FDA Clears LPCN 2101 IND for Adult Epilepsy Treatment

Phase 2 Photosensitive Epilepsy Study Planned for 2H 2022

SALT LAKE CITY, July 11, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on developing innovative products to treat metabolic and central nervous system ("CNS") disorders with high unmet medical needs, announced today that the U.S. Food and Drug Administration ("FDA") has accepted the company's Investigational New Drug Application ("IND") for its neuroactive steroid ("NAS") candidate, LPCN 2101, as a potential treatment for adults with epilepsy. Lipocine plans to initiate a Phase 2 photosensitive epilepsy ("PSE") study to evaluate the safety, tolerability, and efficacy of oral LPCN 2101.

Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. commented, "We are excited to advance further testing of LPCN 2101. We believe it has the potential to address the unmet medical needs in epilepsy management as well as mood disorders comorbidities, particularly in women of childbearing age. We look forward to initiating the planned proof-of concept study."

About LPCN 2101

LPCN 2101 is an orally delivered, endogenous neuroactive steroid ("NAS"), a positive allosteric modulator ("PAM") of $GABA_A$ receptor, with potential therapeutic effects in neurological and mood disorders. No concerning safety and tolerability signals were observed in the preclinical studies with LPCN 2101 while demonstrating a favorable pharmacokinetic profile.

About Phase 2 Photosensitive Epilepsy ("PSE") Study Model

The photosensitivity study model enrolls patients who have an EEG-measurable photoparoxysmal response ("PPR") triggered by light stimulation. Reduction in photosensitivity can be quantified after a single dose of a potential anti-seizure medication ("ASM"). Reportedly, positive results in the PSE model have proven to be a reliable marker of antiseizure efficacy for most approved ASMs.

About Women with Epilepsy

Epilepsy is a disorder of the brain that causes seizures. It is estimated that approximately 900,000 women of childbearing age suffer from active epilepsy in the U.S. These women with epilepsy of childbearing age face specific challenges throughout their lifespan because of seizures, efficacy and safety risks associated with the current ASMs, hormonal fluctuations, and coexisting mood disorders. Several currently available ASMs are teratogenic and have the potential to induce contraception failures, reproductive hormone imbalance, and mood disorders. There remains an unmet need for an ASM with no to low fetal-neonatal toxicity as well as potential to treat associated psychiatric comorbidities.

About Lipocine

Lipocine is biopharmaceutical company leveraging its commercially validated proprietary technology to develop innovative products to treat metabolic and CNS disorders with high unmet medical need. Our candidates target diseases with potential for orphan drug designation, comprise endogenous actives for favorable benefit to risk profile, and represent enablement of patient friendly oral delivery options. Lipocine's clinical development pipeline includes: LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107 and oral neuroactive steroids including LPCN 1154 and LPCN 2101. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis. 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 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 primary and secondary endpoints. 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. Neuroactive steroids are currently being evaluated including LPCN 1154 for the potential treatment of postpartum depression and LPCN 2101 for the potential treatment of epilepsy. 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 achievement of milestones within and 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.

SOURCE Lipocine Inc.

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