Lipocine Announces Outcome of FDA Advisory Committee Meeting for TLANDO™, Testosterone Replacement Therapy in Adult Males with Hypogonadism

SALT LAKE CITY, Utah, Jan. 10, 2018 /PRNewswire/ -- 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") voted six in favor and thirteen against the benefit/risk profile of TLANDO, the Company's 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 role of BRUDAC is to provide recommendations to the FDA. The FDA decision on whether or not to approve the TLANDO New Drug Application ("NDA") is anticipated by the assigned Prescription Drug User Fee Act ("PDUFA") goal date of May 8, 2018.

"We continue to believe that efficacy and safety results from numerous clinical studies with TLANDO are consistent with other FDA approved TRT products," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "We look forward to continuing to work with the FDA through the remainder of the review process."

The BRUDAC discussions were based on the NDA currently under review by the FDA. The NDA includes efficacy and safety data on TLANDO including the results from three Phase 3 clinical trials: the Dosing Validation ("DV") clinical study, the Dosing Flexibility ("DF") clinical study and the Study of Oral Androgen Replacement ("SOAR") clinical study. Lipocine resubmitted the NDA to the FDA in August 2017 based on the results of the DV study. The DV study confirmed the efficacy of TLANDO with a fixed dose regimen without the need for dose adjustment. TLANDO successfully met the FDA primary efficacy guidelines in the DV study safety statistical analysis set ("SS") where 80% of the subjects achieved average testosterone levels ("Cavg") within the normal range with a lower bound confidence interval ("CI") of 72%. TLANDO was well tolerated upon 52-week exposure with no reports of drug related Serious Adverse Events ("SAEs").

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

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. 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 impact of the BRUDAC recommendation on the FDA's decision process, 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.

SOURCE Lipocine Inc.

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