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# Antares Pharma Receives FDA Fast Track Designation for ATRS-1902 for Adrenal Crisis Rescue

EWING, N.J., Jan. 18, 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 granted Fast Track designation for ATRS-1902 for adrenal crisis rescue. The development program for ATRS-1902 supports a proposed indication for the treatment of acute adrenal insufficiency, known as adrenal crisis, in adults and adolescents, using our Vai™ novel proprietary auto-injector platform to deliver a liquid stable formulation of hydrocortisone.

The FDA's Fast Track designation process is designed to accelerate the development and review of treatments for serious and life-threatening diseases where no treatment exists or where the treatment in discovery may provide advantages over what is currently available. A drug candidate that receives Fast Track designation is eligible for more frequent communication with the FDA throughout the drug development process and a rolling and/or priority review of its marketing application if relevant criteria are met.

"We are very pleased that ATRS-1902 has received Fast Track designation from the FDA, a distinction that underscores the urgent need for an improved therapy for these patients who suffer from a potentially life-threatening situation. We look forward to working closely with the agency as we advance our development of ATRS-1902 with an upcoming pivotal clinical study and an additional human factor study that we anticipate will support our 505(b)(2) NDA submission by the end of the year," commented Dr. Peter Richardson, MRCP (UK), EVP, Research and Development and Chief Medical Officer of Antares Pharma.

Robert F. Apple, President and Chief Executive Officer of Antares Pharma, added, "This designation by the FDA represents an important milestone for the clinical development of ATRS-1902. We appreciate the opportunity to work more collaboratively with the FDA on our hydrocortisone rescue pen. ATRS-1902 is one of many rescue pen products that we are currently developing for ourselves or for our partners that we believe can benefit patients with serious medical conditions and support our future growth."

Antares also recently announced positive results of the Phase I cross-over study for ATRS-1902 that met its primary objective showing ATRS-1902 (100 mg) delivered a comparable pharmacokinetic profile to Solu-Cortef® (100 mg), the reference-listed drug, in 32 healthy adults.

**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: 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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