



## **ANTARES PHARMA ANNOUNCES SUBMISSION OF NEW DRUG APPLICATION FOR OTREXUP™**

**EWING, NJ, December 17, 2012** -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for OTREXUP™, a combination product for the delivery of methotrexate (MTX) using Medi-Jet™ technology. OTREXUP was developed for easy subcutaneous administration of MTX to enhance the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA and moderate to severe psoriasis.

“The NDA submission of OTREXUP represents yet another significant accomplishment in the Company’s history,” said Paul K. Wotton Ph.D., President and Chief Executive Officer. “It is the first product designed for convenient subcutaneous delivery of methotrexate in patients with rheumatoid arthritis or psoriasis. We believe OTREXUP will benefit most patients that have not reached a satisfactory response to oral methotrexate alone or in combination with a biologic or another disease-modifying anti-rheumatic drug.”

OTREXUP was developed to optimize the clinical benefit of MTX, leading to cost effective treatment outcomes. Historically, parenteral MTX use has been limited in clinical practice for several reasons including the inconvenience of weekly intramuscular injections by a healthcare professional, and/or the challenges associated with teaching patients with impaired hand function, safe and sterile self-injection techniques. Studies conducted to date indicate OTREXUP is safe, easy and comfortable for RA patients to self-administer precise subcutaneous doses of MTX with improved systemic availability compared to oral doses.

The NDA submission, subject to acceptance and approval by the FDA, was supported by data generated from a clinical development program completed in accordance with the FDA’s guidance and recommendations. Antares executed and completed all of the clinical studies agreed with the agency and described in the clinical development program.

“The dedicated efforts of the entire Antares team have allowed us to submit a New Drug Application to the FDA ahead of schedule,” said Kaushik J. Dave R.Ph., Ph.D., Executive Vice President Product Development. “The results from the clinical development program have shown that OTREXUP can provide greater systemic exposure to methotrexate compared to oral doses. We believe OTREXUP is easy to use and comfortable for RA patients with moderate to severe hand function impairment thereby enhancing self-administration and patient compliance.”

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

Medi-Jet is a proprietary parenteral drug delivery system protected by several issued and pending patents. 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. Medi-Jet is a trademark 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 Rheumatoid Arthritis**

Rheumatoid Arthritis is a form of inflammatory arthritis and an autoimmune disease. In rheumatoid arthritis, the immune system – which is designed to protect our health by attacking foreign cells such as viruses and bacteria – instead attacks the body's own tissues, specifically the synovium, a thin membrane that lines the joints. As a result of the attack, fluid builds up in the joints, causing pain in the joints and inflammation that's systemic – meaning it can occur throughout the body. Rheumatoid arthritis is a chronic, incurable disease. Most people with RA experience intermittent bouts of intense disease activity, called flares. In some people the disease is continuously active and gets worse over time. Evidence shows that early diagnosis and treatment to put the disease into remission is the best means of avoiding joint destruction, organ damage and disability.

### **About Psoriasis**

Psoriasis is a chronic, autoimmune disease that appears on the skin. It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells. Psoriasis is not contagious. There are five types of psoriasis. The most common form, plaque psoriasis, appears as raised, red patches covered with a silvery white build-up of dead skin cells. Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes, heart disease and depression. Psoriasis is the most common autoimmune disease in the U.S. According to the National Psoriasis Foundation, as many as 7.5 million Americans have psoriasis.

### **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 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.

### **Contacts:**

Jack Howarth  
Vice President, Corporate Affairs  
609-359-3016  
[jhowarth@antarespharma.com](mailto:jhowarth@antarespharma.com)