ANTARES PHARMA ANNOUNCES COMPLETION OF THE QUICKSHOT TESTOSTERONE CLINICAL PROGRAM

ANALYSIS OF 26 WEEK SAFETY DATA FROM STUDY QST-15-005 COMPLETED, NDA SUBMISSION REMAINS ON TRACK FOR FOURTH QUARTER 2016

EWING, NJ, September 22, 2016 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced safety results from the dose-blinded, multiple-dose, concentration-controlled, 26-week phase 3 study of QuickShot® Testosterone (QST) administered subcutaneously once each week to adult males with hypogonadism. The study, QST-15-005, included a screening phase, a titration phase and a treatment phase for evaluation of safety and tolerability, including laboratory assessments, adverse events and injection site assessments.

The safety population, defined as patients who received at least one dose of study drug, was comprised of 133 patients. The most common adverse reactions (incidence ≥5%) in this study were increased hematocrit, upper respiratory tract infection and injection site ecchymosis. There were four patients with treatment emergent serious adverse events (SAE’s), which included one patient with transient visual impairment determined not to be drug related, one patient with appendicitis that was not drug related and one patient with deep vein thrombosis (DVT). The investigator attributed DVT as possibly drug related, which is consistent with known testosterone class SAE’s. The fourth patient had multiple hospitalizations related to septic arthritis and coronary artery disease, with a complicated clinical course post-angioplasty. These multiple reported events from the fourth patient were deemed not to be drug related. There have been no reported adverse events consistent with urticaria (hives), POME or anaphylaxis. The safety data collected also included an assessment of pain. Of the 965 injections assessed, pain was reported one time. In that instance, the pain reported was classified as mild.

“We are extremely pleased with the 26-week safety data from study QST-15-005 as well as the previously announced safety data and pharmacokinetic results from study QST-13-003. Our goal has been to produce a safe, convenient and virtually painless treatment alternative to current topical and intramuscular therapies, potentially eliminating both transference issues associated with topical therapies and the peaks and troughs commonly observed with various injectable dosing regimens,” stated Robert F. Apple, President and Chief Executive Officer. “We believe that a once-weekly, subcutaneous dose of QST can restore and maintain steady state testosterone levels consistently, and that the conclusion of this supplemental safety study completes the clinical work necessary to begin the New Drug Application submission process. We will continue to work closely with the Food and Drug Administration toward a potential approval for this unique treatment for hypogonadism.”

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 U.S. commercial launch of VIBEX® Sumatriptan Injection USP for the acute treatment of migraine and cluster headache. 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.

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; Teva’s ability to successfully commercialize VIBEX® Sumatriptan Injection USP and the amount of revenue from the same; continued growth of prescriptions and sales of OTREXUP™; FDA action with respect to Teva’s Abbreviated New Drug Application (“ANDA”) filed for the Exenatide pen (generic version of Byetta) 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; the outcome of the pending patent litigation between Teva and Eli Lilly and Company regarding the Teriparatide multi-dose pen (generic version of Forteo); the timing and approval by the FDA of Teva’s ANDA for the Teriparatide multi-dose pen and any future revenue resulting therefrom; 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.

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