



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

### ***LAST PATIENT COMPLETES TREATMENT IN THE SAFETY AND EFFICACY STUDY QST-13-003***

**EWING, NJ, October 30, 2015** -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced that the last patient has completed treatment in the dose-blinded, multiple-dose 52 week Phase 3 study to evaluate the efficacy and safety of QuickShot<sup>®</sup> Testosterone (QS T) administered subcutaneously once each week to adult males with hypogonadism.

“We are very excited to announce that the last patient has completed week 52 in our Phase 3 study in testosterone deficient adult males,” stated Eamonn P. Hobbs, President and Chief Executive Officer. “Once the 26 week supplemental safety study currently underway has concluded, we will combine the previously announced positive pharmacokinetic data and safety portion of this study into our New Drug Application and plan to work closely with the Food and Drug Administration toward a potential approval.”

Approximately 150 patients were enrolled in this multicenter dose-blinded, multiple-dose study. Patients meeting all eligibility criteria were assigned to receive 75 mg of QS T once weekly for six weeks. Adjustment to dose, if needed, was made at week seven based upon the week six  $C_{trough}$  value. Additional strengths of 100 mg and 50 mg were utilized in dose titration. Patients were dosed for 12 weeks prior to collecting a full pharmacokinetics (PK) profile and determining the primary endpoint. The pre-specified success criteria required that at week 12 (i) at least 75% of all patients'  $C_{avg}$  are within the range of 300 to 1100 ng/dL, with the lower limit of the 95% 2-sided confidence interval greater than or equal to 65%, (ii) at least 85% of patients'  $C_{max}$  are less than 1500 ng/dL and (iii) no more than 5% of patients had a  $C_{max}$  greater than 1800 ng/dL. As we previously disclosed, the primary endpoint of the population that received one or more doses of QS T was met by 139 out of 150 patients, equating to 92.7% with a 95% confidence interval of 87.3% to 96.3%. Among the 137 patients that completed all 12 weeks of dosing and PK sampling, 98.5% were within the pre-defined range. Overall, the regimen demonstrated a mean ( $\pm$  standard deviation) steady state concentration of testosterone of  $553.3 \pm 127.3$  ng/dL at 12 weeks. No patient had a measured  $C_{max}$  exceeding 1500 ng/dL. Upon completion of this PK phase, patients continued on weekly dosing and were followed for an additional 40 weeks to assess safety of QST

### **About Antares Pharma**

Antares Pharma focuses on self-administered parenteral pharmaceutical products. The Company's product, OTREXUP<sup>™</sup> (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<sup>®</sup> Testosterone for testosterone replacement therapy, and VIBEX<sup>®</sup> Sumatriptan for the acute treatment of migraines. The Company's technology platforms include VIBEX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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; the growth of sales of OTREXUP<sup>™</sup>; the approval by the FDA of the VIBEX<sup>®</sup> Epinephrine Pen, the timing and therapeutic equivalence rating thereof and any corresponding revenue; 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<sup>®</sup> 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; 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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