



## **ANTARES PHARMA ENTERS INTO EXCLUSIVE LICENSE AGREEMENT WITH LIPOCINE FOR TLANDO® IN U.S.**

*Expands Proprietary Portfolio and Complements Testosterone Offering to Physicians and Patients*

**EWING, NJ, October 18, 2021** – Antares Pharma, Inc. (NASDAQ: ATRS) (the “Company”), a specialty pharmaceutical company, today announced that it entered into an exclusive license agreement with Lipocine Inc. (“Lipocine”), a clinical-stage biopharmaceutical company, for TLANDO® (testosterone undecanoate), an oral treatment for testosterone replacement therapy (“TRT”) in the United States (“U.S.”).

TLANDO® was granted tentative approval from the U.S. Food and Drug Administration (“FDA”) as a twice-daily oral formulation of testosterone for testosterone replacement therapy indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. In granting tentative approval, the FDA concluded that TLANDO® met all required efficacy, quality and safety standards necessary for approval and will be eligible for final approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus Therapeutics, Inc. for JATENZO® on March 27, 2022.

Robert F. Apple, President and Chief Executive Officer of Antares Pharma, commented, “Testosterone replacement therapy is a large and growing market, and we believe the expansion of our proprietary portfolio with TLANDO enhances our growth opportunities. Upon expiration of the JATENZO exclusivity period and anticipated final FDA approval, we are excited to be able to complement our current offering of XYOSTED with an oral formulation of testosterone to physicians and patients. Leveraging strong physician relationships, our commercial organization will continue to expand to help build upon the success we have already achieved with XYOSTED. Overall, TLANDO broadens our offerings in the TRT market to those patients seeking an oral dosage option and we look forward to the opportunity to accelerate our market share gains and revenue growth in the testosterone market.”

“We believe physicians and patients prefer more than one therapy option and the addition of TLANDO highlights our commitment to the testosterone market. We expect to expand our commercial field organization and leverage our existing relationships with urologists, endocrinologists and primary care physicians in tandem with a strong clinical acumen of the testosterone market to support the anticipated U.S. launch of TLANDO. We believe our future growth will be supported by a larger commercial portfolio including TLANDO, XYOSTED and NOCDURNA,” added Joseph Renda, Senior Vice President, Commercial of Antares Pharma.

Under the terms of the agreement, Lipocine received an upfront payment of \$11.0 million and is eligible for additional milestone payments up to \$10.0 million and tiered royalty and commercial milestones based on net sales of TLANDO® in the U.S.

The agreement also grants Antares the option to license and develop LPCN 1111 (TLANDO XR), an investigational product containing testosterone tridecanoate. Upon exercise of the option, Antares shall pay an additional \$4.0 million in license fees in two installments. Antares shall also be responsible for additional development and commercial milestone payments as well as tiered royalties on net sales of TLANDO XR in the U.S.

TLANDO XR is a potential once daily oral testosterone product in development for the treatment of hypogonadism in adult males. Results of the Phase 2b study for TLANDO XR met its primary endpoints, including identifying the dose expected to be tested in a Phase 3 study. TLANDO XR was well tolerated with no drug-related severe or serious adverse events reported and the target Phase 3 dose also met its primary and secondary endpoints in the Phase 2b study. TLANDO XR is an investigational drug and has not been approved by the FDA.

### **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.

### **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](http://www.lipocine.com).

### **SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

**This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to: uncertainties regarding future FDA approval of TLANDO®, market acceptance and future revenue from the same, whether Antares will exercise the option for TLANDO XR and if exercised, future timing and success of the clinical development program for TLANDO XR and future FDA approval, market acceptance and revenue from the same; the Company's ability to achieve the 2021 full-year revenue guidance; the uncertainty regarding the ongoing COVID-19 pandemic, including new strains of the virus, and the mitigation measures and other restrictions implemented in response to the same and the impact on demand for our products, new patients and prescriptions, future revenue, product supply, clinical trials, and our overall business, operating results and financial condition; commercial success of XYOSTED® and future revenue from the same; market acceptance of Teva's generic epinephrine auto-injector product and future revenue from the same; future prescriptions and sales of OTREXUP®;**

successful commercialization of NOCDURNA<sup>®</sup> in the U.S. and market acceptance and future revenue from the same; whether the FDA will withdraw marketing approval for AMAG Pharmaceuticals' Makena<sup>®</sup> subcutaneous auto injector following the FDA letter seeking withdrawal, the outcome of the FDA hearing and whether Makena<sup>®</sup> will be successful and future prescriptions, market acceptance and revenue from the same; Teva's ability to successfully commercialize VIBEX<sup>®</sup> Sumatriptan Injection USP and the amount of revenue from the same; Teva's ability to successfully commercialize generic teriparatide in Europe, Canada and Israel and future revenue from the same, successful development including the timing and results of the Phase 3 trial of the drug device combination product for selatogrel with Idorsia Pharmaceuticals and FDA and global regulatory approvals and future revenue from the same; the timing and results of the clinical development program for ATRS-1902 adrenal crisis rescue auto-injector, future NDA submission and FDA approval of the same, and if approved, future market acceptance and revenue for the same; FDA approval of Teva's ANDAs for both generic Forteo<sup>®</sup> and Byetta<sup>®</sup> and future revenue from the same; the timing and results of the Company's or its partners' research projects or clinical trials of product candidates in development including the Company's urology assets in development as well as Pfizer's undisclosed development product; actions by the FDA or other regulatory agencies with respect to the Company's products or product candidates of its partners; continued growth in product, development, licensing and royalty revenue; the Company's ability to repay the debt obligation to Hercules Capital; the Company's ability to obtain financial and other resources for its research, development, clinical, and commercial activities and other statements regarding matters that are not historical facts, and involve predictions. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, achievements or prospects to be materially different from any future results, performance, achievements or prospects expressed in or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as "may", "will", "should", "would", "expect", "intend", "plan", "anticipate", "believe", "estimate", "predict", "potential", "seem", "seek", "future", "continue", or "appear" or the negative of these terms or similar expressions, although not all forward-looking statements contain these identifying words. Additional information concerning these and other factors that may cause actual results to differ materially from those anticipated in the forward-looking statements is contained in the "Risk Factors" section of the Company's Annual Report on Form 10-K, and in the Company's other periodic reports and filings with the Securities and Exchange Commission. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to the Company on the date hereof, and the Company undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.

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