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Antares Pharma Announces Positive Results From Phase I Study For ATRS-1902 For Adrenal Crisis Rescue

EWING, N.J., Jan. 11, 2022 (GLOBE NEWSWIRE) -- Antares Pharma, Inc. (NASDAQ: ATRS) (the "Company"), a specialty pharmaceutical company, today announced positive results from a Phase I study for ATRS-1902 for adrenal crisis. The positive results support the advancement of the ATRS-1902 development program to a pivotal clinical study for the treatment of acute adrenal insufficiency, known as adrenal crisis, in adults and adolescents, using our Vai™ novel proprietary rescue pen platform to deliver a liquid stable formulation of hydrocortisone.

The results of the Phase I cross-over study 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. The study also demonstrated that ATRS-1902 was safe and well tolerated.

"We are pleased that the results from this Phase I study support the advancement of ATRS-1902 to a pivotal clinical study which we anticipate starting in the second quarter of 2022. As we remain focused on strengthening our clinical development pipeline, we expect to file the 505(b)(2) NDA with the FDA by the end of 2022 assuming the successful completion of the pivotal study and an additional human factor study. We look forward to the opportunity to provide an essential treatment that can be easily administered for a potentially life-threatening situation," 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, "These positive results reinforce our commitment to improving the current standard of care for adrenal crisis patients and advancing our proprietary development pipeline. As a leader in rescue pen technology, our recently developed Vai device allows for a simple injection for patients in crisis. With a clear development timeline, we expect ATRS-1902 to support our future revenue growth and leverage our commercial organization and one of our current therapeutic footprints in endocrinology."

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 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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