



## **ANTARES PHARMA ANNOUNCES PODIUM PRESENTATION OF OTREXUP™ DOSE CONVERSION DATA AT AMERICAN COLLEGE OF RHEUMATOLOGY ANNUAL MEETING**

**EWING, NJ, November 9, 2015** - Antares Pharma, Inc. (NASDAQ: ATRS) today announced that data derived from its Phase 2 study of the pharmacokinetics of subcutaneous versus oral methotrexate in the treatment of rheumatoid arthritis, was selected for a live, oral presentation on November 10, 2015 at the Rheumatoid Arthritis-Small Molecules, Biologics and Gene Therapy Strategies session to be held during the 2015 Annual Meeting of the American College of Rheumatology, November 7 - 11 in San Francisco. The abstract, entitled “Oral to Subcutaneous Methotrexate Dose-Conversion Strategies in the Treatment of Rheumatoid Arthritis,” authored by Michael H. Schiff, MD et al., was among a select group of key abstracts awarded the distinction of a live, oral presentation.

In a Phase 2, 12-week open label, crossover study, 49 adults with rheumatoid arthritis (RA) already receiving oral methotrexate (MTX) for more than three months were given 10, 15, 20 or 25 mg of OTREXUP™ based on their current MTX dose and disease control. The patients were randomized as to dose order. After dosing, blood samples for pharmacokinetic analysis were collected, analysed and dose-normalized parameter ratios were calculated. Using regression analysis methods, researchers identified a dose-conversion strategy that could provide guidance to rheumatologists seeking to convert oral methotrexate patients to OTREXUP™.

“Although exposure to oral methotrexate is seen to plateau at 15 mg, methotrexate administered subcutaneously had no exposure plateau and results in higher blood levels than comparable oral doses,” wrote lead author Michael H. Schiff, MD, of the University of Colorado, Denver. “The difference in drug exposure levels creates the need for guidance on a predictive dose conversion strategy.”

When using OTREXUP™ (methotrexate), the most commonly prescribed form of subcutaneous methotrexate in an auto injector, researchers concluded that a 10 mg oral dose should be converted to 10 mg subcutaneous dose, 15 and 20 mg oral doses should be converted to a 15 mg subcutaneous dose, and a 25 mg oral dose should be converted to a 20 mg subcutaneous dose.

“This is the first study to establish a successful dose conversion strategy between oral methotrexate and this subcutaneous methotrexate auto-injector formulation in RA, which may help clinicians optimize the use of MTX for better disease control,” Dr. Schiff concluded.

The details for Dr. Schiff’s oral presentation are as follows:

**Date & Time:** Tuesday November 10 from 4:30-6:00 p.m. PT

**Location:** South – Esplanade, 307 Moscone Center

**Presentation Number:** 3194

For full prescribing information please visit [WWW.OTREXUP.COM](http://WWW.OTREXUP.COM)

### **IMPORTANT SAFETY INFORMATION**

OTREXUP™ is a single-dose auto-injector containing a prescription medicine, methotrexate. Methotrexate is used to:

- treat certain adults with severe, active rheumatoid arthritis (RA), and children with active polyarticular juvenile idiopathic arthritis (pJIA), after treatment with other medicines including non-steroidal anti-inflammatory (NSAIDs) have been used and did not work well.
- control the symptoms of severe, resistant, disabling psoriasis in adults when other types of treatment have been used and did not work well.

OTREXUP should not be used for the treatment of cancer.

OTREXUP should not be used for the treatment of children with psoriasis.

### **Methotrexate includes the following boxed warning:**

**OTREXUP can cause serious side effects that can lead to death, including:**

- **Organ system toxicity.** People who use methotrexate for the treatment of cancer, psoriasis, or rheumatoid arthritis, have an increased risk of death from organ toxicity. Types of organ toxicity can include: gastrointestinal, bone marrow, liver, immune system, nerve, lung, kidneys and skin.

**Your doctor will do blood tests and other types of tests before you take and while you are taking OTREXUP to check for signs and symptoms of organ toxicity. Call your doctor right away if you have any of the following symptoms of organ toxicity: vomiting, diarrhea, mouth sores, fever, confusion, weakness, temporary blindness, seizures, headache, back pain, neck stiffness, paralysis, irritability, sleepiness, and problems with coordination, dry cough, trouble breathing and severe skin rash.**

- **Women who are pregnant are at increased risk for death of the baby and birth defects. Women who are pregnant or who plan to become pregnant must not take OTREXUP. A pregnancy test should be performed before starting OTREXUP.**

**Contraception should be used by both females and males while taking OTREXUP. Pregnancy should be avoided if either partner is receiving OTREXUP:**

- **For a minimum of 3 months after treatment with OTREXUP for males.**
- **During and for at least 1 menstrual cycle after treatment with OTREXUP for females.**

### **What are the possible side effects of OTREXUP?**

OTREXUP may cause serious side effects, including:

See "What is the most important information I should know about OTREXUP?"

- **Fertility problems.** Methotrexate, the active ingredient in OTREXUP, may affect your ability to have a baby. Males may have a decreased sperm count, and females may have changes to their menstrual cycle. This can happen while taking OTREXUP and for a short period of time after you stop.
- **Certain cancers.** Some people who have taken methotrexate have had a certain type of cancer called Non-Hodgkin's lymphoma and other tumors. Your doctor may tell you to stop taking OTREXUP if this happens.
- **Tissue and bone problems.** Taking Methotrexate while having radiation therapy may increase the risk of your tissue or bone not receiving enough blood. This may lead to death of the tissue or bone.

**Common side effects of OTREXUP include:** nausea, stomach pain, indigestion (dyspepsia), mouth sores, and rash.

### **What should I tell my doctor before taking OTREXUP?**

Before you take OTREXUP, tell your doctor if you have any other medical conditions. Tell your doctor about all of the medicines you take, including prescription, over-the-counter medicines, vitamins, and herbal supplements.

OTREXUP may affect how other medicines work, and other medicines may affect how OTREXUP works causing side effects. Ask your doctor or pharmacist for a list of medicines if you are not sure.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of OTREXUP. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information, go to [www.OTREXUP.com](http://www.OTREXUP.com) or call 1-855- OTREXUP (1-855-687-3987).

## **About Antares Pharma**

Antares Pharma focuses on self-administered parenteral pharmaceutical products. The Company's product, OTREXUP™ (methotrexate) injection for subcutaneous use, is approved in the U.S. for the treatment of adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. Antares Pharma is also developing QuickShot® Testosterone for testosterone replacement therapy, and VIBEX® Sumatriptan for the acute treatment of migraines. The Company's technology platforms include VIBEX® disposable auto injectors, disposable multi-use pen injectors and reusable needle-free injectors. Antares Pharma has a multi-product deal with Teva Pharmaceutical Industries, Ltd. that includes VIBEX® epinephrine, exenatide multi-dose pen, and another undisclosed multi-dose pen. Our reusable needle-free injector for use with human growth hormone (hGH) is sold worldwide by Ferring B.V.

### **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. Factor that may cause such differences include, but are not limited to: continued growth of prescriptions and sales of OTREXUP™; the timing and results of the phase 3 studies for QuickShot® Testosterone (QS T) and acceptance of the data by the U.S. Food and Drug Administration (FDA); the Company's ability to successfully complete a New Drug Application for QS T and submit to the FDA and approval of the same; approval by the FDA of the VIBEX® Epinephrine Pen ("VIBEX® Epi Pen"); the timing and therapeutic equivalence rating thereof, and any revenue pre or post FDA approval; FDA action with respect to the ANDA filed for the Exenatide pen; the Company's response to the complete response letter from the FDA with respect to its ANDA for VIBEX® Sumatriptan and FDA action with respect to the same; the timing and results of research projects, clinical trials, and product candidates in development; actions by the FDA or other regulatory agency with the respect to the Company's products or product candidates and product candidates of its partners; continued growth in product, development, licensing and royalty revenue; 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 for the year ended December 31, 2014, 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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