NDA for Eagle Pharmaceuticals' Orphan Drug Ryanodex® for the Treatment of Malignant Hyperthermia Accepted by FDA, Priority Review Granted

March 20, 2014

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. ("EAGLE") (NASDAQ:EGRX) announced today that the United States Food and Drug Administration has accepted the company's New Drug Application for Ryanodex® (dantrolene) and granted a priority review classification. The PDUFA date is July 22, 2014.

In January 2014, Eagle filed its NDA with the FDA for the treatment of malignant hyperthermia. In February 2014, the FDA conditionally accepted Eagle's trade name Ryanodex. Ryanodex has previously been granted Orphan Drug designation and Eagle currently owns three U.S. patents covering the product. Eagle intends to commercialize Ryanodex after approval and will retain exclusive marketing rights in the U.S.

Scott Tarriff, CEO of Eagle Pharmaceuticals, said, "We believe that the immediate benefits of our improved and more concentrated formulation can be clinically significant in critical care situations. Each vial of Ryanodex is reconstituted in less than one minute by the anesthesiologist in contrast to the need to mix and administer approximately 12 vials of currently marketed products. This reduction in the time to treat patients can result in notable improvement in patient outcomes. Additionally, the currently marketed formulation requires significant drug product volume to be administered. Eagles' Ryanodex formulation has reduced the required volume by more than 95% for an equivalent dose."

About Malignant Hyperthermia

Malignant Hyperthermia is a condition that can be triggered when genetically susceptible individuals come in contact during surgery with certain inhaled anesthetics or the muscle relaxant succinylcholine. These patients can experience tachycardia, elevated blood pressure, raised CO_2 levels and very high body temperature levels. If not treated immediately, the hyper-metabolic episode can be fatal to the patient.

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 "expect(s)," "feel(s)," "believe(s)," "will," "may," "intends," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the benefits of Ryanodex in critical care situations, including the reduction in time to treat patients and the reduction in drug volume, and our ability to obtain regulatory approval for Ryanodex. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether and when, if at all, Ryanodex will receive final approval from FDA or equivalent foreign regulatory agencies and for which indications; whether Ryanodex will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; competition from other pharmaceutical and biotechnology companies; the development of, and our ability to take advantage of, the market for our therapeutic products; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our Prospectus filed with the Securities and Exchange Commission on February 13, 2014, and our other periodic and interim reports filed from time to time with the 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.

ABOUT EAGLE

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b) (2) regulatory pathway. The company develops products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products.

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