Lipocine Announces FDA Acknowledgement of TLANDO™ ("LPCN 1021") NDA Resubmission; PDUFA Goal Date, February 8, 2018

SALT LAKE CITY, Aug. 14, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that the U.S. Food & Drug Administration ("FDA") has acknowledged receipt of the Company's New Drug Application ("NDA") resubmission for TLANDO, its 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 FDA has deemed the resubmission a complete response to its June 2016 Complete Response Letter ("CRL") that requested additional information related to the dosing algorithm for the proposed label. The FDA has assigned a new Prescription Drug User Fee Act ("PDUFA") goal date of February 8, 2018. The TLANDO NDA is based on the results of the Dosing Validation ("DV" **)** study. The DV study confirmed the efficacy of TLANDO with a fixed dose regimen without need for dose adjustment. TLANDO was well tolerated upon 52week exposure with no reports of drug related Serious Adverse Events ("SAEs").

"The FDA's acceptance of the TLANDO NDA resubmission brings us one step closer to providing an innovative oral testosterone replacement treatment option to patients. We believe TLANDO addresses a significant unmet medical need for men with hypogonadism," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

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 TLANDO, LPCN 1111 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. TLANDO was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing and is currently under FDA review. 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 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and 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 product candidates and related clinical trials and the FDA review process relating to its product candidates, our belief that we have addressed the CRL deficiency, the expected timing of the FDA review process related to our resubmitted NDA, the path to approvability by the FDA of Lipocine's development programs, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including that the FDA will determine there are deficiencies in our resubmitted NDA, risks related to the possibility of an advisory committee meeting related to TLANDO, 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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