



ANTARES PHARMA ANNOUNCES COMPLETION OF THE 52 WEEK QUICKSHOT® PHASE 3 STUDY IN TESTOSTERONE DEFICIENT MEN

COLLECTION OF 52 WEEK SAFETY DATA COMPLETE

EWING, NJ, March 16, 2016 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced 12 week efficacy and 52 week safety results from the phase 3 clinical study (QST-13-003) evaluating 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. Pre-scheduled blinded adjustments to dose were then made when necessary, and full pharmacokinetic (PK) profiles were obtained during the 12th week of treatment. Remaining participants in the study were followed for an additional 40 weeks for a full collection of 52 weeks of safety data. The study enrolled subjects aged 25 to 78 with a mean age of 53.4 years, body mass index (BMI) ranging from 19.4 to 39.9 kg/m with an average BMI of 31.19 kg/m and average baseline testosterone of ~230.4 ng/dL.

12 Week Pharmacokinetic Data

As previously disclosed, the trial met all of the primary endpoints. The protocol for this initial phase 3 study required that at the week 12 efficacy endpoint: (i) at least 75% of all patients' C_{avg} are within the 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. In the overall analysis for efficacy, 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 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 study regimen demonstrated a mean (\pm standard deviation) steady state concentration of testosterone of 553.3 ± 127.3 ng/dL at 12 weeks.

52 Week Safety Data

The safety population, defined as patients who received at least one dose of study drug, was comprised of 150 patients. The most common adverse reactions (incidence $\geq 5\%$) in this Phase 3 study were increased hematocrit, hypertension, increased PsA, Upper Respiratory Tract Infection, sinusitis, injection site bruising and headache. Serious adverse events (SAE's) 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.

"We are very pleased with the outcome of the first phase 3 study of QuickShot testosterone in hypogonadal adult males. If approved by the Food and Drug Administration, we believe that patients may benefit greatly from this novel, home-based therapy using our proprietary QuickShot device which demonstrated in our clinical trial that normal testosterone levels can be rapidly restored and then reliably maintained through a convenient once-a-week administration," stated Robert F. Apple, President and Chief Executive Officer of Antares Pharma. "In addition to eliminating the risk of transference that exists with the topical gel products, we believe that our auto-injector provided a virtually painless experience, which we believe will be important to patients. Conventional, intramuscular injectable testosterone is often regarded as very uncomfortable. We are committed to working closely with the FDA on the collection of additional data from our phase 3 supplemental safety study which we believe will satisfy the requirements necessary to file a New Drug Application late this year or early in 2017."

About QuickShot[®] Auto Injector

The proprietary QuickShot[®] auto-injector is designed to allow 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. The QuickShot[®] auto injector can also provide the patient with the ease and speed of self-administration, comfort and discretion.

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'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 has recently received a therapeutically equivalent approval for VIBEX[®] Sumatriptan USP for the acute treatment of migraine and cluster headache in the U.S. 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 license and development deal with Teva Pharmaceutical Industries, Ltd. that includes VIBEX[®] epinephrine, exenatide multi-dose pen, and another undisclosed multi-dose

pen, which have not been approved. 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.

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 (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 by the FDA; the timing of the launch of Vibex Sumatriptan Injection USP and the amount of revenue from the same; Teva's ability to adequately and timely respond to the FDA's complete response letter (CRL) related to their epinephrine auto injector ANDA and FDA approval of the same, the timing and therapeutic equivalence rating thereof, and any revenue pre or post FDA approval; FDA action with respect to Teva's ANDA for the Exenatide pen; continued growth of prescriptions and sales of OTREXUP™; the timing and results of research projects, clinical trials, and product candidates in development including the development project with AMAG Pharmaceuticals for a subcutaneous auto injector for their product Makena and Teva's undisclosed Pen 1 project; 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