# ADDITIONAL DOSAGE STRENGTHS OF OTREXUP™ (METHOTREXATE) INJECTION APPROVED BY FDA

***Now Available – 12.5 mg/0.4 ml, 17.5 mg/0.4 ml and 22.5 mg/0.4 ml***

**EWING, N.J., March 29, 2016 —** Antares Pharma, Inc. (NASDAQ: ATRS) today announced the approval by the U.S. Food and Drug Administration (FDA) of three new dosage strengths of OTREXUP™ (methotrexate) injection. The new dosage strengths of 12.5 mg/0.4 ml, 17.5 mg/0.4 ml and 22.5 mg/0.4 ml will complement the already approved and marketed strengths of 7.5 mg/0.4 ml, 10 mg/0.4 ml, 15 mg/0.4 ml, 20 mg/0.4 ml, and 25 mg/0.4 ml. New, interim dose-strength options will enable physicians to select more specific, optimal doses to help achieve patient treatment goals.

"OTREXUP™ has always been available in the most commonly prescribed strengths of methotrexate, but our new interim dose options may provide physicians even more opportunity to give their patients precisely what is needed to achieve disease control," said Robert Apple, President and Chief Executive Officer of Antares Pharma. "Each and every patient treatment regimen is different, so providing a step approach to therapy may extend and optimize the use of OTREXUP™ for patients. New interim strengths are also covered by OTREXUP™ *TotalCare* so all eight dosing options are eligible for up to $125 of patient co-pay assistance."

OTREXUP™ was the first FDA-approved subcutaneous methotrexate 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 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. In addition, OTREXUP™ is also approved for use in children with active polyarticular juvenile idiopathic arthritis as well as for use in adults for symptomatic control of severe recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy.

For full prescribing information please visit 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 you 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 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)[i] 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. 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 has recently received a therapeutically equivalent approval for VIBEX® Sumatriptan USP for the acute treatment of migraine and cluster headache in the U.S. 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 license and development deal with Teva Pharmaceutical Industries, Ltd. that includes VIBEX® epinephrine, exenatide multi-dose pen, and another undisclosed multi-dose pen, which have not been approved. Our reusable needle-free injector for use with human growth hormone (hGH) is sold worldwide by Ferring B.V. The Company is also working with AMAG Pharmaceuticals on a subcutaneous method of administering Makena, a progesterone product indicated for use in lowering the risk of pre-term birth.

**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. Factors that may cause such differences include, but are not limited to: the utilization of the new dosage strengths of 12.5 mg/0.4ml, 17.5 mg/0.4 ml and 22.5 mg/0.4 ml of Otrexup™ and 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 by the FDA; the timing of the launch of Vibex Sumatriptan Injection USP and the amount of revenue from the same; Teva's ability to adequately and timely respond to the FDA's complete response letter (CRL) related to their epinephrine auto injector ANDA and FDA approval of the same, the timing and therapeutic equivalence rating thereof, and any revenue pre or post FDA approval; FDA action with respect to Teva's ANDA for the Exenatide pen;; the timing and results of research projects, clinical trials, and product candidates in development including the development project with AMAG Pharmaceuticals for a subcutaneous auto injector for their product Makena and Teva's undisclosed Pen 1 project; actions by the FDA or other regulatory agencies with the respect to the Company's products or 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, 2015, 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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