Lipocine And Antares Pharma Enter Into U.S. Licensing Agreement To Commercialize TLANDO®

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Under the terms of Agreement Lipocine to receive:

- Up to $21.0 million in licensing fees, including $11.0 million payable immediately and $10.0 million to be paid in the future subject to certain conditions
- Commercial sales milestone payments of up to $160.0 million
- Tiered royalties on net sales of TLANDO from mid-teens up to 20%
- Antares Pharma to undertake all commercialization, post-marketing study obligations, and sourcing of TLANDO in the U.S.
- Lipocine grants Antares Pharma an option to license TLANDO XR for development and commercialization in the U.S. Upon exercise of the option, Lipocine to receive:
    - An additional $4.0 million in license fees, clinical and regulatory milestone payments of up to $35.0 million, and tiered royalties on net sales from mid-teens up to 20%
    - Antares Pharma to be responsible for all clinical development costs, regulatory filings, commercialization, and post-marketing commitments
- Lipocine retains all rights for ex-U.S. territories, and non TRT indications for TLANDO and TLANDO XR

Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced it has entered into an exclusive licensing agreement with Antares Pharma, Inc. to commercialize TLANDO in the United States. TLANDO is an oral testosterone product for 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).

As previously announced, the U.S. Food and Drug Administration ("FDA") granted tentative approval to TLANDO. Upon the expiration of the exclusivity period granted to Clarus Therapeutics, Inc., with respect to its drug, JATENZO®, under the Hatch-Waxman Act, which expires on March 27, 2022, TLANDO will be eligible for final approval. The FDA has affirmed the NDA resubmission for final approval will be a Class 1 resubmission which includes a two-month FDA review goal period.

Under the terms of the agreement, Lipocine will receive an immediate upfront cash payment of $11.0 million and, subject to certain conditions, an additional $5.0 million licensing payment in January 2025 and another $5.0 million licensing payment in January 2026. Lipocine will also be entitled to receive sales-based commercial milestone payments totaling up to $160.0 million based on TLANDO net sales and, if Antares Pharma exercises its option, TLANDO XR sales, in addition to tiered royalty payments at rates ranging from the mid-teens to up to 20% on net sales of TLANDO. Lipocine retains all rights for ex-US territories, and non TRT indications for TLANDO. Under the agreement, Antares Pharma will undertake all commercialization, post-marketing obligations, and sourcing of TLANDO in the U.S.

In addition, Lipocine has granted Antares Pharma an option to license, on or before March 31, 2022, TLANDO XR, a next-generation, potential once-daily oral product candidate for TRT, in the U.S. TLANDO XR met primary and secondary regulatory end points for TRT in an earlier Phase 2 clinical study. Upon exercise of the TLANDO XR option, Lipocine is entitled to receive an additional $4.0 million in license fees, clinical and regulatory milestone payments of up to an aggregate of $35.0 million, and tiered royalties on net sales at rates ranging from the mid-teens to up to 20%. Antares Pharma will be responsible for development costs, regulatory filings, commercialization, and post-marketing commitments for TLANDO XR.

"We are very pleased to be partnering with Antares Pharma, a strong market leader with one of the largest sales forces in the TRT space," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine. Dr. Patel further stated, "Our agreement with Antares Pharma demonstrates our commitment to ensure efficient and effective patient access to TLANDO in the U.S. We are confident in Antares Pharma's capabilities, given its established marketing experience and demonstrated success in the TRT space. Consistent with our current core competency, this agreement allows us to focus diligently on progressing our innovative pipeline candidates with the goal of serving patients with serious unmet needs."

About Lipocine Inc.

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: TLANDO, LPCN 1144, TLANDO XR, LPCN 1148, LPCN 1154, and LPCN 1107. 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 1144, an oral prodrug of bioidentical testosterone, recently completed a Phase 2 clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. TLANDO XR, 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 daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of cirrhosis. LPCN 1154 is an oral neuro-steroid targeted for the treatment of post-partum depression. 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.

About Antares Pharma

Antares Pharma, Inc. is a specialty pharmaceutical company focused primarily on the development and commercialization of self-administered injectable pharmaceutical products using advanced drug delivery auto injector technology. The Company has a portfolio of proprietary and partnered commercial products with several product candidates in various stages of development, as well as significant strategic alliances with industry leading pharmaceutical companies including Teva Pharmaceutical Industries, Ltd. (Teva), AMAG Pharmaceuticals (AMAG), Pfizer Inc. (Pfizer) and Idorsia Pharmaceuticals Ltd. (Idorsia). Antares Pharma's FDA-approved products include XYOSTED® (testosterone enanthate) injection, OTREXUP® (methotrexate) injection for subcutaneous use and Sumatriptan Injection USP, which is distributed by Teva. The Company also markets NOCDURNA® (desmopressin acetate) in the U.S., which was licensed from Ferring Pharmaceuticals.

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 the receipt of final FDA approval of TLANDO, the timing and amount of sales and development milestone payments and royalties under the License Agreement, the exercise of Antares' option with respect to TLANDO XR, the costs and timing of any post-marketing studies of TLANDO and clinical studies relating to TLANDO XR, our ability to compete in the TRT market, the degree to which TLANDO will gain market share in the TRT market, if at all, Antares Pharma's ability to successfully commercialize TLANDO, the benefits to Lipocine and Antares Pharma under the License Agreement, the potential benefits of TLANDO to patients, Lipocine's product candidates and related clinical trials, 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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