Lipocine Announces Presentations at the 21st Annual Fall Meeting of the Sexual Medicine Society of North America

-- Is Oral Testosterone a Potential Treatment for COVID-19 in Men?
-- TLANDO™, Oral Testosterone Replacement Therapy Without Dose Titration Requirement

SALT LAKE CITY, Oct. 14, 2020 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced it will present results from studies suggesting that low testosterone levels may play an important role on the clinical outcomes of COVID-19 in men as well as the safety and efficacy of TLANDO™, an oral testosterone replacement therapy without a dose titration requirement, at the 21st Annual Fall Scientific Meeting of the Sexual Medicine Society of North America ("SMSNA"). Lipocine will outline the possible mechanisms and clinical evidence that suggests men with low testosterone have poor COVID-19 outcomes, and the rationale of using an oral testosterone therapy for men with COVID-19. Results from the previously completed dose validation ("DV") study of a fixed dose TLANDO in hypogonadal males will also be presented at the meeting. The presentations will take place virtually on November 9, 2020 from 7:00 p.m. – 9:00 p.m. EST during Session 2 (Androgens and Ejaculation/Orgasm Disorders).

https://www.smsna.org/V1/2020/program/scientific-program?where_person=44
https://www.smsna.org/V1/2020/program/scientific-program?where_person=42

"We know that while COVID-19 infection rates are comparable between men and women, men are developing severe symptoms and dying at a significant higher rate than women. Furthermore, men with comorbidities commonly associated with lower testosterone are at greater risk for severe disease and death," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "The presentation on COVID-19 highlight key clinical evidences suggesting that low testosterone levels may play an important role on the clinical outcomes of COVID-19 in men. Based on the published data, the use of oral testosterone with the goal of achieving physiological testosterone levels should be evaluated in clinical trials of COVID-19."

Dr. Anthony DelConte, Chief Medical Director of Lipocine further stated, "TLANDO will be the first oral testosterone for treatment hypogonadism without titration requirement. It is expected to be easy to prescribe and use." Dr. DelConte added, "The SMSNA presentation on TLANDO highlights the key safety and efficacy data from multiple clinical studies supporting TLANDO's ability to effectively restore testosterone levels in hypogonadal men without need for any dose adjustment."

Is Oral Testosterone a Potential Treatment for COVID-19 in Men? (Benjamin J. Bruno *et al*)

The authors performed a literature search to understand the possible mechanisms and clinical evidence concerning testosterone levels in COVID-19 patients. A recent clinical study investigating testosterone levels in men with COVID-19 found 80% of men who died due to COVID-19 had low total or bioavailable testosterone levels at the time of hospital admission. Those with severe Acute Respiratory Distress Syndrome ("ARDS") had acutely depressed total testosterone compared to patients who did not exhibit severe ARDS. The mean total testosterone levels for men who required invasive ventilation was 29 ng/dL (normal range ~300-1100 ng/dL), whereas those who were discharged from the ICU had mean total T of 254 ng/dL at the time of ICU admission.

In comparison to other routes of testosterone administration, oral testosterone therapy may be the most convenient and suitable for acute treatment of COVID-19 in both inpatient and outpatient settings. Oral testosterone can rapidly increase the transiently reduced hormone. This may prevent unfavorable COVID-19 outcomes through multiple mechanisms of action and its effects on the lung, immune cells, and liver.

TLANDO, Oral Testosterone Replacement Therapy Without Dose Titration Requirement (Anthony DelConte *et al*)

The authors reviewed a 24 day, open-label, single-arm, multicenter study (NCT03242590) which was designed to assess whether TLANDO™, an oral TRT , can safely and effectively restore testosterone levels in hypogonadal men without the need for any dose adjustment. Ninety-five subjects were enrolled and received 225 mg TLANDO orally twice a day, with 94 of these subjects completing the study. A majority (81%) of hypogonadal subjects achieved average testosterone levels within the normal range post ~3 weeks of treatment without dose adjustment (95% CI 72% - 88%). The results confirm the validity of a fixed dose approach without the need for dose titration to orally administering TLANDO.

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, LPCN 1144, TLANDO XR, LPCN 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. Lipocine has resubmitted its NDA to the FDA for TLANDO. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. 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 daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate, with end of phase 2 meeting completed, 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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