Lipocine Announces Successful Ex Vivo Conversion Assessment of TLANDO™

SALT LAKE CITY, Dec. 31, 2018 /PRNewswire/ -- Lipocine, Inc. (NASDAQ: LPCN), a specialty pharmaceutical company, today announced completion of a definitive phlebotomy study ("Phlebotomy Study") to assess the extent, if any, of clinically meaningful *ex vivo* conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes.

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.

The Phlebotomy Study was designed based on the U.S. Food and Drug Administration's ("FDA") protocol recommendations and conducted in response to a deficiency cited in the TLANDO Complete Response Letter ("CRL") by the FDA to confirm the reliability of TLANDO Phase 3 study results.

The Phlebotomy Study measured T concentrations in blood samples collected in plain serum separation tubes ("SST") at three-hour and five-hour time points (N=24) post dose and processed within 30 minutes of sample collection under the tube manufacturer's recommended conditions and consistent with Phase 3 instructions. The Phlebotomy Study enrolled 12 hypogonadal male subjects and dosed subjects with a single oral 225 mg TU dose of TLANDO. The T measurements in SST were compared against the FDA's recommended time zero control (processed immediately) measurement of T concentrations in blood samples in plasma tubes with EDTA ("PT") to assess *ex vivo* conversion, if any.

The topline results of the study demonstrated that the overall (N=24) mean percentage difference and the associated percentage standard deviation post dose of T concentrations measured between SST samples and PT samples are -1.0% and 9.2%, respectively. This difference was not statistically significant ($p = 0.91$) which suggests no significant *ex vivo* TU to T conversion occurrence with T measurements done consistent with the provided Phase 3 study instructions for blood collection and sample processing.

"We are pleased with the Phlebotomy Study results which supports the reliability of TLANDO T clinical measurements. We believe these results address one of the FDA's identified deficiencies and a successful step towards the resubmission of the TLANDO NDA," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We remain committed to bring TLANDO to patients in a timely manner as it represents a growing unmet need," Dr. Patel added.

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 a proof-of-concept MRI PDFF based liver fat imaging clinical study. 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 definitive phlebotomy study and the ABPM study for TLANDO as well as ongoing LPCN 1144 clinical trials, 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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