



ANTARES PHARMA ANNOUNCES POSITIVE TOP-LINE PHARMACOKINETIC RESULTS FROM THE QUICKSHOT® PHASE 3 STUDY IN TESTOSTERONE DEFICIENT MEN

- PRIMARY STUDY ENDPOINT MET – 92.7% OF ENROLLED PATIENTS HAD TESTOSTERONE LEVELS WITHIN THE PRE-DEFINED RANGE
- NO PATIENT HAD MAXIMUM CONCENTRATION (C_{max}) VALUES GREATER THAN 1500 ng/dL

EWING, NJ, February 25, 2015 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company’s ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males.

In the study, 150 adult males with hypogonadism (low testosterone) and testosterone blood levels less than 300 ng/dL received a starting dose of 75 mg of subcutaneously administered testosterone enanthate (QuickShot® Testosterone, or QS T) once weekly for six weeks. Blinded adjustments to dose were made when necessary at week seven based upon the week six pre-dose blood level, and full pharmacokinetic (PK) profiles were obtained during the 12th week of treatment.

The protocol for the study required that at the week 12 endpoint: (i) at least 75% of all patients’ C_{avg} are within the normal range of 300 to 1100 ng/dL, with a lower limit of a 95% 2-sided confidence interval of 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. 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. The top-line results are summarized in the table below.

Population/Analysis	C_{avg} Lower limit of the 95% 2-sided C. I.	C_{avg} % in range 300 – 1100 ng/dL n (%)	C_{max} <1500 ng/dL n (%)	C_{max} >1800 ng/dL n (%)
Primary analysis* N=150	87.3%	139 (92.7%)	137 (91.3%)**	0%
Completers N=137	94.8%	135 (98.5%)	137 (100%)	0%
Protocol-Required Outcomes	≥65%	75%	≥85%	≤5%
* All patients with 1 or more doses, C_{avg} 0-168 hours post week 12 injection or last measured concentration carried forward				
**Patients without a C_{max} determination at week 12 are assigned above 1500 ng/dL				

Overall, the regimen demonstrated a mean (\pm standard deviation) steady state concentration of testosterone of 553.3 ± 127.3 ng/dL at 12 weeks.

Participants in the study will remain on QS T and will be followed for an additional 40 weeks, and the collection of safety data is ongoing. One hundred fifty patients have received at least one dose of study drug and to date, there have been no reported deaths and one serious adverse event (SAE) of hospitalization for worsening depression. This patient received a single dose of QS T, and the SAE was not considered to be related to study drug. Thus far, there have been no reported adverse events consistent with urticaria (hives).

“We remain optimistic about the potential for a once-weekly, self-administered, subcutaneous dose of testosterone based on the positive outcome of this phase of the study. If approved by the Food and Drug Administration, we believe that patients may benefit greatly from this novel and convenient home-based therapy using our proprietary QuickShot device which has shown, based on our current data, that normal testosterone levels can be rapidly restored and then reliably maintained,” stated Eamonn P. Hobbs, President and Chief Executive Officer of Antares Pharma. “We are committed to working closely with the FDA on the additional data required to file a New Drug Application.”

On January 13, 2015, the Company announced that it had received written recommendations from the FDA related to its clinical development program for QS T. The Company believes that it has already factored many of the recommendations cited in the advice letter into the protocol of the ongoing phase 3 study (QST-13-003), the top line results of which are announced today, and into the protocols for planned human use studies as a result of prior guidance provided by FDA. The FDA has recommended that the Company create a larger safety database, including approximately 350 subjects exposed to QS T with 200 subjects exposed for six months and 100 subjects exposed for a year. Based on the number of subjects in previous studies and in the current phase 3 study (QST-13-003), the Company anticipates that it may need approximately 70 additional subjects exposed to QS T for six months.

About QuickShot® Auto Injector

The proprietary QuickShot® auto injector emphasizes enhanced performance on the attributes contributing most to patients successfully controlling their testosterone deficiency – reliable and consistent blood levels, ease and speed of self-administration, comfort and discretion. The state-of-the-art precision engineering of the QuickShot® device allows rapid subcutaneous self-administration of highly viscous drugs such as testosterone and biologics using high spring pressure through a fine gauge needle. Conventional auto injectors or even a vial, needle and syringe could not inject these drugs efficiently or as fast and easy as the QuickShot® device.

About Testosterone Deficiency

Testosterone deficiency, also known as male hypogonadism or Low T, is a condition in which the body does not produce enough testosterone – the hormone that plays a key role in masculine growth and development during puberty, and maintenance of musculoskeletal and mental health in maturity. Symptoms of male hypogonadism can be treated with testosterone replacement therapy.

About Antares Pharma

Antares Pharma focuses on self-administered parenteral pharmaceutical products. The Company markets OTREXUP™ (methotrexate) injection for subcutaneous use in the treatment of adults with severe active rheumatoid arthritis and children with active polyarticular juvenile idiopathic arthritis. LEO Pharma markets OTREXUP™ to dermatologists for 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 Pharmaceuticals BV.

Safe Harbor Statement

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 statements made with respect to the potential for QuickShot® Testosterone (QS T) and its benefits to patients; protocols of the ongoing phase 3 clinical study of QuickShot® Testosterone (QS T) and of planned human use

studies and the incorporation of recommendations from the U.S. Food and Drug Administration therein; the timing, cost and design, including number of patients, of the study to provide additional data; the timing of the release of data from the Company's ongoing phase 3 clinical trial for QS T; the submission by the Company to FDA of a New Drug Application for QS T and the approval thereof; the performance of the QuickShot[®] device compared to conventional auto injectors and needle, vial and syringe delivery; products in development; 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, 2013, 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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