

# ANTARES PHARMA ANNOUNCES PUBLICATION OF QUICKSHOT® TESTOSTERONE DATA IN PRESTIGIOUS HEALTH JOURNAL

 Results of the study showed rapid restoration and consistent maintenance of steady blood levels was achieved with once-weekly subcutaneous administration of testosterone using the QuickShot® auto injector -

**EWING, NJ, September 28, 2015 --** Antares Pharma, Inc. (NASDAQ: ATRS) today announced that the journal *Sexual Medicine* has published the previously disclosed positive results from a multicenter, phase II clinical study evaluating the pharmacokinetic (PK) profile of testosterone enanthate administered once-weekly by subcutaneous injection using the VIBEX® QuickShot® auto injector in testosterone deficient men. The publication is entitled "Pharmacokinetic Profile of Subcutaneous Testosterone Enanthate Delivered via a Novel, Prefilled Single-Use Autoinjector: A Phase II Study" authored by Jed Kaminetsky, MD et al. Dr. Kaminetsky is a urologist at University Urology Associates, Medical Director of Manhattan Medical Research and clinical assistant professor of urology at New York University School of Medicine. The study has been published in the October, 2015 issue of **Sexual Medicine** and can be located using the following link: <a href="http://onlinelibrary.wiley.com/doi/10.1002/sm2.80/full">http://onlinelibrary.wiley.com/doi/10.1002/sm2.80/full</a>.

Thirty-nine men with a mean age of 52.9 years and a history of physician-diagnosed hypogonadism (low testosterone), were enrolled in the study. Following a washout period, 29 patients were randomized to receive either 50 mg or 100 mg testosterone enanthate administered subcutaneously (SC) with the QuickShot<sup>®</sup> auto injector once weekly. Full PK profiles were collected for each patient in the subcutaneous treatment arms at weeks 1, 5 and 6. Pre-dose trough and 24 hours post-dose samples were collected at each of the 6 weekly treatment visits.

Rapid restoration, consistent maintenance of normal testosterone levels and dose proportionality of the 50 mg and 100 mg strengths was achieved. During week 6 of the study, when patients were already at steady state pharmacokinetic conditions, the 50 mg and 100 mg SC groups had average plasma testosterone values within the normal range at 422.4 ng/dL and 895.5 ng/dL, respectively. The normal range for Testosterone is generally defined as 300 ng/dL to 1100 ng/dL.

According to the authors, the once-weekly injection was generally well tolerated. No injection site pain was reported by 28 of 29 patients dosed subcutaneously and 17 of the patients reported mild to moderate unrelated adverse events. There were no deaths, cardiovascular events, serious adverse events, or discontinuations due to adverse events in the study.

Eamonn P. Hobbs, President and Chief Executive Officer, stated, "We were very pleased that the results of our phase II study were accepted for publication in such a prestigious health journal and we continue to be optimistic about the potential for a self-administered, once-weekly subcutaneous dose of testosterone based on the outcome of this phase II study and the 12-week PK phase III data released earlier this year, which showed consistent results." He continued, "As the injectable testosterone market continues to grow, we look forward to potentially introducing a novel, subcutaneous option for treating low testosterone which may reduce peak to trough fluctuations associated with current intramuscular injections as well as the increased risk of transference associated with topical treatments."

## About QuickShot® Auto Injector

The proprietary VIBEX<sup>®</sup> QuickShot<sup>®</sup> auto injector platform emphasizes enhanced performance on the attributes contributing most to patients successfully controlling reliable and consistent blood levels, ease and speed of self-administration, comfort and discretion. The State-of-the-Art precision engineering of the QuickShot<sup>®</sup> device allows rapid subcutaneous self-administration of highly viscous drugs such as testosterone and biologics. Conventional auto injectors or even a vial, needle and syringe could not inject these drugs efficiently or as fast and easy as the QuickShot<sup>®</sup> device.

#### **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, including future clinical trial results consistent with the phase II QuickShot® Testosterone (QS T) study referenced herein, the timing and results of the supplemental phase 3 safety study for QS T; acceptance of the data from the supplemental phase 3 safety study by the U.S. Food and Drug Administration (FDA); FDA actions with respect to QS T including modified or additional clinical trials; the Company's ability to successfully complete a New Drug Application for QS T to the FDA and FDA approval of the same and future market acceptance and revenue from QS T, the growth of sales of OTREXUP™; the approval by the FDA of VIBEX® Epinephrine Pen, the timing thereof, the therapeutic equivalence rating therefor and future sales by Teva; FDA action with respect to the ANDA filed for the exenatide pen; the Company's ability to adequately and timely respond to the complete response letter 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 and 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. 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, 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 forwardlooking 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