

Lipocine Announces Completion of Enrollment in Ambulatory Blood Pressure Study for TLANDO™

SALT LAKE CITY, Nov. 1, 2018 /PRNewswire/ -- [Lipocine Inc.](#) (NASDAQ: LPCN), a specialty pharmaceutical company, today announced the completion of enrollment in the ambulatory blood pressure ("ABPM") clinical study 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. This study is being conducted to definitively characterize TLANDO's blood pressure increase effect, if any.

"We are pleased to have completed enrollment in the ABPM study for TLANDO, which is expected to provide data in the first quarter of 2019, and look forward to bringing TLANDO to patients," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. "Across our 52-week SOAR Phase 3 clinical trial, TLANDO did not show a mean increase at any time point (i.e., 3 weeks, 7 weeks, 13 weeks, 26 weeks, 39 weeks, 52 weeks) using office visit cuff blood pressure measurements with the proposed market dosing regimen."

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 four development programs TLANDO, LPCN 1144, 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 1144, an oral prodrug of bioidentical testosterone, is being developed as a treatment of non-alcoholic steatohepatitis ("NASH") and is currently being studied in two proof-of-concept clinical studies. 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 and has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA has been completed. 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 and the FDA review process relating to its product candidates, the timing of completion of clinical trials including the ABPM study for TLANDO, the path to approvability by the FDA of Lipocine's development programs, 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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For further information: Morgan Brown, Executive Vice President & Chief Financial Officer, Phone: (801) 994-7383, mb@lipocine.com or Investors: Hans Vitzhum, Phone: (646) 597-6979, hans@lifesciadvisors.com

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