Lipocine Presents 52 Week Results from LPCN 1148 Phase 2 Study in Late Breaking Session at EASL Congress 2024

SALT LAKE CITY, June 10, 2024 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company, today announced that Phase 2 results on LPCN 1148 in cirrhosis were featured in a late breaking oral presentation at the European Association for the Study of Liver (EASL) Congress on Saturday, June 8, in Milan, Italy. The presentation **"Intervention with oral LPCN 1148 improves sarcopenia and hepatic encephalopathy (HE) in patients with cirrhosis: a 52-week phase 2 randomized clinical trial"** was presented by Arun J. Sanyal, MD, Director, Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University. The presentation is featured in the symposium "Revolutionary Advances in Liver Disease Research Unveiled at EASL Congress 2024" (https://www.hepmag.com/article/revolutionary-advances-liver-disease-research-unveiled-easl-congress-2024) highlighting significant advances in liver disease.

A copy of Dr. Sanyal's presentation delivered at EASL Congress 2024 can be found on the Lipocine corporate website here.

www.lipocine.com

About Cirrhosis

Cirrhosis is an end stage liver disease of varying etiologies such as alcoholic liver disease, chronic viral hepatitis, nonalcoholic fatty liver disease and primary cholangitis. Complications of cirrhosis include decompensation events such as hepatic encephalopathy due to systemic ammonia buildup, variceal bleeding, and ascites, which require frequent hospitalizations. In addition, many patients exhibit sarcopenia (low muscle mass).

Over 382,000 patients have been diagnosed with decompensated liver cirrhosis in the US, with few options for managing their disease other than liver transplant. Poor quality of life is common while waiting for a liver transplant. Although there is a limited supply of donor livers, transplant is the only cure for end-stage cirrhosis.

About HE

HE is a frequent complication and one of the most debilitating manifestations of liver disease, severely affecting the lives of patients and their caregivers. For patients with decompensated liver cirrhosis and sarcopenia, clinical outcomes tend to be worse - both sarcopenia and myosteatosis are associated with an increased risk of HE.

HE is an episodic neurological disorder with a high recurrence rate. Up to 50% of patients with cirrhosis will experience an HE episode in their lifetime. Patients can exhibit global neurological, psychiatric, and musculoskeletal deficits. HE has a complex pathophysiology that includes impairment of ammonia clearance and increased inflammatory cytokine and HE recurrence is common, despite use of standard-of-care therapies. Options for prevention/treatment are limited, resulting in significant enduring unmet medical need as the 1-year survival for patients with HE is ~50%. Furthermore, cognitive impairment associated with cirrhosis results in utilization of more health care resources.

About the Phase 2 study

This multi-center study enrolled and dosed a total of 29 patients across 8 centers in the United States. The primary objective was to evaluate the efficacy of 24 weeks of LPCN 1148 treatment in men with cirrhosis and sarcopenia. The secondary objective was to evaluate the safety and tolerability of LPCN 1148. Following Week 24, the open-label stage of the study began (Stage 2), wherein all participants received LPCN 1148 (no placebo in Stage 2).

Baseline characteristics, including age, disease etiology baseline L3-SMI, and other comorbidities were generally well-balanced between groups. Overall, the average baseline Model for End-Stage Liver Disease (MELD) score was 16.8, and 97% of patients had previously experienced at least one clinical decompensation event. Sarcopenia, or low muscle mass, was assessed by computed tomography (CT) scan; total skeletal muscle area at the third lumbar vertebra was measured by CT scan and normalized by participant height (L3-SMI, L3-skeletal muscle index). Patients had study visits every four weeks, with CTs performed at Weeks 12, 24, 36, and 52. Patients with a variety of cirrhosis etiologies were eligible. During the study there were no restrictions on standard of care medications, procedures, or other interventions. Further details on the study design, including inclusion and exclusion criteria, can be found on Clinicaltrials.gov (NCT04874350).

About LPCN 1148

Lipocine is currently evaluating LPCN 1148 comprising testosterone laurate ("TL") for the management of decompensated cirrhosis. The Company believes LPCN 1148 targets unmet needs for patients with cirrhosis including improvement in the quality of life of patients while on the liver transplant waiting list, prevention or reduction in the occurrence of new decompensation events such as hepatic encephalopathy ("HE"), and improvement in post liver transplant survival, including outcomes and costs.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products for CNS disorders. Lipocine has drug candidates in development as well as drug candidates for which we are exploring partnerships. Our drug candidates represent enablement of differentiated, patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine's clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy, LPCN 2203 an oral candidate targeted for the management of essential tremor, LPCN 2401 an oral proprietary combination of anabolic androgen receptor agonist and α-tocopherol, an antioxidant, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in chronic weight management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis including prevention of the recurrence of overt hepatic encephalopathy. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, LPC 2401 for obesity management and LPCN 1144, our candidate for treatment of non-cirrhotic NASH. 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, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, the timing and outcome of product studies, our development of and filing of an NDA with the FDA for LPCN 1154, 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 have sufficient capital to complete the development processes for our product candidates, 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 and our ability to utilize a streamlined approval pathway for LPCN 1154, 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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