

Lipocine Announces Peer-Reviewed Publication of Phase 3 Study Results for TLANDO®

SALT LAKE CITY, Jan. 27, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced the peer-reviewed publication of positive Phase 3 clinical data from the Dosing Validation ("DV") study which evaluated the fixed-dose oral testosterone undecanoate, TLANDO, for the treatment of hypogonadism. As previously disclosed, the DV study met its primary endpoint, with TLANDO restoring testosterone levels to the normal range in hypogonadal males. The paper entitled, "A New Oral Testosterone (TLANDO) Treatment Regimen Without Dose Titration Requirement for Male Hypogonadism," is published in *Andrology* and can be found online [here](#).

The U.S. Food and Drug Administration ("FDA") previously granted tentative approval to TLANDO in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

"We are pleased by the publication of our positive Phase 3 DV study results," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "The primary efficacy results confirm that TLANDO administered without dose titration restores testosterone levels to the normal range in hypogonadal men. We believe TLANDO's easy to use and prescribe attributes, no titration requirement and meal flexibility, are preferred by patients and physicians and could be an important differentiated attribute profile for TLANDO, if approved."

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®, TLANDO XR, LPCN 1144, LPCN 1148, LPCN 1107 and oral neurosteroids. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. 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 or twice daily, TLANDO XR met the typical primary and secondary endpoints. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a Phase 2 clinical study demonstrating potential utility in the treatment of non-cirrhotic NASH. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. 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, 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.

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