

Lipocine Announces FDA Advisory Committee Meeting for TLANDO™

SALT LAKE CITY, Sept. 20, 2017 (GLOBE NEWSWIRE) -- [Lipocine Inc.](#) (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that the Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC") of the U.S. Food and Drug Administration ("FDA") plans to discuss the New Drug Application ("NDA") submitted by the Company for TLANDO, its oral testosterone product candidate for the proposed indication of testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The advisory committee meeting date has not been finalized but will occur prior to the Prescription Drug User Fee Act ("PDUFA") goal date of February 8, 2018.

"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. "With TLANDO's robust primary endpoint results, comparable safety profile to the active control, flexibility in dietary fat consumption, and no requirement for dose titration, we remain confident in our ability to potentially bring the first oral TRT option to patients and look forward to discussing our NDA with BRUDAC."

BRUDAC reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology and related specialties, and makes appropriate recommendations to the Commissioner of the FDA.

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, 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, the risk that BRUDAC may make a negative recommendation to the Commissioner of the FDA with respect to TLANDO, 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, 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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