Eagle Pharmaceuticals Receives Complete Response Letter from FDA on RYANODEX for Exertional Heat Stroke Application

July 26, 2017

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) ("Eagle" or "the Company") announced today that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) regarding its 505(b)(2) New Drug Application for RYANODEX® (dantrolene sodium) for the treatment of exertional heat stroke (EHS), in conjunction with external cooling methods.

In its letter to Eagle, the FDA has requested that the Company conduct an additional clinical trial for RYANODEX for Exertional Heat Stroke.

"We are reviewing our options and will evaluate the FDA's response to chart a path forward for RYANODEX for this important indication and life-threatening condition," said Scott Tarriff, Chief Executive Officer of Eagle.

RYANODEX remains approved for the treatment of malignant hyperthermia in conjunction with appropriate supportive measures, and for the prevention of malignant hyperthermia in patients at high risk.

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 such as "will," "may," "can," "could be," "believe," "intends," "anticipate(s)," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: our confidence in the clinical benefits of RYANODEX; our ability to address the FDA's Complete Response Letter and to chart a path forward for RYANODEX for EHS; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2016, and its other filings with the U.S. Securities and Exchange Commission. 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 whether Eagle's management and/or board of directors will be effective in managing Eagle's business and future growth, whether Eagle will maintain successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses, as well as the other risks described in Eagle's filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do 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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