ANTARES PHARMA ANNOUNCES DATA PRESENTATION AT THE 2018 SEXUAL MEDICINE SOCIETY SCIENTIFIC ANNUAL MEETING

XYOSTED™ AMBULATORY BLOOD PRESURE ABSTRACT HAS BEEN SELECTED FOR POSTER PRESENTATION

EWING, NJ, November 9, 2018 – Antares Pharma, Inc. (NASDAQ: ATRS) today announced that data from the 26-week Phase 3 study of the safety and tolerability of XYOSTED™ will be presented as a moderated poster presentation on Friday November 9, 2018 at the 24th Annual Fall Scientific Meeting of the Sexual Medicine Society of North America (SMSNA).

Moderated Poster Presentation

The poster entitled "Effect of Testosterone Enanthate on 24-hour Ambulatory Blood Pressure is Less in Patients with Hypertension at Baseline" will be presented by Mohit Khera, MD, Laboratory for Andrology Research, Baylor College of Medicine, Houston Tx. The submission was among a select group of key abstracts awarded the distinction of a moderated poster presentation.

The Phase 3, 26-week, dose-blind, multicenter trial of XYOSTED, a proprietary, pre-filled subcutaneous testosterone enanthate auto-injector administered weekly, examined 133 hypogonadal adult men with baseline testosterone (T) levels of <300 ng/dL. Patients received 75 mg of testosterone enanthate administered via auto injector once-weekly for 6 weeks. At week 7, dose adjustments were conducted according to a simple titration scheme if necessary and were based on week-6, pre-dose blood levels in the patients. The XYOSTED™ clinical program included a rigorous ambulatory blood pressure monitoring (ABPM) study to fully characterize the potential side effects of testosterone replacement on blood pressure.

The study endpoints included standard safety evaluations plus 24-hour ambulatory blood pressure monitoring (ABPM) in all patients. Overall compliance was >99%. The study identified increases in systolic blood pressure (SBP) from baseline to week 26 of 125.6 mmHg to 129.0 mmHg (3.4 mmHg) and increases in diastolic blood pressure (DBP) from 78.2 mmHg at baseline to 80.0 mmHg (1.8 mmHg) at week 26. Overall, 34 patients experienced adverse drug reactions (ADRs) with the majority considered mild or moderate. The most frequently reported ADRs were increased hematocrit, injection site hemorrhage, injection site bruising, and increased prostate-specific antigen.

Patients with hypertension at baseline appeared to experience less impact on blood pressure following treatment. Furthermore, those patients using antihypertensive medications experienced comparable blood pressure changes as those patients not on antihypertensive medications. Based upon the data, blood pressure measurements do not demonstrate increased susceptibility to testosterone therapy in patients with hypertension at baseline or in those patients currently taking antihypertensive medication.

Date: Friday November 9, 2018 – 1:55 p.m.
Session: Moderated Poster Session: Androgens
Session Time: 1:30 p.m.- 3:30 p.m. Eastern Time
Location: Loews Miami Beach, Fl., Poinciana 3 & 4

For full prescribing information please visit WWW.ANTARESPHARMA.COM

XYOSTED™ (testosterone enanthate) injection, for subcutaneous use CIII

Initial US approval: 1953

IMPORTANT SAFETY INFORMATION

BOXED WARNING: BLOOD PRESSURE INCREASES

- **XYOSTED™ can cause blood pressure increases that can increase the risk for major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease.**
- **Before initiating XYOSTED™, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Starting approximately 6 weeks after initiating therapy, periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension in patients on XYOSTED™.**
- **Re-evaluate whether the benefits of XYOSTED™ outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease while on treatment.**
- **Due to this risk, use XYOSTED™ only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

XYOSTED™ INDICATIONS AND USAGE

XYOSTED™ (testosterone enanthate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

LIMITATIONS OF USE

- Safety and efficacy of XYOSTED™ in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established
- Safety and efficacy of XYOSTED™ in males less than 18 years old have not been established

CONTRAINDICATIONS

XYOSTED™ is contraindicated in:

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate.
- Women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman.
- Men with known hypersensitivity to XYOSTED™ or any of its ingredients (testosterone enanthate and sesame oil).
- Men with hypogonadal conditions, such as "age-related hypogonadism", that are not associated with structural or genetic etiologies. The efficacy of XYOSTED™ has not been established for these conditions, and XYOSTED™ can increase blood pressure (BP) that can increase the risk of MACE.

WARNINGS AND PRECAUTIONS

Blood Pressure Increases—In clinical trials, XYOSTED™ increased systolic BP in the first 12 weeks of treatment by an average of 4 mmHg based on ambulatory blood pressure monitoring (ABPM) and by an average of 4 mmHg from baseline following 1 year of treatment based on blood pressure cuff measurements. In the 1-year trial, 10% of XYOSTED™-treated patients were started on antihypertensive medications or required changes to their antihypertensive medication regimen.

BP increases can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors for cardiovascular disease.

In some patients, the increase in BP with XYOSTED™ may be too small to detect, but can still increase the risk for MACE.

Before initiating XYOSTED™, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled. Check BP approximately 6 weeks after initiating XYOSTED™ and periodically thereafter. Treat new-onset hypertension or exacerbations of pre-existing hypertension. Re-evaluate whether the benefits of continued treatment with XYOSTED™ outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease.

Polycythemia—Increases in hematocrit, reflective of increases in red blood cell mass, may require discontinuation of XYOSTED™. Check that hematocrit is not elevated prior to initiating XYOSTED™. Evaluate hematocrit approximately every 3 months while the patient is on XYOSTED™. If hematocrit becomes elevated, stop XYOSTED™ until the hematocrit decreases to an acceptable level. If XYOSTED™ is restarted and again causes hematocrit to become elevated, stop XYOSTED™ permanently. An increase in red blood cell mass may increase the risk of thromboembolic events.

Cardiovascular Risk—Long-term clinical safety trials have not been completed to assess the cardiovascular outcomes of testosterone replacement therapy in adult males. To date, epidemiologic studies and randomized controlled trials have been inconclusive for determining the risk of MACE, such as non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, with the use of testosterone compared to non-use. Some studies, but not all, have reported an increased risk of MACE in association with use of testosterone replacement therapy in adult males. XYOSTED™ can cause BP increases that can increase the risk of MACE. Patients should be informed of this possible risk when deciding whether to use or to continue to use XYOSTED™.

Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer—Patients with BPH treated with androgens are at an increased risk of worsening of signs and symptoms of BPH. Monitor patients with BPH for worsening signs and symptoms. Patients treated with androgens may be at an increased risk for prostate cancer. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens.

Venous Thromboembolism (VTE)—There have been post-marketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as XYOSTED™. Evaluate patients who report symptoms of pain, edema, warmth and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a venous thromboembolic event is suspected, discontinue treatment with XYOSTED™ and initiate appropriate workup and management.

Abuse of Testosterone and Monitoring of Serum Testosterone Concentrations—Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions.
If testosterone abuse is suspected, check serum testosterone concentrations to ensure they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and anabolic androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.
Not for Use in Women—Due to lack of controlled studies in women and potential virilizing effects, XYOSTED™ is not indicated for use in women.
Potential for Adverse Effects on Spermatogenesis—With large doses of exogenous androgens, including XYOSTED™, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH) which could possibly lead to adverse effects on semen parameters including sperm count. Patients should be informed of this possible risk when deciding whether to use or to continue to use XYOSTED™.
Hepatic Adverse Effects—Prolonged use of high doses of orally active 17-alpha-alkyl androgens (e.g., methyltestosterone) has been associated with serious hepatic adverse effects (peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, and jaundice). Peliosis hepatis can be a life-threatening or fatal complication. Long-term therapy with intramuscular testosterone enanthate, which elevates blood levels for prolonged periods, has produced multiple hepatic adenomas. XYOSTED™ is not known to produce these adverse effects. Nonetheless, patients should be instructed to report any signs or symptoms of hepatic dysfunction (e.g., jaundice). If these occur, promptly discontinue XYOSTED™ while the cause is evaluated.
Edema—Androgens, including XYOSTED™, may promote retention of sodium and water. Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
Gynecomastia—Gynecomastia may develop and may persist in patients being treated for hypogonadism.
Sleep Apnea—Treatment with testosterone products, including XYOSTED™, may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.
Lipids—Changes in the serum lipid profile may require dose adjustment of lipid lowering drugs or discontinuation of testosterone therapy. Monitor the lipid profile periodically, particularly after starting testosterone therapy.

Hypercalcemia—Androgens, including XYOSTED™, should be used with caution in cancer patients at risk of hypercalcemia (and associated hypercalciuria). Monitor serum calcium concentrations regularly during treatment with XYOSTED™ in these patients.

Decreased Thyroxine-binding Globulin—Androgens, including XYOSTED™, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

Risk of Depression and Suicide—Depression and suicidal ideation and behavior, including completed suicide, have occurred during clinical trials in patients treated with XYOSTED™. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes.

ADVERSE REACTIONS

The safety of XYOSTED™ was evaluated in 2 clinical studies in a total of 283 men who received weekly subcutaneous doses for up to 1 year. All patients were started on 75 mg weekly, then the dose was titrated to 50 mg or 100 mg weekly, as needed, to achieve pre-dose total testosterone concentrations of ≥350 ng/dL and <650 ng/dL.

The most commonly reported adverse reactions (>5%) were: hematocrit increased, hypertension, PSA increased, injection site bruising, and headache.

DRUG INTERACTIONS

Insulin—Changes in insulin sensitivity or glycemic control may occur in patients treated with androgens. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, may necessitate a decrease in the dose of anti-diabetic medication.

Oral Anticoagulants—Changes in anticoagulant activity may be seen with androgens, therefore, more frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at the initiation and termination of androgen therapy.

Corticosteroids—The concurrent use of testosterone with corticosteroids may result in increased fluid retention and requires careful monitoring, particularly in patients with cardiac, renal or hepatic disease.

Medications that May Also Increase Blood Pressure—Some prescription medications and nonprescription analgesic and cold medications contain drugs known to increase blood pressure. Concomitant administration of these medications with XYOSTED™ may lead to additional increases in blood pressure.

USE IN SPECIFIC POPULATIONS

Pregnancy—XYOSTED™ is contraindicated in pregnant women. Testosterone is teratogenic and may cause fetal harm when administered to a pregnant woman based on data from animal studies and its mechanism of action. Exposure of a female fetus to androgens may result in varying degrees of virilization. In animal developmental studies, exposure to testosterone in utero resulted in hormonal and behavioral changes in offspring and structural impairments of reproductive tissues in female and male offspring. These studies did not meet current standards for nonclinical development toxicity studies.

Lactation—XYOSTED™ is not indicated for use in females.

Females and Males of Reproductive Potential - During treatment with large doses of exogenous androgens, including XYOSTED™, spermatogenesis may be suppressed through feedback inhibition of the hypothalamic-pituitary-testicular axis. Reduced fertility is observed in some men taking testosterone replacement therapy. The impact on fertility may be irreversible.

Pediatric Use—Safety and effectiveness of XYOSTED™ in pediatric patients less than 18 years old have not been established. Improper use may result in acceleration of bone age and premature closure of epiphyses.

Geriatric Use—There have not been sufficient numbers of geriatric patients in controlled clinical studies with XYOSTED™ to determine whether efficacy or safety in those over 65 years of age differs from younger subjects. Of the 283 patients enrolled in the 6-month and 1-year efficacy and safety clinical study utilizing XYOSTED™, 49 (17%) were over 65 years of age. Additionally, there are insufficient long-term safety data in geriatric patients to assess the potentially increased risk of cardiovascular disease and prostate cancer. Geriatric patients treated with androgens may also be at risk for worsening of signs and symptoms of BPH.

DRUG ABUSE AND DEPENDENCE

XYOSTED™ contains testosterone enanthate, a Schedule III controlled substance in the Controlled Substances Act.

Abuse and misuse of testosterone are seen in male and female adults and adolescents. Testosterone, often in combination with other anabolic androgenic steroids, may be abused by athletes and bodybuilders.

Serious adverse reactions have been reported in individuals who abuse anabolic androgenic steroids, and include cardiac arrest, myocardial infarction, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility, and aggression.

The following adverse reactions have been reported in men: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidemia, testicular atrophy, subfertility, and infertility.

The following adverse reactions have been reported in women: hirsutism, virilization, deepening of voice, clitoral enlargement, breast atrophy, male pattern baldness, and menstrual irregularities.

The following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth, and precocious puberty.

Withdrawal symptoms can be experienced upon abrupt discontinuation in patients with addiction. Withdrawal symptoms include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido, and hypogonadotropic hypogonadism. Drug dependence in individuals using approved doses for approved indications have not been documented.
For more information, call 1-844-XYOSTED (1-844-996-7833).Please see full Prescribing Information, including Boxed Warning and Medication Guide.

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. (see Indications and Usage above)

About SMSNA

Established in 1994, the Sexual Medicine Society of North America's objective has been to promote, encourage, and support the highest standards of practice, research, education, and ethics in the study of the anatomy, physiology, pathophysiology, diagnosis, and treatment of human sexual function and dysfunction. Further, SMSNA provides a forum for the free exchange and discussion of new ideas, thoughts, and concepts in sexual medicine. Consisting of over 700 active members, the organization is composed of North American surgeons, physicians, mental health professionals, scientists, residents and medical students all committed to sexual health.

The SMSNA seeks to identify existing and emerging issues in the field of human sexual function and dysfunction, provide accurate and credible information to medical professionals, develop standards and guidelines for SEXUAL MEDICINE research and practice, and produce educational programs that bring leading-edge concepts of research, clinical practice, ethics, and politics to health care professionals interested in SEXUAL MEDICINE and related matters.

About Antares Pharma

Antares Pharma, Inc. is a specialty pharmaceutical company focused on the development and commercialization of self-administered parenteral pharmaceutical products using advanced drug delivery auto injector technology. The Company has a portfolio of proprietary and partnered commercial products with several product candidates in advanced stages of development, as well as significant strategic alliances with industry leading pharmaceutical companies including Teva Pharmaceutical Industries, Ltd. (Teva), AMAG Pharmaceuticals, Inc. and Pfizer Inc. (Pfizer). Antares Pharma's proprietary products include XYOSTED™ (testosterone enanthate) injection, OTREXUP® (methotrexate) injection for subcutaneous use and Sumatriptan Injection USP, which is distributed by Teva.

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: market acceptance, adequate reimbursement coverage and commercial success of XYOSTED™ and future revenue from the same; market acceptance, adequate reimbursement coverage and commercial success of Teva's generic epinephrine auto-injector product and future revenue from the same; future market acceptance and revenue from AMAG's Makena® subcutaneous auto injector; ;; 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®; successful completion of the asset sale transaction with Ferring International Center, S.A.; the timing and results of the Company's or its partners' research projects or clinical trials of product candidates in development including projects with Teva and Pfizer; actions by the FDA or other regulatory agencies with 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, 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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