Lipocine Announces Favorable Regulatory Pathway on Oral LPCN 1154 for Post-Partum Depression (PPD)

- FDA agrees with Lipocine establishing LPCN 1154 pathway to efficacy through a pharmacokinetic (PK) bridge to an approved IV infusion brexanolone
- Lipocine has demonstrated that the brexanolone exposure of LPCN 1154 is similar to the levels observed in third trimester pregnant women samples
- A pilot PK bridge study is planned with results expected in 1Q 2023

SALT LAKE CITY, Sept. 15, 2022 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company focused on developing innovative products targeting large addressable markets with significant unmet needs to treat central nervous system ("CNS") and metabolic disorders, announced today that the U.S. Food and Drug Administration ("FDA") has agreed with Lipocine's proposal for establishing the efficacy of LPCN 1154 through a single pivotal pharmacokinetic ("PK") bridge to an approved IV infusion brexanolone via a 505(b)(2) NDA filing. Lipocine plans additional work in parallel to pursue a well differentiated label.

LPCN 1154 is an oral neuroactive steroid being developed for the treatment of PPD. It is a non-invasive oral product candidate comprised of brexanolone, an endogenous positive allosteric modulator of γ-aminobutyric acid ("GABA") receptor. Lipocine has demonstrated that the brexanolone exposure of LPCN 1154 is similar to the levels observed in third trimester pregnant women samples. These results represent the first enablement of potentially efficacious oral brexanolone for PPD.

"We are truly excited about the encouraging FDA pathway feedback and oral enablement of brexanolone through leveraging of our proprietary Lip'ral technology platform," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "If approved, LPCN 1154 is expected to be the fastest acting oral option for PPD with potential for out-patient use."

Lipocine plans to initiate a pilot PK bridge study of LPCN 1154 and an FDA approved IV infusion brexanolone in 4Q 2022, with results expected in 1Q 2023.

About PPD

PPD (Postpartum depression) is a type of under diagnosed major depressive disorder impacting approximately 1 in 7 women after giving birth. PPD can lead to devastating consequences for a woman, her newborn and her family. Numerous factors limit the utilization of injectable brexanolone, including the requirement of a 60-hour continuous IV infusion in a supervised medical setting, a demanding ask for a mother with a newborn. Moreover, the pharmacotherapy costs coupled with hospitalization/childcare costs limit its accessibility and affordability to women most in need of the therapy. Currently, there is no oral therapy approved for the treatment of PPD.

About Lipocine

Lipocine is biopharmaceutical company employing a value-driven strategy based on its proprietary technology platform to identify and develop product candidates for CNS and metabolic disorders. Lipocine has candidates in development and candidates for which we are exploring partnering which target large addressable markets with significant unmet medical need. Our candidates represent enablement of patient friendly oral delivery options for favorable benefit to risk profile. Lipocine's product candidate pipeline includes: LPCN 1148, LPCN 1154, LPCN 2101, LPCN 1107, LPCN 1144, and LPCN 1111. 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.

Lipocine clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 1148, an oral prodrug of bioidentical testosterone targeted for the management of symptoms associated with liver cirrhosis, and LPCN 2101 for the potential treatment of epilepsy. Lipocine is exploring partnering LPCN 1144, our candidate for treatment of non-cirrhotic NASH, LPCN 1107, our candidate for prevention of pre-term birth, and LPCN 1111, a once-a-day therapy candidate for TRT. 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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