

LIPOCINE ANNOUNCES ITS PARTNER RECEIVED FDA APPROVAL OF TLANDO™

Commercial launch expected in 2Q 2022

SALT LAKE CITY, March 29, 2022 [/PRNewswire/](#) -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on developing innovative products for neuroendocrine and metabolic disorders, announced today that Antares Pharma, Inc. issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has approved TLANDO™ (testosterone undecanoate), an oral treatment for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. Lipocine licensed the exclusive U.S. commercialization rights for TLANDO™ to Antares Pharma.

"The approval of TLANDO is a significant milestone achievement for Lipocine," commented Dr. Patel. "I would like to thank the participants in our clinical trials, the investigators and their staff, key opinion leaders and consultants, and our employees who made this approval possible. We are excited that patients are one step closer to having the ability to access a much needed and convenient testosterone replacement option with TLANDO."

For full prescribing information, please visit www.antaresspharma.com.

About Lipocine

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on neuroendocrine and metabolic disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107 and oral neuroactive steroids including LPCN 1154 and LPCN 2101. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. 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 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. In a phase 2 clinical evaluation when administered as once or twice daily, LPCN 1111 met primary and secondary endpoints. 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. Neuroactive steroids are currently being evaluated including LPCN 1154 for the potential treatment of postpartum depression and LPCN 2101 for the potential treatment of epilepsy. 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: Krista Fogarty, Phone: (801) 994-7383, kf@lipocine.com; Investors: Hans Vitzthum, Phone: (617) 430-7875, hans@lifesciadvisors.com

<https://ir.lipocine.com/2022-03-29-LIPOCINE-ANNOUNCES-ITS-PARTNER-RECEIVED-FDA-APPROVAL-OF-TLANDO-TM>