Lipocine Validates "No Titration" Dosing Regimen With Positive Topline Efficacy Results for LPCN 1021, Oral Testosterone Candidate

LPCN 1021 achieved primary endpoints confirming the efficacy of twice daily oral administration
LPCN 1021 generally met the pre-specified per dose secondary endpoints for twice daily oral administration
New Drug Application resubmission planned in the third quarter of 2017

SALT LAKE CITY, June 19, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced results from both the Dosing Validation ("DV") and the Dosing Flexibility ("DF") studies evaluating efficacy and tolerability of LPCN 1021. LPCN 1021 is an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The results from these studies confirm the validity of a fixed dose approach without the need for dose titration to orally administering LPCN 1021.

LPCN 1021 successfully met the FDA primary efficacy guidelines in the DV study where 81% of the subjects achieved average testosterone levels ("C_{avg}") within the normal range with a lower bound confidence interval ("CI") of 72%. The DF study restored 70% of the subjects' average testosterone levels within the normal range (C_{avg}) confirming that twice daily ("BID") dosing is the appropriate dosing regimen for LPCN 1021 and will be the basis for resubmission.

The adverse event profile of LPCN 1021 in both the DV and DF studies was consistent with the previously conducted 52-week Phase 3 Study of Androgen Replacement ("SOAR") clinical trial. All drug related adverse events ("AEs") were either mild or moderate in intensity and none were severe. To date, the safety database of LPCN 1021 includes ~525 hypogonadal men demonstrating a profile consistent with other TRT products.

The secondary endpoints assessed the maximum total testosterone concentration ("C_{max}") post dosing using predetermined limits developed by U.S. Food and Drug Administration ("FDA") for transdermals. Consistent with the definition of C_{max} and the pharmacokinetic profile of multiple times a day dosing, two pre-specified analyses were performed, C_{max} per dose and C_{max} per day.

In the DV study Cmax per dose analysis, the percentage of subjects with C_{max} less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively. Deviations from the predetermined limits in the DV study were observed in the C_{max} per day dose analysis for these thresholds. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.

The DF study met all Cmax thresholds in per dose and per day dose analyses.

"We are pleased with the confirmation of LPCN 1021 efficacy, especially with a more practical patient and physician preferred "no titration" dosing regimen. We believe the results should address the label-related deficiency cited by the FDA in our NDA submission," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. Dr. Patel further stated, "We consider LPCN 1021 to be a differentiated TRT option for treating hypogonadism in men with the potential to both improve patient compliance and eliminate the risk of testosterone transference. We look forward to resubmitting the NDA in the third quarter of 2017."

About LPCN 1021

LPCN 1021 is an oral testosterone replacement therapy product candidate containing Testosterone Undecanoate that is designed to help restore normal testosterone levels in hypogonadal men. Lipocine expects LPCN 1021 will help fulfill an unmet need in the treatment of hypogonadism. The current testosterone market primarily uses short-acting injectable products as well as topical products that carry an FDA "black box" warning related to inadvertent transfer of testosterone to others. Per the IMS Health database, an average of 540,000 prescriptions a month have been dispensed from January 2016 through December 2016 for testosterone 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 clinical development pipeline includes three development programs LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1021 was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing. LPCN 1111, a novel oral prodrug of testosterone, originated 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 has been 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 regarding Lipocine's FDA review

process relating to LPCN 1021, the DV and DF studies, including the efficacy of LPCN 1021 and whether the results will address the label-related deficiency cited by the FDA in our NDA submission, the path to approvability by the FDA of LPCN 1021 and the other development programs for LPCN 1111 and LPCN 1107, the potential impact of LPCN 1021 on users and the timing and results of the resubmission of the NDA. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will not agree with our conclusions from the DV and DF studies or approve LPCN 1021 or any of our other products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the FDA approval process, risks related to the possibility that the FDA will require an advisory committee meeting with respect to LPCN 1021, the receipt of regulatory approvals, the results and timing 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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