



NEWS RELEASE

ANTARES PHARMA ANNOUNCES RECEIPT OF ORPHAN DRUG DESIGNATION FOR THE TREATMENT OF ECTOPIC PREGNANCY WITH METHOTREXATE

EWING, NJ, March 28, 2019 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced receipt of orphan drug designation to evaluate the use of subcutaneous methotrexate ("MTX") for the treatment of ectopic pregnancy that meets predefined criteria for medical management. Antares plans to initiate a development program utilizing a proprietary auto injector device with doses of methotrexate not commercially approved or available in an auto injector in order to provide potential benefits for both patients and healthcare professionals.

Ectopic pregnancy is simply defined as a pregnancy that occurs outside of the uterine cavity. Due to several potential causes, the nonviable pregnancy tissue grows in the abnormal location with the most common site being the fallopian tube. If untreated, the pregnancy may continue to grow, rupture the tube and create catastrophic bleeding with subsequent death of the patient. Most cases of unruptured ectopic pregnancy can be successfully treated with either minimally invasive surgical techniques (laparoscopy) or with medical management using intramuscular methotrexate in an "off-label" fashion.

Dr. James P. Tursi, Executive Vice President, Head of Research & Development, Chief Medical Officer, stated, "The use of subcutaneous methotrexate has the potential to effectively medically treat an ectopic pregnancy resolving the risk of rupture, hemorrhage and subsequent death without the need for laparoscopic surgery or emergency surgical intervention." He continued, "We believe the potential avoidance of surgical intervention and associated risks of surgery and anesthesia may reduce patient morbidity and costs to the healthcare system. Medical treatment with methotrexate may also help to preserve future fertility and may obviate the need for surgical intervention or future infertility intervention. This is potentially both life-saving and cost-saving. The subcutaneous approach utilizing our proprietary auto injector technology may reduce patient discomfort when compared to traditional intramuscular injections. We are not aware of any sponsor that has conducted well-designed clinical studies to fully characterize the appropriate dosing, safety and efficacy of MTX for the treatment of unruptured ectopic pregnancy."

Ectopic pregnancy accounts for approximately 2% of all reported pregnancies in the United States. Approximately 128,000 ectopic pregnancies occur annually. Despite improvements in diagnosis and management, ectopic pregnancy continues to be a significant cause of pregnancy-related morbidity and mortality. Hemorrhage from ectopic pregnancy is the leading cause of pregnancy-related maternal death in the first trimester and accounts for 4% to 10% of all pregnancy related deaths in the U.S.

The Orphan Drug Designation program is overseen by the U.S. Food and Drug Administration (FDA) and provides orphan designation status to drugs and biologics for rare diseases/conditions, defined as diseases/conditions that affect fewer than 200,000 people in the U.S. The purpose of the designation was to create incentives for companies to develop new drugs and biologics for rare diseases. These incentives may include a partial tax credit for certain clinical trial expenditures, the waiver of certain FDA user fees, and potential eligibility for 7 years of orphan drug marketing exclusivity if approved. The granting of an orphan designation request does not alter the standard regulatory requirements or the approval standard and process for obtaining marketing approval.

About Antares Pharma

Antares Pharma, Inc. is a combination drug device company focused on the development and commercialization of self-administered parenteral 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 advanced stages of development, as well as significant strategic alliances with industry leading pharmaceutical companies including Teva Pharmaceutical Industries, Ltd. (Teva), AMAG Pharmaceuticals, Inc. and Pfizer Inc. (Pfizer). Antares Pharma's proprietary products include XYOSTED™ (testosterone enanthate) injection, OTREXUP® (methotrexate) injection for subcutaneous use and Sumatriptan Injection USP, which is distributed by Teva.

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 with orphan designation to evaluate the use of subcutaneous methotrexate for the treatment of ectopic pregnancy that meets predefined criteria for medical management; the ability to maintain orphan drug designation, receive ultimate product approval, and receive the advantages of orphan drug designation; market acceptance, adequate reimbursement coverage and 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; successful completion of the transaction with Ferring International Center, S.A.; future market acceptance and revenue from Makena® subcutaneous auto injector; Teva's ability to successfully commercialize VIBEX® Sumatriptan Injection USP and the amount of revenue from the same; continued growth of prescriptions and sales of OTREXUP®; the timing and results of the Company's or its partners' research projects or clinical trials of product candidates in development including projects with Teva and Pfizer; 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; achievement of the 2019 revenue guidance; 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:

Jack Howarth
Vice President, Corporate Affairs
609-359-3016
jhowarth@antarespharma.com