Lipocine Completes Enrollment of LPCN 1148 Phase 2 Study for Decompensated Cirrhosis

Top-line 24-week results from proof-of-concept study expected mid-2023

SALT LAKE CITY, Dec. 19, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System ("CNS") disorders by leveraging its proprietary platform to develop differentiated products, today announced that it has completed enrollment in its Phase 2 proof-of-concept ("POC") study evaluating the therapeutic potential of LPCN 1148 for the management of decompensated cirrhosis of various etiologies. Lipocine intends to explore partnering LPCN 1148.

"We are excited to complete enrollment which leads to topline results mid-2023 for a serious end-stage condition with high unmet medical need," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Muscle disorder and hepatic encephalopathy (HE) are highly prevalent in cirrhotic patients, adversely impacting survival rates. We believe LPCN 1148 has the potential to improve quality of life, prevent or reduce the occurrence of new decompensation events (e.g., HE, ascites, etc.), and improve post liver transplant survival, including outcomes and costs, for those with cirrhosis."

The ongoing Phase 2 POC study is a prospective, multi-center, randomized, placebo-controlled two-stage in male sarcopenic cirrhotic patients. Subjects have been randomized to one of two arms. The treatment arm is an oral dose of LPCN 1148, and the second arm is a matching placebo. The primary endpoint is change in skeletal muscle index at week 24. Key secondary endpoints include change in liver frailty index and myosteatosis, rates of breakthrough HE, and number of waitlist events including all-cause mortality. Total treatment duration (placebo controlled - stage 1, and the single-active arm, open-label extension - stage 2) is 52 weeks. For more information, refer to ClinicalTrials.gov NCT04874350.

About Liver Cirrhosis

Decompensated liver cirrhosis is estimated to affect more than 500,000 Americans, with men affected at twice the rate of women, and results in approximately 45,000 deaths every year. The only cure, liver transplant, has a high economic burden (~$878,500/transplant). The hypothalamus-pituitary-gonadal axis is profoundly altered in advanced cirrhotic patients, leading to endocrine dysfunction. Subjects with cirrhosis have impaired hepatocellular function and reduced albumin synthesis due to dysregulated proteostasis.

About Muscle Disorder in Cirrhosis

Sarcopenia (loss of muscle mass/area), observed in 60-80% of cirrhotic men, and frailty (a state of decreased physiological reserve) 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) has been shown to correlate with low muscle mass, strength, and mobility, an increased MELD score, worse median survival, and higher rates of mortality in patients with cirrhosis.

About Hepatic Encephalopathy

HE, a significant decompensation event, is a metabolically induced, potentially reversible, functional disturbance of the brain leading to "brain fog." In patients with cirrhosis, myo/neuro toxic ammonia accumulates due to the liver's (primary organ) and muscle's (secondary organ) compromised ability to eliminate ammonia from systemic circulation. Furthermore, HE is a known risk factor for hospitalization, accidental trauma, and mortality. Clinically overt HE is significantly more prevalent in cirrhotic patients with muscle depletion, decreased muscle strength, or endocrine dysfunction. Additionally, anemia is a predictor of HE in cirrhotic liver transplant candidates.

About LPCN 1148

LPCN 1148 is a novel prodrug of androgen receptor agonist for oral administration with compelling multi modal action to improve liver and muscle function, resulting in improved quality of life while awaiting liver transplant, decreased hospital admissions, and prevention or reduction in occurrence and recurrence of decompensation events.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop products for CNS disorders. Lipocine has candidates in

development as well as candidates for which we are exploring partnering. Our candidates represent enablement of patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy and LPCN 1148, an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering for LPCN 1107, our candidate for prevention of pre-term birth, LPCN 1148, LPCN 1144, our candidate for treatment of non-cirrhotic NASH, and LPCN 1111, a once-a-day therapy candidate for testosterone replacement therapy (TRT). TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. 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 our product development efforts, our strategic plans for developing products to treat CNS disorders, our ability to monetize non-core product candidates, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the achievement of milestones within and completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates to treat CNS disorders, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, 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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