FDA Grants Priority Review for Eagle Pharmaceuticals' Ryanodex NDA for the Treatment of Exertional Heat Stroke

March 27, 2017

-PDUFA Date of July 23, 2017-

Eagle Pharmaceuticals (Nasdaq:EGRX) ("Eagle" or "the Company") announced today that their 505(b)(2) New Drug Application (NDA) for Ryanodex® (dantrolene sodium) for the treatment of exertional heat stroke (EHS) has been accepted for filing and granted a priority review designation by the U.S. Food and Drug Administration (FDA). The FDA grants priority review to medicines that may offer major advances in care or provide a treatment option where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA will aim to complete its review within six months of the NDA submission; the PDUFA date for the NDA has been set for July 23, 2017.

"There is currently no approved pharmacological treatment for EHS. If Ryanodex is approved, Eagle will be the first to market with a potentially transformational therapy. EHS can strike anyone, but athletes, our military and outdoor workers are especially vulnerable. We look forward to working with the FDA throughout the review process and to their expedited decision in July 2017," said Scott Tarriff, Chief Executive Officer of Eagle.

"The number of injuries associated with exertional heat illness in the U.S. increased over 130% between 1997 and 2006. And, we believe the incidence of EHS is significantly under-reported. There may be approximately 75,000 cases of EHS annually. Ryanodex will represent Eagle's most significant self-launched commercial product and we are continuing to build our commercial capabilities to serve the healthcare profession upon approval," added David Pernock, President and Chief Commercial Officer of Eagle Pharmaceuticals.

The NDA is supported by safety and efficacy data from a controlled clinical trial in EHS patients, and preclinical data from animal studies conducted under the 'Animal Rule' to further support the efficacy of Ryanodex. The clinical study supported the known and well-characterized safety profile of Ryanodex and demonstrated that administration of Ryanodex in addition to body cooling showed substantial evidence of increased clinically meaningful effectiveness in treating patients with EHS, compared to body cooling alone. In addition, animal data provided further evidence supporting the efficacy of Ryanodex in the treatment of this rare and life-threatening condition.

"We evaluated Ryanodex in our clinical study conducted in a real-world acute care setting, and in a well-established animal model. Clinical data showed that Ryanodex offered a clinically meaningful benefit to EHS patients when combined with traditional cooling methods, which is further supported by statistically significant results from our animal work," said Adrian Hepner, MD, PhD, Chief Medical Officer of Eagle Pharmaceuticals.

Information regarding Eagle's pivotal animal study can be found in Eagle's press release dated December 13, 2016. Additional information regarding Eagle's clinical study can be found in Eagle's press release dated December 17, 2015.

About EHS

EHS is a sudden and unpredictable disorder that constitutes a medical emergency, which may result in severe multi-organ dysfunction and death. EHS is more commonly seen in young people undergoing exertional physical activity in a hot weather environment, and is one of the leading causes of death in young athletes and military personnel in non-combat situations. EHS cases are also observed in outdoor workers, firefighters, and people randomly performing intense recreational physical activity.

Currently, there is no approved drug product for the treatment of EHS, one of the most severe forms of heat-related illness, characterized by core body temperature of 104° F (40° C) or greater and significant neurological dysfunction. EHS carries high rates of morbidity and mortality. The central nervous system is particularly sensitive to hyperthermia, which may lead to severe neurologic complications and permanent brain damage.

About Ryanodex

RYANODEX® (dantrolene sodium) for injectable suspension is indicated for the treatment of malignant hyperthermia ("MH") in conjunction with appropriate supportive measures, and for the prevention of malignant hyperthermia in patients at high risk.

In February 2015, RYANODEX® was granted seven years of U.S. market exclusivity for the treatment of MH by the U.S. Food and Drug Administration ("FDA").

Important Safety Information

RYANODEX® is not a substitute for appropriate supportive measures in the treatment of malignant hyperthermia, including:

Discontinuing triggering anesthetic agents

Increasing oxygen

Managing the metabolic acidosis

Instituting cooling when necessary

Administering diuretics to prevent late kidney injury due to myoglobinuria (the amount of mannitol in RYANODEX® is insufficient to maintain diuresis).

Precautions should be taken when administering RYANODEX® preoperatively for the prevention of malignant hyperthermia, including monitoring vital signs, avoiding known triggering agents, and monitoring for early clinical and metabolic signs of malignant hyperthermia that may indicate additional treatment is needed.

The administration of dantrolene sodium is associated with loss of grip strength and weakness in the legs, as well as drowsiness, dizziness, dysphagia, dyspnea, and decreased inspiratory capacity. Patients should not be permitted to ambulate without assistance until they have normal strength and balance. Care must be taken to prevent extravasation of RYANODEX® into the surrounding tissue due to the high pH of the reconstituted RYANODEX® suspension and potential for tissue necrosis.

RYANODEX® full Prescribing Information can be found at www.RYANODEX.com

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," "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: Eagle's ability to gain successful FDA approval of Ryanodex® for Exertional Heat Stroke and the impact, if any of such approval; the timing and level of success of a future launch of Ryanodex® for Exertional Heat Stroke; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; the strength of the patent portfolio protecting Ryanodex® and the ability of Eagle to defend against third party attempts to design around or invalidate those patents; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; the commercial success of Eagle's commercial portfolio, including Ryanodex® for Exertional Heat Stroke once launched; the ability of Eagle to deliver sustained shareholder value over time; 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, 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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