



## **ANTARES PHARMA ANNOUNCES UPDATE TO QUICKSHOT® TESTOSTERONE PROGRAM**

**EWING, NJ, January 13, 2015** -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced that it has received written recommendations from the U.S. Food and Drug Administration (FDA) related to its clinical development program for QuickShot® Testosterone (QS T). The recommendations received were in response to various clinical, CMC (Chemistry, Manufacturing and Controls) and user study submissions made by the Company through November 2014. The Company believes that it has already factored many of the recommendations cited in the advice letter into the protocol of the ongoing phase 3 study and into the protocols for planned human use studies as a result of guidance provided by FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in the Company's phase 2 study, which the FDA characterized as an apparent allergic reaction, as well as the known safety experience with other parenteral testosterone products, the FDA is recommending that the Company create a larger safety database, including approximately 350 subjects exposed to QS T with 200 subjects exposed for six months and 100 subjects exposed for a year. The Company does not believe that the adverse event of hives reported in the phase 2 study was related to study drug. Based on the number of subjects in previous studies and in the current phase 3 study, the Company anticipates that it may need approximately 70 additional subjects exposed to QS T for six months. The Company is assessing the FDA's comments in the advice letter and their impact on the timing of the filing of a New Drug Application for QS T with the FDA. The timing, cost and design of the study to obtain the additional 70 subjects and data required will be determined based on further discussion with the FDA. The Company continues to expect to release top-line pharmacokinetic data from the current phase 3 study in the second quarter of 2015.

Eamonn P. Hobbs, President and Chief Executive Officer, stated, "We are committed to working closely with the FDA on all aspects of the QS T clinical development program and believe that we will be able to provide a novel product for once-weekly self-administration of testosterone at home that offers a new route of administration for treating hypogonadism or Low T."

As previously announced, the Company is conducting a double-blind, multiple-dose, phase 3 study to evaluate the efficacy and safety of QS T administered subcutaneously once each week to testosterone-deficient adult males. Patients enrolled in this study had a documented diagnosis of hypogonadism or testosterone deficiency defined as having repeated testosterone levels below 300 ng/dL. The study includes a screening phase, a treatment titration and efficacy phase and an extended treatment phase. Approximately 150 patients are enrolled in this study. Patients meeting all eligibility criteria were assigned to receive a starting dose of 75 mg QS T once weekly for six weeks. Blinded adjustments to dose are made at week 7 based upon the week 6 pre-dose blood level. The efficacy of QS T and dose adjustment to regulate testosterone levels will be evaluated after 12 weeks of treatment. Upon completion of this phase, patients may remain on their optimized QS T dose and will be followed for an additional 40 weeks.

### **About Antares Pharma**

Antares Pharma focuses on self-administered parenteral pharmaceutical products. The Company markets OTREXUP™ (methotrexate) injection for subcutaneous use in the treatment of adults with severe active rheumatoid arthritis and children with active polyarticular juvenile idiopathic arthritis. LEO Pharma markets OTREXUP™ to dermatologists for adults with severe recalcitrant psoriasis. Antares Pharma is also developing QuickShot® Testosterone for testosterone replacement therapy. The Company's technology platforms include VIBEX® disposable Medi-Jet, disposable multi-use pen injectors and reusable needle-free injectors. Antares Pharma has a multi-product deal with Teva that includes VIBEX® epinephrine and several other products. Our reusable needle-free injector for use with human growth hormone (hGH) is sold worldwide by Ferring Pharmaceuticals. 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<sup>®</sup> (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.

#### **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, including statements made with respect to the protocols of the ongoing phase 3 clinical study of QuickShot<sup>®</sup> Testosterone (QS T) and of planned human use studies and the incorporation of recommendations from the U.S. Food and Drug Administration therein; the timing, cost and design, including number of patients, of the study to provide additional data; the timing of the Company's ongoing phase 3 clinical trial for QS T and the release of top-line data therefrom; the submission by the Company of a New Drug Application for QS T and the approval thereof; 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. 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. 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, 2013, 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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