EWING, NJ, April 5, 2018 -- Antares Pharma, Inc. (NASDAQ: ATRS) (the Company) today announced that the U.S. Food and Drug Administration (FDA or the Agency) acknowledged receipt of the Company’s March 29, 2018 resubmission to the Complete Response Letter (CRL) received in connection with the XYOSTED™ (testosterone enanthate subcutaneous injection) New Drug Application. The FDA considered this resubmission a complete, class 2 response and has assigned a user fee goal date of September 29, 2018.

“We are pleased that the FDA accepted our response to the XYOSTED CRL, and look forward to working closely with the Agency throughout the next review cycle,” said Robert F. Apple, President and Chief Executive Officer of Antares Pharma.

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 an investigational new drug, XYOSTED™, for the treatment of testosterone deficiency (hypogonadism). The Company filed a New Drug Application for XYOSTED™ and received a Complete Response Letter. The Company’s technology platforms include VIBEX® disposable auto injectors and disposable multi-use pen injectors. Antares Pharma has license, development and supply agreements with Teva that include VIBEX® epinephrine, exenatide multi-dose pen, and teriparatide multi-dose pen. The Company also provides AMAG Pharmaceuticals with a subcutaneous QuickShot® auto injector for administering Makena® (hydroxyprogesterone caproate injection). 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 Company’s ability to resolve the deficiencies identified by the FDA in the Complete Response Letter for XYOSTED™, FDA approval of the Company’s NDA for XYOSTED™ and future market acceptance and revenue for XYOSTED™; the timing of the commercial launch of the Makena subcutaneous auto injector product in the U.S. and future market acceptance and revenue from the same; successful completion of the transaction with Ferring International Center, S.A. and satisfaction of the various conditions in the Ferring asset purchase agreement and payment of the full purchase price; 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®; the timing and results of the Company’s or its partners’ research projects or clinical trials of product
candidates in development; actions by the FDA or other regulatory agencies with the respect to the Company's products or product candidates or product 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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