



## ANTARES PHARMA ANNOUNCES POSTER PRESENTATION AT THE SEXUAL MEDICINE SOCIETY SCIENTIFIC ANNUAL MEETING

**EWING, NJ, November 20, 2015** - Antares Pharma, Inc. (NASDAQ: ATRS) today announced that data from its Phase 3 study of the pharmacokinetics and safety of subcutaneous testosterone enanthate delivered through the QuickShot<sup>®</sup> auto injector was selected for a moderated poster presentation on November 21, 2015 at the 21<sup>st</sup> Annual Fall Scientific Meeting of the Sexual Medicine Society of North America.

The poster, entitled “Testosterone enanthate administered once-weekly by subcutaneous auto-injector in men with hypogonadism: pharmacokinetic and safety results from a phase III trial,” was authored by Jed C. Kaminetsky, MD, Manhattan Medical Research, University Urology, New York, NY, et al. The submission was among a select group of key abstracts awarded the distinction of a moderated poster presentation.

The dose-blind, multicenter Subcutaneous Testosterone Efficacy and Safety in Adult Men Diagnosed with Hypogonadism (STEADY<sup>™</sup>) trial of a proprietary, pre-filled auto injector enrolled 150 hypogonadal adult men with baseline testosterone (T) levels of <300 ng/dL. Patients received 75 mg of testosterone enanthate administered via auto injector once-weekly for 6 weeks. At week 7 blinded dose adjustments were based on week-6, pre-dose blood levels in the patients. Full pharmacokinetic (PK) profiles were obtained at week 12.

The study’s primary endpoint required  $\geq 75\%$  of patients to achieve average ( $C_{avg}$ ) serum testosterone levels within the normal range of 300 to 1,100 ng/dL, with a lower limit of a 95% 2-sided confidence interval (CI)  $\geq 65\%$ . Additionally,  $\geq 85\%$  of week-12 serum maximum ( $C_{max}$ ) values of <1500 ng/dL and no more than 5% of  $C_{max}$  values of >1,800 ng/dL were required. Patients without a  $C_{max}$  determination at week 12 due to dropping out of the study were assigned to the above 1,500 ng/dL group.

Top-line Pharmacokinetic data was previously released by the Company in February, 2015. In the intent to treat analysis, at week 12,  $C_{avg}$  was within the 300 to 1100 ng/dL range in 139 out of the patients enrolled (92.7%), with 95% CI lower limit of 87.3%.  $C_{max}$  was <1500 ng/dL in 137 out of 150 patients (91.3%). In addition, one-hundred thirty-seven patients completed all study procedures at 12 weeks. Among the completers at week 12,  $C_{avg}$  was within the 300 to 1100 ng/dL range in 135 out of 137 patients (98.5%) with 95% CI lower limit of 94.8% and  $C_{max}$  was <1500 ng/dL in 137 patients (100%). Patients achieved a mean ( $\pm$  standard deviation) steady-state T concentration of  $553.3 \pm 127.3$  ng/dL at 12 weeks.

“A starting dose of 75 mg testosterone enanthate via auto injector, followed by a week 6 dose adjustment, was shown to achieve normal T levels when dosed weekly for 12 weeks in men with hypogonadism,” Kaminetsky wrote. “The treatment was well tolerated and the safety profile was consistent with testosterone replacement treatments already on the market” according to Dr. Kaminetsky.

“Despite the availability of many testosterone replacement therapy products for men with hypogonadism, suboptimal delivery systems create a need for new, safe, and effective treatments,” said Eamonn P. Hobbs, CEO of Antares Pharma. Mr. Hobbs continued, “Therefore, we believe that

our investigational product, the QuickShot subcutaneous auto injector, may offer a reliable new delivery method for treating adult men with low levels of testosterone.”

### **About QuickShot® Testosterone**

The investigational subcutaneous testosterone enanthate auto injector is a proprietary self-administered testosterone replacement option for men with hypogonadism that is designed to be injected at home, on a weekly basis. Results from the previously reported Phase 3 pharmacokinetic study showed that testosterone delivered subcutaneously using the QuickShot® testosterone auto injector provided rapid, steady, and reliable efficacy by restoring testosterone to pre-defined physiologic levels.

To date, three serious adverse events including one case each of depression, suicide and vertigo were recorded, with no major cardiac events reported in the study. The most common adverse events reported in the study were polycythemia, PSA elevation and various injection site reactions. The QuickShot® testosterone auto injector has not been approved by the United States Food and Drug Administration.

The details for Dr. Kaminetsky’s poster presentation are as follows:

**Date:** Saturday, November 21, 2015

**Session:** Moderated Posters 11: Androgens 2

**Session Time:** 1:30-2:30 p.m. PT

**Location:** Wynn Encore, 3131 South Las Vegas Blvd., Las Vegas, Nevada

### **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: 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; continued growth of prescriptions and sales of OTREXUP™; 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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