Lipocine Receives Complete Response Letter for TLANDO From U.S. Food and Drug Administration

SALT LAKE CITY, May 9, 2018 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, announced today that it has received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") regarding its New Drug Application ("NDA") for 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. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.

The CRL identified four deficiencies which include the following: determining the extent, if any, of*ex vivo* conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an ambulatory blood pressure monitoring study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. The CRL also identified additional comments that are not considered approvability issues. The next step will be to request a meeting with the FDA to further evaluate the deficiencies raised and to agree upon a path forward for a potential approval of TLANDO.

"While we are disappointed by the FDA's decision, the deficiencies identified in the CRL are within our expectations following the meeting we had on January 10, 2018 with the Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC") of the FDA. We are assessing the content of the CRL, including the information that may be needed to resolve the deficiencies. We remain committed to work with the FDA to bring TLANDO to patients," 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 received a Complete Response Letter from the FDA on May 8, 2018. 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, is currently in Phase 2 testing 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, the FDA review process relating to its product candidates, the path to approvability by the FDA of Lipocine's product candidates, 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 additional clinical trials will be required before the FDA will consider approving TLANDO, that the FDA may 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 any NDA we may submit or resubmit, the receipt of receiving further complete response letters or not receiving regulatory approvals, the results, timing, delays and monetary costs 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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