



## **ANTARES PHARMA ANNOUNCES POSITIVE RESULTS FROM FINAL MTX MEDI-JET™ CLINICAL STUDY**

### **MTX MEDI-JET™ SHOWN TO INCREASE AND PROVIDE CONSISTENT MTX SYSTEMIC AVAILABILITY COMPARED TO ORAL MTX**

**EWING, NJ, November 13, 2012** -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced positive results from an open-label, randomized, crossover study comparing the systemic availability of MTX Medi-Jet to oral methotrexate (MTX) in adult patients with rheumatoid arthritis (RA).

This study was designed to compare the relative systemic availability of MTX following oral administration to subcutaneous (SC) self-administered MTX using the Medi-Jet device. Patients were assigned to one of four dose levels of MTX, 10 mg, 15 mg, 20 mg, and 25 mg. Results showed that the systemic availability of methotrexate following oral dosing plateaus above 15 mg. Following administration of MTX with Medi-Jet, the systemic availability increased proportionally at every dose, which will extend the range of exposure compared to patients receiving oral therapy.

Historically, parenteral MTX use has been limited in clinical practice for several reasons including the inconvenience of weekly injections by a healthcare professional, and/or the challenges associated with teaching patients with impaired hand function, safe and sterile self-injection techniques. To address these issues, the easy to use, single-use MTX Medi-Jet auto injector was developed to optimize the clinical benefit of MTX, leading to cost effective treatment outcomes.

Dr. Lee S. Simon, Co-managing Director SDG LLC, stated, "Methotrexate has become the gold standard for first line disease modifying drugs used in the treatment of rheumatoid arthritis. Understanding how to optimize methotrexate therapy for better patient outcomes has become increasingly important." Dr. Simon continued, "Treating to target in relation to biologic therapies, so that patients can achieve a low activity state of disease is optimal, and it is now time to address this same idea with methotrexate taking advantage of the MTX Medi-Jet to improve patient care."

"Greater exposure to MTX when administered with MTX Medi-Jet could enhance the efficacy with improved response to disease control." said Kaushik J. Dave R.Ph., Ph.D., Executive Vice President Product Development.

### **About VIBEX Medi-Jet and Methotrexate**

VIBEX Medi-Jet is a proprietary parenteral drug delivery system protected by several issued and pending patents. VIBEX Medi-Jet is designed to enable patients to quickly and easily self-administer a drug subcutaneously or intramuscularly, reliably and comfortably while also enhancing safety with an integrated, shielded needle that protects against accidental needle stick and drug exposure. VIBEX and Medi-Jet are trademarks of Antares Pharma.

Methotrexate is a commonly prescribed disease-modifying anti-rheumatic drug (DMARD), used in an estimated 70% of rheumatoid arthritis patients either on its own or in combination with biological therapies. Methotrexate is started at a low dose, generally 7.5mg given orally, once-a-week, and titrated up for greater therapeutic effect, or until the patient incurs side effects. The maximum oral

dose given is generally 20mg to 25mg per week. Published studies have reported that 30% to 60% of patients experience gastrointestinal side effects with oral methotrexate, preventing further dose escalation or requiring discontinuation in some patients. Oral absorption of methotrexate varies considerably between patients and between doses in the same patient and has been shown to decline with increasing doses, which may also contribute to insufficient therapeutic response even after dose escalation. Switching patients from oral to parenteral methotrexate improves absorption and has been associated with improved therapeutic response. Additionally, some studies have shown a lower incidence of gastrointestinal side effects in patients that were switched from oral to parenteral methotrexate.

## **About Antares Pharma**

Antares Pharma focuses on self-administered parenteral pharmaceutical products and topical gel-based medicines. The Company's technology platforms include VIBEX™ disposable Medi-Jet, disposable multi-use pen injectors and Vision™ reusable needle-free injectors marketed as TJet® and Zomajet® by Teva Pharmaceutical Industries, Ltd (Teva) and Ferring Pharmaceuticals (Ferring), respectively. Antares Pharma has a multi-product deal with Teva that includes Tev-Tropin® human growth hormone (hGH), VIBEX epinephrine and several other products. Antares Pharma's partnership with Ferring includes Zomacton® hGH. In the U.S. Antares has received FDA approval for Gelnique 3%™, a treatment for overactive bladder that is marketed by Watson Pharmaceuticals, Inc. Elestrin® (estradiol gel) is FDA approved for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, and is marketed in the U.S. by Meda Pharma. Antares Pharma has two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted Medi-Jet and pen injector systems. The Company's corporate head office and Product Development Group are located in Ewing, New Jersey.

## **Forward-Looking Statement**

This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are indicated by the words "may," "will," "plans," "intends," "believes," "expects," "anticipates," "potential," "could," "would," "should," and similar expressions. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties include, among others, changes in revenue growth and difficulties or delays in the initiation, progress, or completion of product development. 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 for the year ended December 31, 2011, 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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