



ANTARES PHARMA ANNOUNCES SUCCESSFUL RESULTS FROM VIBEX MTX ACTUAL HUMAN USE STUDY

VIBEX™ MEDI-JET™ SHOWN TO BE RELIABLE, SAFE AND EASY TO USE

EWING, NJ, September 25, 2012 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced positive results from an Actual Human Use (AHU) study for VIBEX Methotrexate (MTX). The clinical trial was conducted as a multi-center, open-label, single-arm, in-clinic study to evaluate the actual human use of methotrexate administered via the VIBEX Medi-Jet in adult patients with rheumatoid arthritis (RA).

The study assessed the safe usability of VIBEX MTX for self-administration of parenteral MTX in adult RA patients after standardized training by site personnel and review of written instructions. Secondary objectives included evaluation of the reliability, ease of use and robustness of the VIBEX Medi-Jet; assess the safety and local tolerance of Medi-Jet administered MTX and to evaluate the effectiveness of the patient education tools including written instructions for use.

“We believe that the successful completion of this study is important for Antares as we continue to build our company and further control our key product programs,” said Paul K Wotton, Ph.D., President and Chief Executive Officer. “The performance of the VIBEX Medi-Jet in this clinical study also validates our technology platform upon which we are developing multiple products like MTX and Testosterone, optimizing treatment options and allowing patients to self-administer parenteral medications conveniently at home and potentially reduce overall healthcare costs.”

The Actual Human Use study consisted of three visits over nine days and included a screening period, a treatment period and a follow-up visit. In total, 101 patients were enrolled in four study dose groups, 10 mg. (n=20), 15 mg. (n=30), 20 mg. (n=31) and 25 mg. (n=20). The single MTX dose was self-administered by the patient from one of the four dose groups using the VIBEX Medi-Jet.

The results of this study show that self-administration of MTX using the VIBEX Medi-Jet is safe and well tolerated. Following standardized training by site personnel and review of written instructions, all 101 patients performed the self-administration successfully. In addition, the VIBEX Medi-Jet functioned correctly and as intended for each and every administration thereby demonstrating reliability and robustness. Results of the Ease of Use Questionnaire indicated that 98% of patients found the VIBEX Medi-Jet easy to use and 100% of patients found the instructions and training to be clear and easy to follow. Patients were also asked to report site administration pain at the end of the treatment period. Administration site pain was measured using a 100 mm Visual Analog Scale (VAS) and showed that patients experienced minimal or no pain with a mean value of 3.6 mm on a scale of 100 mm. Importantly, no patients experienced treatment-emergent serious adverse events related to the drug.

“We are extremely pleased with the results of the Actual Human Use study,” said Kaushik J. Dave R.Ph., Ph.D., and Executive Vice President Product Development. “The study demonstrated that rheumatoid arthritis patients were able to successfully self-administer MTX with the VIBEX Medi-Jet which we believe is safe, well tolerated and easy to use. These study results along with the positive Usability Study results previously reported in patients with severe to very severe hand function impairment keep us on schedule for an early 2013 filing of the New Drug Application for VIBEX MTX, a potential new treatment option for patients who suffer with RA.”

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. The 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 Jazz Pharmaceuticals. 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 VIBEX 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.

Contacts:

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