FDA Grants Fast Track Designation to Lipocine for LPCN 1148 as a Treatment for Sarcopenia in Patients with Decompensated Cirrhosis

SALT LAKE CITY, Dec. 17, 2024 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery, today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track Designation to LPCN 1148 as a treatment for sarcopenia in patients with decompensated cirrhosis. LPCN 1148, an oral prodrug of bioidentical testosterone, was recently studied in a proof-of-concept (POC) Phase 2 study in patients with decompensated cirrhosis. Treatment with LPCN 1148 in the POC study improved sarcopenia and associated clinical outcomes. LPCN 1148 is targeted to be a "First in Class" product candidate with a novel mechanism of action for management of cirrhosis.

"We are excited the FDA has recognized that sarcopenia in patients with cirrhosis is a serious condition and that LPCN 1148 has the potential to provide clinical benefits for these patients where no therapy currently exists," said Dr. Mahesh Patel, President and Chief Executive Officer of Lipocine. "We are encouraged that the positive primary endpoint results from our successful proof-of-concept study were recognized by the FDA as evidence of clinical effectiveness of LPCN 1148 in improving sarcopenia in patients with cirrhosis."

The Fast Track program is designed to accelerate the development and expedite the review of products, such as LPCN 1148, which are intended to treat serious diseases and for which there is an unmet medical need. Fast Track designation lends eligibility for some, or all, of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed

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 Sarcopenia

Sarcopenia, a progressive loss of muscle mass and function, is a common and debilitating complication in patients with decompensated cirrhosis. It significantly impacts quality of life and worsens clinical outcomes, including reduced survival rates.

Patients with decompensated cirrhosis and sarcopenia exhibit significantly shorter overall survival than those without sarcopenia. Currently, the only curative therapy for decompensated cirrhosis is liver transplant. There are no FDA approved drugs to treat sarcopenia in decompensated cirrhosis beyond treatment of the underlying conditions.

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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