



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

**QUICKSHOT® TESTOSTERONE DATA HAS BEEN SELECTED FOR BOTH ORAL AND POSTER PRESENTATIONS**

**EWING, NJ, November 2, 2016** - Antares Pharma, Inc. (NASDAQ: ATRS) today announced that data from the 52 week phase 3 study of the pharmacokinetics and safety of subcutaneous testosterone enanthate delivered through the QuickShot® auto injector was selected for an oral podium presentation at the 22<sup>nd</sup> Annual Fall Scientific Meeting of the Sexual Medicine Society of North America (SMSNA). A moderated poster presentation featuring additional data from the same 52 week phase 3 study which tracked psychosexual function in hypogonadal men will also be presented at the same meeting. Both presentations will be held on November 3, 2016.

### Oral Podium Presentation

The abstract, entitled "Safety and efficacy results from the phase 3, double blind, multicenter STEADY trial of a novel, pre-filled, subcutaneous (SC) auto injector for testosterone (T) replacement therapy," was authored by Ronald S. Swerdloff, MD, Los Angeles Biomedical Research Institute and Harbor-UCLA Medical Center, Los Angeles, CA, et al. The submission was among a select group of key abstracts awarded the prestige of an oral podium presentation.

The dose-blind, multicenter Subcutaneous Testosterone Efficacy and Safety in Adult Men Diagnosed with Hypogonadism (STEADY™) 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.

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.

The details for Dr. Swerdloff's podium presentation are as follows:

**Date:** Thursday, November 3, 2016

**Session:** Oral Presentations: Hormones

**Session Time:** 4:30 p.m. MT

**Location:** The Phoenician, Scottsdale Arizona

### **Moderated Poster Presentation**

The poster entitled “Improvements in psychosexual function among hypogonadal men enrolled in the STEADY trial of a novel, subcutaneous auto injector for testosterone replacement” was authored by Christina Wang, MD, Los Angeles Biomedical Research Institute and Harbor-UCLA Medical Center, Los Angeles, CA, et al. The submission was among a select group of key abstracts awarded the distinction of a moderated poster presentation.

Psychosexual function can be measured by a patient diary called the Psychosexual Daily Questionnaire (PDQ). The PDQ is a validated patient inventory used to assess sexual desire, enjoyment, activity, erection and positive and negative mood for seven consecutive days. PDQ's were administered in hypogonadal men in a phase 3, double-blind, multicenter study of Subcutaneous Testosterone Efficacy and Safety in Adult Men Diagnosed with Hypogonadism (STEADY™) trial of a novel, pre-filled auto injector. The 52 week study 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 six weeks. At week six and beyond, testosterone doses were adjusted based on serum trough testosterone levels. Men completed the PDQ at baseline, weeks one, six, twelve and twenty six.

The results of the study showed overall improvement in sexual function in all PDQ domains. Sexual desire increased from baseline 2.3(±1.43) to 3.4 (±1.63) (p<.0001) at week 26. Enjoyment without a partner increased from 0.9 (±1.01) to 1.7 (±1.63) (p<.0001); Enjoyment with a partner increased from 0.9 (±1.13) to 1.5 (±1.81) (p<.0001); Percent full erection increased from 67.5 to 76.1 (p=0.34); Sexual Activity Score increased from 1.8 (±1.62) to 3.0 (±2.18) (p<.0001); Positive mood from 4.0 (±1.14) to 4.5 (±1.12) (p<.0001). Negative mood decreased from 2.0(±1.10) to 1.6 (±1.01) (p<.0001).

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

**Date:** Thursday, November 3, 2016

**Session:** Moderated Poster Presentations: Hormones

**Session Time:** 5:30 p.m. MT

**Location:** The Phoenician, Scottsdale Arizona

“We are very pleased that our phase 3 QuickShot testosterone data has been accepted for presentation at the annual fall meeting of the Sexual Medicine Society of North America,” said Robert F. Apple, CEO of Antares Pharma. Mr. Apple continued, “It is our belief that administering testosterone once weekly using our investigational product, the QuickShot subcutaneous auto injector, may offer a reliable new delivery method for treating adult men with testosterone deficiency. We expect to submit a New Drug Application to the Food and Drug Administration late this year and we will work closely with the agency toward a potential approval.”

### **About SMSNA**

Established in 1994, the Sexual Medicine Society of North America's objective has been to promote, encourage, and support the highest standards of practice, research, education, and ethics in the study of the anatomy, physiology, pathophysiology, diagnosis, and treatment of human sexual function and dysfunction. Further, SMSNA provides a forum for the free exchange and discussion of new ideas, thoughts, and concepts in sexual medicine. Consisting of over 700 active members, the organization is composed of North American surgeons, physicians, mental health professionals, scientists, residents and medical students all committed to sexual health.

The SMSNA seeks to identify existing and emerging issues in the field of human sexual function and dysfunction, provide accurate and credible information to medical professionals, develop standards and guidelines for SEXUAL MEDICINE research and practice, and produce educational programs

that bring leading-edge concepts of research, clinical practice, ethics, and politics to health care professionals interested in SEXUAL MEDICINE and related matters.

### **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.

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 and Teva Pharmaceutical Industries, Ltd. (Teva) recently announced the commercial launch of VIBEX® Sumatriptan Injection USP for the acute treatment of migraine and cluster headache in the United States. Antares Pharma is also developing QuickShot® Testosterone for testosterone replacement therapy. 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 that includes 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 of 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: the timing and results of the phase 3 studies for QuickShot® Testosterone (QST) and acceptance of the data by the U.S. Food and Drug Administration (“FDA”); the timing and Company’s ability to successfully complete a New Drug Application (“NDA”) for QST, acceptance of the NDA for QST by the FDA and approval of the same by the FDA; FDA action with respect to Teva’s Abbreviated New Drug Application (“ANDA”) filed for the Exenatide pen and future revenue from the same; Teva’s ability to adequately and timely respond to the Complete Response Letter received from the FDA for the VIBEX® 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; the outcome of the pending patent litigation between Teva Pharmaceutical Industries, Ltd. (Teva) and Eli Lilly and Company regarding the Teriparatide multi-dose pen; the timing and approval, if any, by the FDA of Teva's ANDA for the Teriparatide multi-dose pen and any future revenue resulting therefrom; continued growth of prescriptions and sales of OTREXUP<sup>™</sup>; the timing and results of the development project with AMAG Pharmaceuticals for an auto injector for Makena; 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, 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.

**Contacts:**

Jack Howarth  
Vice President, Corporate Affairs  
609-359-3016  
[jhowarth@antarespharma.com](mailto:jhowarth@antarespharma.com)