Lipocine Announces Publication and Discussion of LPCN 1148 Manuscript at The Liver Meeting 2024 Editor's Cut Session

SALT LAKE CITY, Nov. 18, 2024 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery, today announced the publication and discussion of a manuscript *"Oral LPCN 1148 Improves Sarcopenia and Hepatic Encephalopathy in Male Patients with Cirrhosis: a randomized, placebo-controlled Phase 2 trial"* in the journal Hepatology and discussion at The Liver Meeting (AASLD) 2024 Editor's Cut: Clinical Study Session held on November 16, 2024. LPCN 1148 is targeted to be a "First in Class" product candidate with a novel mechanism of action for overt hepatic encephalopathy and sarcopenia indications. A copy of the publication can be accessed here.

The publication features the results from a Phase 2 proof-of-concept clinical trial (LPCN 1148-21-001) that evaluated LPCN 1148 in men with cirrhosis and sarcopenia awaiting liver transplantation. The trial was conducted in two stages. Stage 1 was double blind, placebo-controlled with participants randomized 1:1, to receive either oral LPCN 1148 or placebo. This was followed by Stage 2, a 28-week single-arm open label extension. The publication reports the analyses from the Stage 1 readout.

The results at 24 weeks showed that LPCN 1148 therapy resulted in a significant improvement in sarcopenia when compared with placebo. Furthermore, despite most participants already on background therapies for HE, participants receiving LPCN 1148 also experienced significantly fewer episodes of overt hepatic encephalopathy (OHE) compared to those on placebo. Additional beneficial effects of LPCN 1148, including improved muscle quality, hemoglobin, and patient reported symptom improvement are also covered in the manuscript.

The publication was discussed at The Liver Meeting during 'The Editors Cut: Clinical Studies' session. This session critically discusses the most notable, influential, cutting edge, game changing clinical research papers published during the past year.

"We are pleased to publish the results from this important proof-of-concept study of LPCN 1148 in Hepatology, a leading peer-reviewed journal," said Benjamin Bruno, Ph.D., Pharm.D., Vice President of Clinical Development at Lipocine and lead author on the publication. "To our knowledge, LPCN 1148 therapy is the first pharmacologic agent to demonstrate improvements in both sarcopenia and overt HE outcomes in patients with cirrhosis. Our findings support further research on the efficacy of LPCN 1148 in managing cirrhosis complications, a critical unmet medical need."

For more information on the study, refer toClinicalTrials.gov NCT04874350.

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 OHE

OHE 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 OHE.

OHE is an episodic neurological disorder with a high recurrence rate. Up to 50% of patients with cirrhosis will experience an OHE 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 OHE is ~50%. Furthermore, cognitive impairment associated with cirrhosis results in utilization of more health care resources.

About LPCN 1148

LPCN 1148 comprises testosterone dodecanoate, a unique androgen receptor agonist. It is targeted as a differentiated intervention option with a novel multimodal MOA to elicit potential benefits in management of cirrhosis and associated comorbidities of cirrhosis.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products. 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 anabolic androgen receptor agonist, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in obesity management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 2401 for obesity management, LPCN 1148, for the management of decompensated cirrhosis, 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 development and commercialization of TLANDO and TLANDO XR (LPCN 1111) by our licensees, the amount of the license fee, milestone payments, and royalty payments we will ultimately receive, the ability of our licensees to grow the TLANDO franchise, our product development efforts, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 1148 and LPCN 2401, the timing of our submission of a 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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