Source: *Antares Pharma, Inc.*

February 03, 2022 08:00 ET

Antares Pharma Announces FDA Acceptance of NDA Resubmission for TLANDO®

PDUFA target action date set for March 28, 2022

EWING, N.J., Feb. 03, 2022 (GLOBE NEWSWIRE) -- Antares Pharma, Inc. (NASDAQ: ATRS) (the "Company"), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration ("FDA") has accepted its New Drug Application ("NDA") resubmission for TLANDO® (testosterone undecanoate), an oral treatment for testosterone replacement therapy ("TRT"). The FDA designated the NDA as a Class 1 resubmission with a two-month review goal period and set a target action date of March 28, 2022, under the Prescription Drug User Fee Act (PDUFA).

TLANDO® was granted tentative approval from the 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.

"As we take this final step moving from tentative approval to potential final approval in late March, we will continue to prepare for the commercial launch of TLANDO. Our National Sales Meeting is set for the end of April and will serve as the venue to train and ready our sales professionals to start promoting TLANDO to the medical professionals who treat testosterone deficiency. We are excited to be able to complement our current offering of XYOSTED with an oral formulation to patients and physicians. We will leverage our strong physician relationships which we believe will accelerate the adoption of TLANDO, support our future revenue growth and drive our market share gains in the testosterone market," commented Robert F. Apple, President and Chief Executive Officer of Antares Pharma.

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 and Sumatriptan Injection USP, which is distributed by Teva. The Company also markets NOCDURNA® (desmopressin acetate) in the U.S. and expects to commercially launch TLANDO® (testosterone undecanoate) in the U.S. pending final FDA approval.

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: FDA action by the PDUFA date and final approval of the NDA for TLANDO®, future commercial launch, market acceptance, prescriptions and revenue for TLANDO®; the timing and results of the clinical development program for ATRS-1902 adrenal crisis rescue auto-injector including the pivotal study and human factors study, future NDA submission, acceptance and FDA approval of the same, and if approved, future market acceptance and revenue for the same; the Company's ability to achieve the updated

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; the timing and results of the Company's or its partners' research projects or clinical trials of product candidates in development; actions by the FDA or other regulatory agencies with respect to the Company's products or product candidates of its partners; commercial success of the Company's products or partner products and continued growth in product, development, licensing and royalty revenue; 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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