Lipocine Announces Regulatory Guidance on LPCN 1144 in Non-cirrhotic NASH

SALT LAKE CITY, March 1, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on neuroendocrine and metabolic disorders, today provided an update from the Type C guidance meeting with the U.S. Food and Drug Administration ("FDA") regarding the development path for LPCN 1144. LPCN 1144 is targeted for treatment for nonalcoholic steatohepatitis (NASH) in non-cirrhotic men. NASH is a more advanced state of non-alcoholic fatty liver disease ("NAFLD") and can progress to a cirrhotic liver or liver failure, require liver transplant, and can result in hepatocellular carcinoma/liver cancer, and can lead to death.

The FDA provided a written response in which it acknowledged that the New Drug Application ("NDA") submission of LPCN 1144 would be via 505(b)2 regulatory pathway. The FDA also agreed that no additional nonclinical studies are needed to support a 505(b)(2) NDA submission for LPCN 1144.

The FDA acknowledged that in the phase 2 study completed by Lipocine to evaluate LPCN 1144 in NASH (the "Liver Fat intervention with oral Testosterone" or LiFT study, NCT04134091), subjects achieved improvements in key components associated with NASH histopathology after 36-weeks of treatment with LPCN 1144 in adult males. The FDA agreed that the proposed multicomponent primary surrogate endpoint is acceptable for seeking approval under the accelerated approval pathway.

The FDA has recommended Lipocine either conduct a separate dose-ranging study prior to phase 3 or evaluate multiple doses in the phase 3 study. The multicomponent primary surrogate endpoint proposed to FDA by Lipocine is acceptable for seeking approval under the accelerated approval pathway and FDA recommended a phase 3 study duration of 72 weeks. The FDA has requested that Lipocine submit an updated phase 3 protocol for FDA feedback on the study design and recommended requesting an end-of-phase 2 meeting to discuss the phase 3 and confirmatory trial designs, including the plan for reading liver histopathology.

"We are pleased to have achieved alignment with the FDA on key elements of a development plan for LPCN 1144 in non-cirrhotic NASH." said Dr. Mahesh Patel, Chairman, President, and Chief Executive Officer of Lipocine. "We plan to submit an updated phase 3 protocol to the FDA for its review."

About Lipocine
Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's development pipeline includes: TLANDO®, LPCN 1111, LPCN 1144, LPCN 1148, LPCN 1107 and oral neurosteroids. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1111, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing. In a phase 2 clinical evaluation when administered as once or twice daily, LPCN 1111 met the typical primary and secondary endpoints. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a phase 2 clinical study demonstrating potential utility in the treatment of non-cirrhotic NASH. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. 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 Lipocine's product candidates and related clinical trials, the timing of completion of clinical trials, the timing and completion of regulatory reviews, outcomes of clinical trials of our product candidates, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that 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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