FDA Advisory Committee Scheduled to Review TLANDO™ on January 10, 2018

SALT LAKE CITY, Oct. 18, 2017 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced the U.S. Food and Drug Administration ("FDA") has scheduled the Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC") meeting on January 10, 2018 to discuss the New Drug Application ("NDA") for TLANDO, the Company's 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 FDA has previously set February 8, 2018 as the Prescription Drug User Fee Act ("PDUFA") goal date.

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. Although the FDA will consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

Lipocine announced on August 14, 2017 that the FDA had acknowledged receipt of the NDA resubmission for TLANDO. The NDA included the results of a Dosing Validation ("DV") study which confirmed the efficacy of TLANDO with a fixed dose regimen without need for dose adjustment, together with an integrated safety set ("ISS") from all conducted clinical trials of TLANDO.

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.

CONTACT:

Morgan Brown
Executive Vice President & Chief Financial Officer
Phone: (801) 994-7383
mb@lipocine.com

Investors:
Hans Vitzhum
Phone: (646) 597-6979
hans@lifesciadvisors.com
