



Eagle Pharmaceuticals Announces Results of Study for Fulvestrant

October 30, 2018

-- Analysis of data shows fulvestrant did not meet bioequivalence criteria --

-- Initial review of fulvestrant clinical data shows an overall improved safety profile over the comparator --

WOODCLIFF LAKE, N.J.--([BUSINESS WIRE](#))--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the Company's fulvestrant formulation has not met the primary bioequivalence endpoints evaluating Eagle's formulation compared to FASLODEX[®] in its open label, randomized, pharmacokinetic (PK) and safety study conducted in 600 healthy female volunteers across multiple U.S. sites.

The Company will continue to evaluate the data, but as a result of this outcome, Eagle intends to focus on advancing the development of other products in its pipeline.

Eagle's fulvestrant product was intended to be administered at the recommended dose with one intramuscular injection instead of two high-viscosity intramuscular injections for FASLODEX, and in less time. In addition, our low-viscosity formulation does not contain castor oil, and was intended for administration with a 23-gauge needle, which is 25% thinner than the current needle required to administer FASLODEX.

"At this time, and given the results of the fulvestrant trial, we plan to focus on other promising programs in our pipeline, including exertional heat stroke, a potential nerve agent indication and intramuscular formulation for RYANODEX, and our pemetrexed and vasopressin assets," stated Scott Tarriff, Chief Executive Officer.

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle's strategy is to utilize the FDA's 505(b)(2) regulatory pathway. Additional information is available on the Company's website at www.eagleus.com.

Forward-Looking Statements

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events including, but not limited to: Eagle's development of fulvestrant; Eagle's plans to continue to evaluate the data with respect to its fulvestrant formulation; and Eagle's plans to focus on other products in its pipeline. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks include, but are not limited to: the possibility that the initial data with respect to Eagle's fulvestrant formulation may be inaccurate or incomplete; the possibility that Eagle's fulvestrant formulation may have more potential than the initial data indicates, and Eagle's decision to prioritize other products in its pipeline may be premature; that Eagle's redirection of resources to other products in its pipeline may not be successful; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the U.S. Securities and Exchange Commission (SEC) on February 26, 2018 and its other filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

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