



SUBCUTANEOUS, SELF-ADMINISTERED METHOTREXATE FOR RHEUMATOID ARTHRITIS DEMONSTRATED SIGNIFICANTLY GREATER BIOAVAILABILITY OVER CURRENT STANDARD OF CARE

-- Study Shows Methotrexate Delivered with an Innovative Delivery Device Achieved Significantly Greater Bioavailability over Oral Methotrexate --

-- Data Presented at 2013 European League Against Rheumatism (EULAR) Annual Congress in Madrid--

EWING, NJ, June 13, 2013 — Antares Pharma, Inc. (NASDAQ: ATRS) today announced subcutaneous methotrexate delivered with a new, self-administration device demonstrates bioavailability that is significantly greater than oral methotrexate in the treatment of adults with rheumatoid arthritis. The clinical study results were presented at the 2013 European League Against Rheumatism (EULAR) Annual Congress.

The data are from a randomized, open-label, three-way crossover study that found four hours after dose, blood concentrations of subcutaneously, self-administered methotrexate were consistently higher than concentrations of orally dosed methotrexate at all levels studied.

Oral methotrexate exposure plateaued at doses of 15 mg and higher, whereas self-administered subcutaneous methotrexate did not plateau, with exposure continuing to increase at each dose. Study investigators concluded that this resulted in higher systemic exposure than the same oral dose, which may have important clinical implications.

“These results represent a significant step forward in exploring the optimization of methotrexate, the disease modifying anti-rheumatic drug most commonly used as first-line for treatment for rheumatoid arthritis around the world,” said Michael H. Schiff, M.D., Clinical Professor of Medicine in the Rheumatology Division at the University of Colorado School Of Medicine in Denver. “Administering methotrexate subcutaneously translates to linear dose absorption which may improve the efficacy of subcutaneous methotrexate compared to oral therapy. This improved efficacy has been previously reported in the literature and observed in clinical practice.¹”

The self-administration device is one component of an investigational product under review by the Food and Drug administration that combines the proprietary VIBEX™ auto-injection delivery device with an injectable version of methotrexate, the drug long regarded as the standard of care in the treatment of rheumatoid arthritis.

The study of fifty adults compared the bioavailability of methotrexate administered using the investigational self-administration device-drug combination product relative to that of the bioavailability of orally dosed methotrexate. It also assessed the safety of the first-in-class delivery system.

Four hours after dosing, mean systemic concentration was consistently higher in patients who received subcutaneously self-administered methotrexate compared with those who received oral methotrexate. The concentration of MTX in the self-administration subcutaneous group was greater at all dose levels (10mg, 15 mg, 20mg, or 25 mg) than in the group receiving oral drug, as measured by pharmacokinetic parameters.

Relative bioavailability of subcutaneous methotrexate delivered with the self-administration device at 10, 15, 20, and 25mg/0.4ml was 121 percent, 114 percent, 131 percent and 141 percent compared with oral dosing, respectively.

Peak concentration increased in a dose-proportional manner for patients in the self-administration subcutaneous group compared with oral MTX. The relative bio-availability of MTX, as measured by the area under the concentration curve, was substantially improved for patients randomized to receive subcutaneous treatment with the self-administration device. The ratio of the dose-normalized area under the concentration curve over a 24-hour period and maximum observed concentration compared with oral MTX was 127.61 (90 percent CI: 122.30-133.15) and 94.88 (90 percent CI: 87.95-103.37), respectively.

“The data presented earlier today suggests there is an opportunity to increase the use of subcutaneous methotrexate which we are developing as OTREXUP™, in patients with rheumatoid arthritis or psoriasis in the U.S.,” said Paul Wotton, Ph.D., President and Chief Executive Officer. “We believe that one of the reasons for the under-utilization of subcutaneous methotrexate may be the absence of an easy-to-use device for self-administration. These new data for self-administered subcutaneous methotrexate provide support for extending the use of methotrexate in rheumatoid arthritis and psoriasis patients.”

About the Study

This randomized, open-label, 3-way crossover study was conducted over a 12-week period in 49 patients over the age of 18 with rheumatoid arthritis. Of 50 randomized patients, 49 were dosed and included in the safety population. Forty-seven patients completed the study; all patients were undergoing treatment with MTX for three or more months prior to randomization.

The primary objective of the study was to compare the relative bioavailability of methotrexate after oral administration with that of subcutaneous administration using the investigational delivery device. Over 12-weeks, two serious adverse events occurred, neither of which was considered to be treatment-related by the investigator. Treatment in both the oral methotrexate and subcutaneous methotrexate arms of the study were generally well tolerated. Five patients (10.2 percent) had a treatment-emergent adverse event; one patient in the oral MTX group experienced mild and transient nausea. Some patients in the delivery device group had slight to barely perceptible erythema at the injection site after administration. No patients experienced bleeding, ecchymosis, or hematoma at the injection site or required countermeasures during the study. No patients discontinued the study because of an injection site reaction.

About Antares Pharma

Antares Pharma focuses on self-administered parenteral pharmaceutical products and topical gel-based medicines. The Company is developing OTREXUP™, a combination product for the delivery of methotrexate using Medi-Jet™ technology for the treatment of rheumatoid arthritis, poly-articular-course juvenile rheumatoid arthritis and psoriasis, as well as VIBEX™ QS T for testosterone replacement therapy. 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 Actavis. 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 and Commercial Groups are located in Ewing, New Jersey.

Safe Harbor 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. In addition, the OTREXUP[™] product referred to in this press release has not yet been approved by the FDA, and the commercialization of OTREXUP[™] is dependent on the Company receiving FDA approval of this product. 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, 2012, 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.

1. Braun J, Kastner P, Flaxenberg P, et al; for the MC-MTX.6/RH Study Group. Comparison of the clinical efficacy and safety of subcutaneous versus oral administration of methotrexate in patients with active rheumatoid arthritis: results of a six-month, multicenter, randomized, double-blind, controlled, phase IV trial. *Arthritis Rheum.* 2008; 58(1):73-81.

Investor Contact:

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

Media Contact:

Elaine Andrecovich
Makovsky
212-508-9675