



**OTREXUP™ (METHOTREXATE) INJECTION APPROVED BY FDA
A NEW TREATMENT FOR ADULTS WITH RHEUMATOID ARTHRITIS, CHILDREN
WITH POLYARTICULAR IDIOPATHIC ARTHRITIS, AND ADULTS WITH PSORIASIS**

-- OTREXUP™: *The First Proprietary Product Featuring the VIBEX® Medi-Jet™ Technology, an Easy-to-Use, Patient Friendly Auto Injector--*

EWING, N.J., October 14, 2013 — Antares Pharma, Inc. (NASDAQ: ATRS) today announced the approval of OTREXUP™ (methotrexate) injection by the U.S. Food and Drug Administration (FDA). OTREXUP™ is the first FDA approved subcutaneous (SC) methotrexate (MTX) for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP™ is indicated for adults with severe active rheumatoid arthritis (RA) who have had an insufficient therapeutic response to or are intolerant of an adequate trial of first line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs), or children with active polyarticular juvenile idiopathic arthritis (pJIA). The FDA also approved adult use of OTREXUP™ for symptomatic control of severe recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy.

In 2012, approximately six million prescriptions were written across all dosage forms of MTX in the U.S. to treat patients for RA, pJIA and psoriasis, the same indications for which OTREXUP™ has been approved. MTX treatment is usually initiated with oral tablets, however; many patients experience an inadequate response for reasons of efficacy or tolerability.

“This new delivery system for methotrexate provides a welcome option for physicians and their patients to continue effective use of methotrexate. OTREXUP™ can be used when a response is inadequate or there are tolerability issues with oral methotrexate, before adding or switching to costlier therapies,” said Dr. Michael Schiff, Clinical Professor of Medicine in the Rheumatology Division at the University Of Colorado School Of Medicine in Denver. “The availability of an easy and safe way to administer subcutaneous methotrexate may overcome some of the current barriers to parenteral administration which could enable more patients to realize the possibility of continued disease control and therefore benefit from subcutaneous methotrexate.”

Human study data submitted to the FDA demonstrated increased bioavailability of SC MTX compared to oral MTX at every dose. These results confirm and strengthen the findings of previously published bioavailability data, and highlight the saturable limitations of oral MTX that result in a bioavailability plateau at 15mg. These important data are included in the approved OTREXUP™ label and have been selected for a prestigious oral presentation this month at the American College of Rheumatology Scientific Meeting.

There has been substantial literature published that documents the potential benefits of SC MTX after an inadequate response to oral MTX. In the United States, however, use of parenteral MTX is often overlooked for the treatment of RA or psoriasis, primarily due to the

challenges of self-administration associated with compromised manual dexterity, needle phobia, or patients' lack of confidence to accurately and safely self-inject with a vial, needle and syringe.

"We are very pleased to receive approval from the FDA for OTREXUP™ because we believe it is an important step up in the standard of care for people living with RA, pJIA and psoriasis," said Paul Wotton, Ph.D., President and Chief Executive Officer of Antares Pharma. "This approval represents a strategic milestone for Antares because we believe it validates our proprietary VIBEX® Medi-Jet™ technology which provides a significant advance in improving health outcomes with high tech but easy self-administration of SC medications. Antares has several other products in development, where this auto-injector technology could provide substantial benefits if the product candidates are approved." He went on to say: "Our VIBEX® proprietary technology is protected by numerous granted patents and OTREXUP™ is protected by several patents through at least 2030."

"We expect the commercial launch of OTREXUP™ in early 2014 will make a meaningful difference in the lives of people living with RA, pJIA and psoriasis and we believe also introduces the potential for a cost effective treatment option for physicians", said LeRoux Jooste, Senior Vice President Sales & Marketing. "I have been fortunate in my career to lead and play a major role in several successful product launches and I am excited to introduce OTREXUP™ with an experienced team of sales and marketing professionals."

For full prescribing information please visit WWW.ANTARESPHARMA.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 or call 1-855-OTREXUP (1-855-687-3987).

About VIBEX[®] Medi-Jet[™]

VIBEX[®] disposable 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, reliably, and comfortably self-administer a drug subcutaneously or intramuscularly, Medi-Jet technology also enhances safety with an integrated, shielded needle that protects against accidental needle stick and drug exposure. Medi-Jet™ is a trademark of Antares Pharma.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, systemic autoimmune disease characterized by pain and inflammation of the joints. In people with RA, the immune system attacks healthy tissue, specifically the thin membrane that lines the joints, causing swelling that leads to pain and inflammation throughout the body. Over long periods of time, RA can cause damage to cartilage, tendons, or ligaments, leading to joint deformity or disability. Additionally, research shows that people with RA, mainly those whose disease is not well controlled, have a higher risk for heart disease and stroke.

About Polyarticular Juvenile Idiopathic Arthritis

Polyarticular juvenile idiopathic arthritis is a subgroup of juvenile idiopathic arthritis (JIA)¹ in which five or more joints are impacted in children within the first six months after disease onset. JIA occurs in people under the age of 18.

In patients with JIA, the immune system attacks healthy tissue, specifically the thin membrane that lines the joints, causing swelling that leads to pain and inflammation throughout the body. Over long periods of time, arthritis can cause damage to cartilage, tendons or ligaments, leading to joint deformity or disability.

Treatments are available that may help relieve symptoms and reduce inflammation. In addition, disease-modifying antirheumatic drugs (DMARDs) and new biologic agents can modify the disease or slow its progression.

About Psoriasis

Psoriasis is a chronic autoimmune skin disease that most commonly appears as raised, red patches with a white buildup of dead skin cells. Psoriasis can affect skin on any part of the body and occurs when the immune system sends out faulty signals that speed the growth cycle of skin cells. Psoriasis is considered recalcitrant psoriasis when it does not respond to therapy, and can be disabling.

Psoriasis is generally considered to be severe if it covers more than 5%-10% of body surface, recalcitrant when it does not adequately respond to treatment and disabling when it interferes with basic functions such as self-care, walking, sleep, etc.

About Antares Pharma

Antares Pharma focuses on self-administered parenteral pharmaceutical products and topical gel-based medicines. The Company is developing 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[®] [somatropin (rDNA origin) for injection] human growth hormone (hGH), VIBEX[®] epinephrine and several other products. Antares Pharma's partnership with Ferring includes Zomacton[®] hGH (somatropin) injection. In the U.S. Antares has received FDA approval for Gelnique 3%[™] (oxybutynin) gel, 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.

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 and include statements regarding our expectations regarding the launch of OTREXUP[™] and the application of the auto injector technology in other product candidates. 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, difficulties or delays in the commercial launch of OTREXUP[™], market acceptance by physicians and patients of new products, delays in product development and changes or delays in the regulatory process for existing or new product candidates. 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.

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