EWING, NJ, February 27, 2017 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced that the New Drug Application (NDA) for QuickShot® Testosterone (QST), a drug-device combination product for the delivery of testosterone enanthate using a subcutaneous auto injector, has been accepted for standard review by the U.S Food and Drug Administration (FDA). QST was developed to treat adult men with low testosterone associated with a diagnosed condition known as hypogonadism.

The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of October 20, 2017, ten months from the official NDA submission. The PDUFA date is the target date for the FDA to complete its review of the NDA.

“The FDA’s acceptance of the QuickShot testosterone NDA is an important start to the review process and marks another significant milestone for our Company,” said Robert F. Apple, President and Chief Executive Officer. “We continue to believe QST could be an excellent treatment option for men with hypogonadism based upon the positive pharmacokinetic and safety data produced in the two phase three studies now on file with the FDA. In addition to virtually eliminating the risk of transference that exists with topical gel products and the uncomfortable deep intramuscular administration associated with current injectable therapies, we believe that the phase three studies demonstrated that weekly subcutaneous administration of testosterone using the QuickShot auto injector can provide patients with physiologically normal and steady levels of testosterone over the course of therapy. The study data also showed patients had a virtually painless treatment experience using the device. We will work closely with the FDA during the regulatory review process toward a potential approval.”

About QuickShot® Testosterone

The investigational subcutaneous testosterone enanthate auto injector is a proprietary, self-administered testosterone replacement option for men diagnosed with hypogonadism that is designed to be injected at home, on a weekly basis.

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. The QuickShot® auto injector can also provide the patient with the ease and speed of self-administration, comfort and discretion.

About Hypogonadism

Hypogonadism, also known as testosterone deficiency 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, metabolic, 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. The Company’s product Sumatriptan Injection USP, is approved in the U.S. for the acute treatment of migraine and cluster headache and is distributed by Teva Pharmaceutical Industries, Ltd. (Teva). Antares Pharma is also developing QuickShot® Testosterone for testosterone replacement therapy and has filed a New Drug Application to the Food and Drug Administration. 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 for 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 outcome of the U.S. Food and Drug Administration (“FDA”) review of the QST NDA, FDA approval of the QST NDA and future market acceptance and revenue for QST; the outcome of the pending patent litigation between Teva Pharmaceutical Industries, Ltd. (Teva) and Eli Lilly and Company regarding the Teriparatide multi-dose pen; FDA action with respect to Teva’s Abbreviated New Drug Application (“ANDA”) for the Teriparatide multi-dose pen and the timing and approval, if any, by the FDA of 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; Teva’s ability to successfully commercialize VIBEX® Sumatriptan Injection USP and the amount of revenue from the same; FDA action with respect to Teva’s ANDA filed for the Exenatide pen and future revenue from the same; continued growth of prescriptions and sales of OTREXUP®; 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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