FDA Approves Eagle Pharmaceuticals' Ryanodex® for the Treatment of Malignant Hyperthermia 7/23/2014

July 23, 2014

-- Novel Antidote Enables Quicker Response to Inherited Life-Threatening Condition --

-- Orphan Drug Designation may Provide Eagle Seven Years Market Exclusivity --

-- First Self Marketed Drug for Eagle with Shipments to begin Shortly --

Eagle Pharmaceuticals, Inc. ("Eagle" or "the Company") (Nasdaq:EGRX) today announced that the U. S. Food and Drug Administration (FDA) has approved Ryanodex® (dantrolene sodium) for injectable suspension indicated for the treatment of malignant hyperthermia (MH), along with the appropriate supportive measures. MH is an inherited and potentially fatal disorder triggered by certain anesthesia agents in genetically susceptible individuals. FDA had designated Ryanodex as an Orphan Drug in August 2013. Eagle has been informed by the FDA that it will learn over the next four to six weeks if it has been granted the seven year Orphan Drug market exclusivity.

"We are very pleased with today's approval of Ryanodex, which enables health care providers to better meet the needs of patients experiencing a life-threatening MH crisis," said Scott Tarriff, CEO of Eagle Pharmaceuticals. "This significant milestone exemplifies our strategy of developing innovative products and we plan to ship the product in the very near future."

Eagle is the exclusive licensee of four U.S. patents for Ryanodex. Approval of Ryanodex represents two major milestones: in addition to adding to the Company's portfolio of approved compounds, Ryanodex represents the first product to be solely marketed by the Company.

Ryanodex is the first significant enhancement to MH treatment options in more than three decades, reformulated to improve performance in managing MH. The product has the potential to become a new standard of care for the treatment of malignant hyperthermia, because it enables anesthesiologists to deliver a therapeutic dose of the only antidote for MH (dantrolene sodium) in a much more expedient manner than currently possible with existing formulations of IV dantrolene sodium, potentially saving lives and reducing MH-related morbidity. Ryanodex can be prepared and administered in less than one minute by a single healthcare practitioner.

Utilizing innovative nanosuspension technology, Ryanodex now provides a therapeutic loading dose of dantrolene sodium in a single vial. 250 mg of Ryanodex is mixed with only 5 mL of sterile water and administered to the patient in less than one minute. Other dantrolene sodium formulations require multiple 20mg vials reconstituted in large volumes of sterile water, a process that can take 15 to 20 minutes to mix reconstitute and administer.

"When a patient experiences malignant hyperthermia during surgery, it is a life-threatening emergency requiring immediate treatment including the administration of the 'antidote' drug dantrolene sodium," said Henry Rosenberg, MD, CPE, a founder and President of the Malignant Hyperthermia Association of the United States (MHAUS). "The ability for healthcare professionals in hospitals and surgery centers to more quickly prepare and administer this new formulation of the antidote dantrolene sodium is expected to bring the crisis under control more rapidly and prevent severe complications from MH."

Ryanodex was granted priority review status by the FDA in March 2014, a regulatory review process that expedites the review of drugs that treat life threatening and serious conditions and provide a significant improvement in safety or effectiveness over the existing therapies. Ryanodex will be available to order through national and regional drug wholesalers in August with product shipping shortly after. For more information about Ryanodex, please visit RYANODEX.COM.

About Ryanodex

Ryanodex (dantrolene sodium) is a novel formulation of the antidote for management of malignant hyperthermia (MH), a potentially fatal disorder described in more detail below. Ryanodex is available in single-use vials containing 250mg of dantrolene sodium in lyophilized powder form. It is formulated for rapid reconstitution and administration in less than one minute to patients in malignant hyperthermia crisis. Ryanodex should be administered by continuous rapid intravenous push beginning with a loading dose of 2.5 mg/kg, and continuing until symptoms subside. Ryanodex is the first significant enhancement to the management of malignant hyperthermia in more than three decades, and has the potential to become the new standard of care in malignant hyperthermia management.

About Malignant Hyperthermia

Malignant Hyperthermia is a condition that can be triggered when genetically susceptible individuals come in contact with certain inhaled (volatile) anesthetics or the muscle relaxant succinylcholine. These patients can experience tachycardia, elevated blood pressure, raised carbon dioxide levels, and very high body temperature levels. If not treated immediately, the hypermetabolic episode can be fatal.

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. The Company's strategy is to utilize the FDA's 505(b)(2) regulatory pathway. For more information: 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 "expect(s)," "feel(s)," "believe(s)," "will," "may," "intends," "anticipate(s)," "look forward," "upcoming," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify

forward-looking statements. These statements include, but are not limited to, statements regarding the receipt of seven years of marketing exclusivity for Ryanodex and the potential benefits of Ryanodex in the treatment of MH, including the reduction in time to treat patients and the potential of becoming a new standard of care. 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: the strength and enforceability of our intellectual property rights, whether Ryanodex will be successfully marketed; our ability to generate anticipated revenues from sales of Ryanodex; competition from other pharmaceutical and biotechnology companies; the development of, and our ability to take advantage of, the market for Ryanodex; 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.



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