Lipocine Announces License and Supply Agreement for TLANDO® in Brazil

SALT LAKE CITY, May 6, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to enable effective oral delivery of therapeutics, today announced that it has entered into license and supply agreement with Aché Laboratórios Farmacêuitcos S.A (Aché) granting exclusive rights to market TLANDO® in Brazil.

The market for prescription testosterone products in Brazil is substantial and rapidly growing with compound annual growth rate (CAGR) of 34% from 2019 to 2023 and no oral testosterone therapy registered in Brazil.

"We are pleased to partner with Aché, one of the leaders in the Brazilian pharmaceutical market, to further expand the opportunity for TLANDO," said Mahesh Patel, CEO of Lipocine. "Brazil represents an important new growth market, and Aché's established commercial capabilities and proven regulatory expertise make them an ideal partner to bring TLANDO to patients in Brazil."

Under the terms of the agreement, Lipocine has received an upfront payment and is eligible to receive additional payments upon the achievement of certain regulatory milestones and royalties on net sales. Aché assumes full responsibility for the regulatory submission and approval process in Brazil.

About TLANDO®
TLANDO is approved by the US FDA as a testosterone replacement therapy (TRT) in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). It was developed using Lipocine's proprietary Lip'ral drug delivery technology platform.

For full prescribing information, please visit www.TLANDO.com.

About Aché

Aché is a Brazilian pharmaceutical company founded nearly 60 years ago with a mission to improve people's lives. A leader in the prescription market in Brazil, Aché's portfolio also includes solutions in generic medicines and over-the-counter (OTC) products. This success is driven by a commitment to excellence and a focus on investments in in-house research and development (R&D), partnerships for open innovation, and in-licensed products.

Aché is recognized as a top-of-mind company and a brand of choice among Brazilian healthcare professionals, with over 350 brands and 900 drug presentations across more than 150 therapeutic categories and 30 medical specialties. Today, Aché's products reach more than 20 countries across Latin America, Africa, Asia, and Europe, in addition to its home base in Brazil.

https://www.ache.com.br/en/about-us/

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to enable effective oral delivery of therapeutics. 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 metabolic dysfunction-associated steatohepatitis (MASH). 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 candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 1154, our P3 safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, potential partnering of our product candidates with third parties, 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, we may not have sufficient capital to complete the development processes for our product candidates or we may decide to allocate our available capital to other product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our non-core assets, safety and efficacy studies, including those relating to LPCN 1154, may not be successful or may not provide results that would support the submission of a NDA, the FDA may 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.

SOURCE Lipocine Inc.

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