Lipocine Announces ABPM Labeling Study Results Consistent with Recently Approved Testosterone Replacement Therapy

SALT LAKE CITY, March 27, 2019 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced findings from the Ambulatory Blood Pressure Monitoring clinical study (NCT03868059) ("ABPM Study") designed to study TLANDO's effects on blood pressure. The objective of the ABPM Study was to characterize blood pressure effects of TLANDO for appropriate U.S. Food and Drug Administration ("FDA") regulatory action, including Risk Evaluation and Mitigation Strategy ("REMS") beyond labeling.

The ABPM Study was an open label, single arm study that enrolled 144 male hypogonadal subjects undergoing four months of treatment with TLANDO, 225 mg BID dosing, with 24-hour blood pressure measurements taken at baseline and at the end of the study. There were 138 subjects who received at least one dose of study drug and 126 subjects completed the study. There were 118 subjects enrolled in the ABPM Study with evaluable weighted average 24-hour ABPM data at both baseline and at the end of the study.

Subjects receiving treatment in the ABPM Study had the following baseline parameters:

Baseline Parameters	Mean (SD)
Age (years)	53.8 (10.2)
BMI (kg/m^2)	33.1 (5.8)
24h SBP (mm Hg)	127 (16)
24h DBP (mm Hg)	79 (6)

SD = Standard Deviation, BMI = Body Mass Index, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Additionally, among the subjects enrolled in the ABPM Study, 48% of the subjects were hypertensive and 24% of subjects were type 2 diabetic.

Top-line results from the ABPM Study are as follows:

Parameter	Mean Change, mm Hg (95% CI)
24-hour SBP	3.82 (1.69, 5.96)
24-hour DBP	1.20 (0.31, 2.08)

CI = Confidence Interval, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Of the subjects (n=25) with baseline 24-hour average systolic blood pressure ("SBP") greater than 140 mm Hg, 32% of the subjects were less than or equal to 140 mm Hg at the end of study. Additionally, of the subjects (n=93) with baseline 24-hour average SBP of less than or equal to 140 mm Hg, 9.7% of the subjects were greater than 140 mm Hg at the end of study.

In the Study of Oral Androgen Replacement clinical study (NCT02081300) ("SOAR"), 0.96% of the subjects required a change to their anti-hypertensive medication regimen following one-year of treatment with TLANDO. No subjects were started on a new anti-hypertensive drug during the SOAR study.

Consistent with safety results from twelve previously completed clinical trials, TLANDO was generally well-tolerated in the ABPM Study with no drug-related Serious Adverse Events ("SAEs"), no Major Adverse Cardiac Events ("MACE") or deaths.

"We are pleased with the TLANDO pressor results which we believe are in line with a recently approved testosterone replacement therapy. We look forward to resubmitting our NDA in the second quarter of 2019," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "We remain committed on bringing our patient-friendly oral testosterone product candidate to patients in a timely manner."

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 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. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of 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 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 including the ABPM Study, the timing of completion of clinical trials, the timing for resubmission of our NDA for TLANDO, 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.

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