



## ANTARES PHARMA ANNOUNCES POSTER PRESENTATION AT THE AMERICAN UROLOGICAL ASSOCIATION ANNUAL MEETING

**EWING, NJ, May 16, 2017** - Antares Pharma, Inc. (NASDAQ: ATRS) announced that data from its Phase 3 study of the pharmacokinetics and safety of subcutaneous testosterone enanthate delivered through the QuickShot® auto injector was selected for a moderated poster presentation and will be presented today, May 16, 2017 at the American Urological Association Annual Meeting being held in Boston, Massachusetts.

The poster, entitled "Safety and Efficacy Results from the Phase 3, Double-Blinded, Multicenter STEADY Trial of a Novel, Prefilled, Subcutaneous Autoinjector for Testosterone Replacement Therapy," was authored by Jed C. Kaminetsky, MD, Clinical Assistant Professor, in the Department of Urology at NYU Langone Medical Center in New York, NY. The submission was among a select group of key abstracts awarded the distinction of a moderated poster presentation.

The double-blind, multicenter Subcutaneous Testosterone Efficacy and Safety in Adult Men Diagnosed with Hypogonadism (STEADY) trial of a novel, pre-filled auto injector enrolled 150 hypogonadal adult men with two baseline testosterone (T) levels of <300 ng/dL. Patients received 75 mg of testosterone enanthate administered via the 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.

"A starting dose of 75 mg testosterone enanthate via auto injector, followed by a week-6 dose adjustment if necessary, 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 the class."

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 <1,500 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 were assigned to the above 1,500 ng/dL group.

One-hundred thirty-seven patients completed all study procedures at 12 weeks, and 98 patients were still receiving treatment at week 52. At week 12,  $C_{avg}$  was within the 300–1,100 ng/dL range in 139/150 patients (92.7%) with 95% CI lower limit of 87.3%.  $C_{max}$  was <1,500 ng/dL in 137/150 patients (91.3%);  $C_{max}$  was below 1,800 ng/dL in all patients. Patients achieved a mean ( $\pm$  standard deviation) steady-state T concentration of  $553.3 \pm 127.29$  ng/dL at 12 weeks.

"We believe that our QuickShot auto injector, recently branded Xyosted, may provide a reliable new delivery method for treating adult men with testosterone deficiency," said Robert Apple, CEO of Antares Pharma. Mr. Apple continued, "We will work closely with the FDA during the regulatory review process toward a potential product approval in the fourth quarter of 2017."

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

**Date:** May 16, 2017

**Session:** MP91-16

**Session Time:** 7:00-9:00 a.m. ET

**Location:** Boston Convention and Exhibition Center, Room 156

### **About The American Urological Association**

Founded in 1902, the AUA is a premier urologic association, providing invaluable support to the urologic community. Their mission is to promote the highest standards of urological clinical care through education, research and the formulation of health care policy.

### **About QuickShot® Testosterone**

The investigational subcutaneous testosterone enanthate auto injector is a proprietary self-administered testosterone replacement option for men diagnosed with hypogonadism that is designed to be injected at home, on a weekly basis.

The most common adverse reactions (incidence  $\geq 5\%$ ) in the phase 3 study referenced in these presentations were increased hematocrit, hypertension, increased PsA, Upper Respiratory Tract Infection, sinusitis, injection site bruising and headache. Serious adverse events reported included one case each of worsening depression, vertigo and suicide. All of the SAE's were not considered to be related to study drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), POME, anaphylaxis, or major adverse cardiovascular events in this study. The safety data collected included an assessment of pain. When pain was reported its intensity was recorded using a 10-point pain scale, with a score of 1 described as barely noticeable and 10 as the worst pain experienced. Of 1519 injections assessed, pain was reported 9 times. In these 9 instances, the pain intensity was reported as either a 1 or a 2, with an average score of 1.3. The QuickShot® testosterone auto injector has not been approved by the United States Food and Drug Administration.

### **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. The Company's product Sumatriptan Injection USP, is approved in the U.S. for the acute treatment of migraine and cluster headache and is distributed by Teva Pharmaceutical Industries, Ltd. (Teva). Antares Pharma is also developing QuickShot® Testosterone for testosterone replacement therapy and has filed a New Drug Application with the Food and Drug Administration. The Company's technology platforms include VIBEX® disposable auto injectors, disposable multi-use pen injectors and reusable needle-free injectors. Antares Pharma has license, development and supply agreements with Teva that include VIBEX® epinephrine, exenatide multi-dose pen, and teriparatide multi-dose pen. 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 for administering Makena, a progesterone product indicated for use in lowering the risk of pre-term birth. For more information, visit [www.antarespharma.com](http://www.antarespharma.com).

### **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: U.S. Food and Drug Administration ("FDA") approval of the QST NDA and future market**

acceptance and revenue for QST; FDA approval of the sNDA submitted by AMAG Pharmaceuticals for an auto injector for Makena and future market acceptance and revenue of the same; the outcome of the pending patent litigation between Teva Pharmaceutical Industries, Ltd. (Teva) and Eli Lilly and Company regarding the Teriparatide multi-dose pen; FDA action with respect to Teva's Abbreviated New Drug Application ("ANDA") for the Teriparatide multi-dose pen and the timing and approval, if any, by the FDA of the same; Teva's ability to adequately respond to the Complete Response Letter received from the FDA for the VIBEX<sup>®</sup> epinephrine pen ANDA and approval by the FDA of the same, the timing and therapeutic equivalence rating thereof, and any future purchase orders and revenue pre or post FDA approval; Teva's ability to successfully commercialize VIBEX<sup>®</sup> Sumatriptan Injection USP and the amount of revenue from the same; FDA action with respect to Teva's ANDA filed for the Exenatide pen and future revenue from the same; continued growth of prescriptions and sales of OTREXUP<sup>®</sup>; the timing and results of research projects, clinical trials, and product candidates in development; 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, 2016, 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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