Lipocine Releases Late Breaking Presentation on LPCN 1148 Phase 2 Results at The Liver Meeting® 2023

Results demonstrate improvements in sarcopenia and other clinically meaningful outcomes

Patients converting from placebo to LPCN 1148 in the ongoing open label extension also showed improvement in sarcopenia

SALT LAKE CITY, Nov. 13, 2023 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on treating Central Nervous System (CNS) disorders, today announced that results of its Phase 2 study evaluating LPCN 1148 are being presented at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023, taking place in Boston MA. The results are featured in a late-breaking oral presentation and e-poster by Dr. Arun Sanyal, MD, Director, Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University, advisor to Lipocine.

"We are very pleased to share the data from our successful Phase 2 study of LPCN 1148 with the hepatology community at this year's Liver Meeting," said Dr. Mahesh Patel, President and CEO of Lipocine. "The data show that LPCN 1148 improved multiple additional clinically meaningful and surrogate outcomes, including hepatic encephalopathy. An Open Label Extension is now ongoing, and we look forward to reporting further data in Q1 2024."

The Phase 2 proof of concept study (NCT # 04874350) is a 52-week ongoing randomized placebo-controlled study in sarcopenic male patients with cirrhosis on the liver transplant waitlist. After week 24, all patients enter a single arm open-label extension ("OLE") stage of the study and receive LPCN 1148. The purposes of the OLE are 1) to evaluate the safety and efficacy of continued exposure with LPCN 1148 in this population, and 2) to increase the number of participants on LPCN 1148 treatment.

A copy of the presentation and e-poster will be available on the Lipocine corporate website.

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 cirrhosis subjects 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 partnering. 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 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, LPCN1154, for rapid relief of postpartum depression, LPCN 1148, for the management of decompensated cirrhosis, 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, the application of our proprietary platform in developing new treatments for CNS disorders, our product candidates and related clinical trials, our development of and filing of a NDA with the FDA for LPCN 1148,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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