

# ANTARES PHARMA® ANNOUNCES AVAILABILITY OF OTREXUP™ (METHOTREXATE) INJECTION FOR SUBCUTANEOUS USE TO TREAT RHEUMATOID ARTHRITIS (RA) AND PSORIASIS IN ADULTS, AND POLYARTICULAR IDIOPATHIC ARTHRITIS (pJIA) IN CHILDREN

# OTREXUP<sup>™</sup> provides a new option that may benefit patients when the response to oral methotrexate is inadequate

**EWING, N.J., January 15, 2014** — Antares Pharma, Inc. (NASDAQ: ATRS) today announced the availability of OTREXUP<sup>™</sup>, the first U.S. Food and Drug Administration (FDA) approved subcutaneous (SC) methotrexate (MTX) product for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP was approved by the FDA in October 2013. OTREXUP is available at distribution centers throughout the USA.

Approximately 1.3 million Americans are diagnosed with RA and about 7.5 million with psoriasis. Initial treatment of these conditions with oral MTX usually provides a good response for many patients. However, some patients find it difficult to tolerate the oral formulation and/or receive limited benefit, especially when higher doses are required for a satisfactory response. Absorption following oral dosing showed a plateau effect at doses of 15 mg and greater.

"OTREXUP provides an attractive new option that may benefit patients who have had an inadequate response to or are intolerant of oral MTX," said Paul K. Wotton, Ph.D., President and Chief Executive Officer, Antares. "OTREXUP is an easy-to-use auto injector that delivers greater blood levels of medication than oral MTX. OTREXUP could extend the use and benefits of MTX and potentially delay or avoid the use of other more expensive treatment options in some patients."

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), and children with active polyarticular juvenile idiopathic arthritis (pJIA). OTREXUP also is indicated for use in adults who need symptomatic control of severe recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy.

"CreakyJoints welcomes new treatment options for patients with RA," said Seth Ginsberg, president and cofounder of CreakyJoints, one of the nation's largest rheumatic disease patient advocacy groups. "Because so many RA patients have limited manual dexterity, conventional syringes for injection of methotrexate are often difficult to use. An easy delivery system that combines subcutaneous methotrexate with a pre-filled auto-injector is an important addition to treatment options available because it expands RA patients' access to care."

The injectable use of MTX after an inadequate response to oral MTX is quite common in Europe and elsewhere in the world. In the United States, however, use of injectable MTX is often overlooked primarily due to the challenges of self-injection. The fear of needles, poor manual dexterity, especially in people living with RA, and a lack of confidence in accurately and safely self-injecting with a vial, needle and syringe may be some of the challenges people have to face.

"OTREXUP is a useful new treatment option that physicians can consider for their patients who could continue to benefit from MTX when their tablets provide an inadequate response," said Alvin F. Wells, MD, PhD, Director, Rheumatology & Immunotherapy Center, located in Franklin, Wisconsin. "An easy-to-use and almost pain-free injection can provide the higher blood levels of medication that may be necessary for these patients."



"Antares is committed to the consistent availability of OTREXUP and the support that patients and healthcare providers need," said LeRoux Jooste, SVP and General Manager, Antares Pharmaceuticals. "We have shipped OTREXUP to distribution centers throughout the US and have ample inventory of OTREXUP available to supply the market. As a research and development company, we plan ahead to ensure that OTREXUP remains an available treatment option for the patients who need it."

For full prescribing information please visit <u>WWW.OTREXUP.COM</u>

#### **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, and children with active polyarticular juvenile idiopathic arthritis (pJIA), after treatment with other medicines, including nonsteroidal antiinflammatory drugs (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, 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 for birth defects in the baby. 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:

• 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.

#### Who should not take Otrexup?

Do not take Otrexup if you:

- Are pregnant or planning to become pregnant
- Are breastfeeding; Otrexup can pass into your breast milk and may harm your baby
- Have alcohol problems (alcoholism)
- Have liver problems
- Have problems fighting infection (immunodeficiency syndrome)
- Have been told you have (or think you have) a blood disorder such as low levels of white blood cells, red blood cells (anemia), or platelets
- Have had an allergy to methotrexate or any of the ingredients in Otrexup

#### 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 medicines, 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information, go to www.Otrexup.com or call 1-855-OTREXUP (1-855-687-3987).

#### **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<sup>TM</sup> 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%<sup>TM</sup> (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 MediJet and pen injector systems. The Company's corporate office and Product Development and Commercial Groups are located in Ewing, New Jersey.

#### **About Creaky Joints**

CreakyJoints (http://www.CreakyJoints.org) is the world's leading arthritis support, education, advocacy and research community for people with arthritis (RA, PsA, OA, and other rheumatic diseases) as well as their caregivers. It is a part of the non-profit Global Healthy Living Foundation (http://www.GHLF.org).CreakyJoints was co-founded by arthritis patient Seth Ginsberg in 1999, and today, has a reach of more than 25 million people per week, according to Facebook (http://www.Facebook.com/CreakyJoints), making it the most popular. GHLF and CreakyJoints work to create an environment where strength, experience, and information can be exchanged to improve quality-of-life through educational programs, supportive social media, innovative research initiatives and nurtured collaborative advocacy among other organizations. Membership within CreakyJoints is free and encouraged for anyone who is impacted by arthritis.

#### 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, including statements regarding the potential benefits of OTREXUP and its consistent availability. 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, market acceptance by physicians and patients of new products, difficulties or delays in the commercial launch of OTREXUP, difficulties or delays in the manufacture, supply or distribution of OTREXUP 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 forwardlooking 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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