

Lipocine Announces TLANDO™ NDA PDUFA Action Date of November 9, 2019

SALT LAKE CITY, May 14, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the U.S. Food and Drug Administration ("FDA") has accepted its New Drug Application ("NDA") for TLANDO as testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The FDA has assigned November 9, 2019 as the Prescription Drug User Fee Act ("PDUFA") goal date.

In 2018, approximately 7.2M scripts were written for non-oral TRT. An easy to use non-invasive oral TRT option has benefit over topicals due to no risk of accidental testosterone transference. TLANDO is designed as a fixed dose oral TRT. Research suggests that a fixed dose TRT regimen may be a preferred regimen by payers, patients, and prescribers. TLANDO and long acting TLANDO XR ("LPCN 1111") are part of Lipocine's TRT franchise of development candidates.

The NDA incorporates data compiled by Lipocine in order to address deficiencies identified by the FDA in a Complete Response Letter ("CRL") to the Company in 2018 and discussed in the Post Action Meeting with the FDA.

About Lipocine

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes TLANDO, LPCN 1144, TLANDO XR ("LPCN 1111"), LPCN 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of pre-cirrhotic NASH. TLANDO XR, 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. In a phase 2 clinical evaluation when administered as once daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of NASH cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate, with end of phase 2 meeting completed, 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 current and future clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, the timing of the FDA NDA review process, 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 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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