



## **ANTARES PHARMA RECEIVES COMPLETE RESPONSE LETTER FROM THE FDA FOR XYOSTED™**

**EWING, NJ, October 20, 2017** -- Antares Pharma, Inc. (NASDAQ: ATRS) announced that today it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for XYOSTED™ (testosterone enanthate) injection. The CRL indicates that the FDA cannot approve the NDA in its present form.

The CRL identified two deficiencies related to clinical data. Based on findings in studies QST-13-003 and QST-15-005, the FDA is concerned that XYOSTED™ could cause a clinically meaningful increase in blood pressure. In addition, the letter also raised a concern regarding the occurrence of depression and suicidality. The CRL did not cite any Chemistry, Manufacturing and Controls (CMC), device or efficacy issues with regard to XYOSTED™. The next step will be to request a meeting with the FDA to further evaluate the deficiencies raised and to agree upon a path forward for a potential approval of XYOSTED™.

“We are disappointed with the outcome of the review and are assessing the content of the Complete Response Letter, including the information that may be needed to resolve the deficiencies,” said Robert F. Apple, President and Chief Executive Officer. “The Company remains committed to bringing XYOSTED to market and will work closely with the FDA to determine the appropriate responses to the deficiencies noted in the letter.”

### **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 XYOSTED™ for testosterone replacement therapy and has filed a New Drug Application with the U.S. Food and Drug Administration. 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 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](http://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 adequately and timely respond to the deficiencies in the XYOSTED™ CRL issued by the FDA, whether any such response will be accepted by the FDA, the Company's ability and timing to resubmit the NDA for XYOSTED™, and FDA acceptance of the**

resubmitted NDA and any approval of the Company's NDA for XYOSTED™, 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, FDA approval of the sNDA submitted by AMAG Pharmaceuticals for an auto injector for Makena and future market acceptance and revenue of the same; the outcome of the pending patent litigation between Teva Pharmaceutical Industries, Ltd. (Teva) and Eli Lilly and the 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 expectations about timing and approval of the VIBEX® epinephrine pen ANDA by the FDA and potential product launch of the same, the therapeutic equivalence rating thereof, and any future revenue from the same; 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 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, 2016, 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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