LIPOCINE ANNOUNCES PATIENT DOSED IN ITS PHASE 2 STUDY WITH LPCN 1148 FOR MANAGEMENT OF LIVER CIRRHOSIS

SALT LAKE CITY, Dec. 22, 2021 /PRNewswire/ -- Lipocine Inc. (Nasdaq: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced that the first patient has been dosed in its Phase 2 proof-of-concept clinical study (NCT04874350) for the management of liver cirrhosis. The Phase 2 study is a multi-center, randomized, placebo-controlled 52-week study in sarcopenic cirrhotic patients that are on the liver transplant list. The primary endpoint is change from baseline in Skeletal Muscle Index ("SMI") via computed tomography in LPCN 1148 treated subjects compared to placebo at week 24, and key secondary endpoints include measures of frailty (liver frailty index), change in waitlist events, myosteatosis, rate of hospital admissions, all-cause mortality, and decompensation events (including all cause and liver related mortalities and clinically significant worsening) and rates of breakthrough hepatic encephalopathy. Primary endpoint topline results are expected in the second half of 2022.

"We are excited to have this Phase 2 study underway as LPCN 1148 targets a serious unmet need with a strong pharmaco-economic justification as a potential treatment for the management of liver cirrhosis," said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "In addition to being a unique treatment option with a compelling rationale, we plan to apply for Orphan Drug Designation ("ODD") with LPCN 1148 for regressing decompensation events including Hepatic Encephalopathy," said Dr. Patel.

About Liver Cirrhosis: Decompensated liver cirrhosis is estimated to affect more than 630,000 Americans, with men affected at twice the rate as women, and results in approximately 45,000 deaths every year. The only cure, liver transplant, has a high economic burden (~$812,500/transplant). The hypothalamus-pituitary-gonadal axis is profoundly altered in advanced cirrhotic patients, leading to endocrine dysfunction. Testosterone levels fall progressively with increased chronic liver disease severity. Low testosterone levels, reported in the majority of male cirrhotic patients, is known to be associated with increased rates of adverse outcomes including varices in the gastrointestinal tract with internal bleeding, ascites, major infections, hepatic decompensation, and worsening of quality of life while awaiting transplant.

About Compromised Muscle in Cirrhosis: The presence of sarcopenia (loss of muscle mass/area) in 40-70% of cirrhotic men and frailty (a state of decreased physiological reserve/functionality) are associated with increased risk of hospitalization and hepatic decompensation events, a two-fold increase in waitlist mortality, and poor post-transplant outcomes. Moreover, myosteatosis (an excess of fat in muscle tissue) is recognized to negatively correlate with muscle mass, strength, and mobility, an increased MELD score, worse median survival, and higher rates of mortality in cirrhotic patients.

About Hepatic Encephalopathy ("HE"): HE is a metabolically induced, potentially reversible, functional disturbance of the brain condition leading to "brain fog" due to the liver's (primary organ) and muscle's (secondary organ) inability to eliminate myo/neuro toxic ammonia from the systemic circulation and is a significant decompensation event associated with cirrhosis. HE is the most potent risk factor for hospitalization, accidental trauma, and mortality. Clinically overt HE is significantly more prevalent in cirrhotic patients with muscle depletion or decreased muscle strength. Reports suggest low testosterone and fat-free mass depletion are predictors of HE in cirrhotic liver transplant candidates.

About LPCN 1148: LPCN 1148 is a novel prodrug of testosterone, testosterone laurate ("TL"), for oral

administration with compelling potential unique mode of action to improve liver and muscle function, resulting in improved Quality of Life (QOL) while awaiting transplant, decreased hospital admissions, and prevention of progression of decompensation events.

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, LPCN 1154, and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. 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. 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 or twice daily, TLANDO XR met the typical primary and secondary endpoints. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. LPCN 1154 is an oral neuro-steroid targeted for the treatment of post-partum depression. 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. For more information, please visit www.lipocine.com.

Cautionary and 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 and completion of additional clinical trials and studies, the potential uses and benefits of LPCN 1148 for the management of symptoms associated with liver cirrhosis, the timing of additional data and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risk 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. There can be no assurance that we will choose, or have the ability, to conduct further clinical trials with respect to LPCN 1148 and, ultimately, apply for and receive approval from the FDA to market LPCN 1148 for the indications described in this press release. 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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