



## **ANTARES PHARMA ANNOUNCES FDA ACCEPTANCE OF IND APPLICATION FOR ATRS-1902 FOR ADRENAL CRISIS RESCUE**

**EWING, NJ, July 22, 2021** – Antares Pharma, Inc. (NASDAQ: ATRS) (“the Company”), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug Application (IND) for ATRS-1902 for adrenal crisis rescue. The active IND enables Antares to initiate a Phase 1 clinical study for ATRS-1902 for the treatment of acute adrenal insufficiency, known as adrenal crisis, in adults and adolescents, using a novel proprietary auto-injector platform to deliver hydrocortisone.

“The FDA acceptance of this IND is an important milestone in the development of a novel formulation and delivery of hydrocortisone in a crisis situation. We believe acute adrenal insufficiency is a medical emergency which would benefit from a simplified and readily-available way to administer an essential treatment during a possibly life-threatening situation,” commented Dr. Peter Richardson, MRCP (UK), EVP, Research and Development and Chief Medical Officer of Antares Pharma.

Adrenal crisis is a potentially fatal condition associated mainly with an acute deficiency of cortisol, which is a hormone produced and released by the adrenal gland, and commonly occurs in patients with long-term adrenal insufficiency. Current standard of care for the management of acute adrenal crises includes Solu-Cortef<sup>®</sup>, which is an anti-inflammatory glucocorticoid. With hydrocortisone sodium succinate as the active ingredient, Solu-Cortef<sup>®</sup> is provided as a sterile powder that needs to be reconstituted for intravenous or intramuscular injection and can represent a potentially time-consuming and cumbersome injection process, particularly challenging in a crisis situation.

Robert F. Apple, President and Chief Executive Officer of Antares Pharma, added, “We are pleased to be able to advance the development of our proprietary pipeline with the FDA acceptance of this IND. With a novel expansion to our device technology platform, we hope to enhance the clinical benefit and offer key advantages to this important patient population at a critical time. We also look forward to the opportunity to leverage the success that our commercial team continues to garner with XYOSTED to ATRS-1902, as both products have an endocrinology call point. We are excited to continue to invest in our proprietary pipeline to support our potential future growth.”

The IND application for ATRS-1902 includes a protocol for an initial clinical study to compare the pharmacokinetic (PK) profile of the Company’s novel formulation of hydrocortisone versus Solu-Cortef<sup>®</sup>, which is expected to initiate in 2H 2021. Assuming this study is completed successfully, a second study will then be conducted utilizing Antares’ proprietary auto-injector technology which has been developed to provide reliability and ease-of-use in emergency situations by the patient or caregiver. We believe these two studies will be the basis of our anticipated 505(b)(2) NDA filing with the FDA expected towards the end of 2022.

### **About Antares Pharma**

Antares Pharma, Inc. is a specialty pharmaceutical company focused primarily on the development and commercialization of pharmaceutical products and technologies that address unmet needs in targeted therapeutic areas such as urology and endocrinology. 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.

#### **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-1901 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, 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® in the U.S. and market acceptance and future revenue from the same; whether the FDA will withdraw marketing approval for AMAG Pharmaceuticals' Makena® subcutaneous auto injector following the FDA letter seeking withdrawal, whether AMAG will be granted an appeal hearing and if granted, whether Makena® will be successful and future prescriptions, market acceptance and revenue from the same; Teva's ability to successfully commercialize VIBEX® 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; FDA approval of Teva's ANDAs for both generic Forteo® and Byetta® 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.

**Contact:**

Tram Bui

Vice President, Corporate Communications and Investor Relations

609-359-3016

[tbui@antarespharma.com](mailto:tbui@antarespharma.com)