next-Generation-Oral-Testosterone-Replacement-Therapy