

Lipocine Provides Regulatory Update for TLANDO™

SALT LAKE CITY, Aug. 28, 2020 /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 informed the Company that it needs additional time to complete its review of TLANDO's New Drug Application ("NDA") and is committed to taking action as expeditiously as possible. The anticipated Prescription Drug User Fee Act ("PDUFA") goal date was August 28, 2020 for TLANDO. Although the FDA did not provide a timeline on a new action date, the FDA informed the Company that the review is expected to be completed in the coming weeks. The FDA has not asked for any additional data and the Company has provided the FDA with all information requested to date.

TLANDO is 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.

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 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. Lipocine has resubmitted its NDA to the FDA for TLANDO and had a PDUFA date of August 28, 2020 which was delayed by a few weeks. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. 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 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 clinical trials, the timing of completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our 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 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.

For further information: For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, Phone: (801) 519-4090, mb@lipocine.com; Investors, Hans Vitzthum, Phone: (617) 535-7743, hans@lifesciadvisors.com

<https://ir.lipocine.com/2020-08-28-Lipocine-Provides-Regulatory-Update-for-TLANDO-TM>