Eagle Pharmaceuticals Initiates Rolling Submission of NDA for Ryanodex in Exertional Heat Stroke

November 11, 2016

Eagle Pharmaceuticals ("Eagle" or the "Company") (NASDAQ: EGRX) today announced that the Company has initiated the rolling submission of its New Drug Application (NDA) and filed the first part of the application to the U.S. Food and Drug Administration (FDA) for Ryanodex® (dantrolene sodium) for injectable suspension for the treatment of exertional heat stroke (EHS), an investigational new indication for the product. The rolling submission allows completed portions of an NDA to be submitted, which may then be reviewed by the FDA on an ongoing basis. The FDA had previously granted Fast Track Designation for the development of Ryanodex for the treatment of EHS, which allows for submission of parts of an NDA application (rolling review).

The first part of this rolling submission includes the human safety and efficacy data from the clinical study in EHS patients conducted in a 'real-world' clinical setting, at the Emergency Department of four hospitals during the 2015 Hajj Islamic Pilgrimage, in the Kingdom of Saudi Arabia.

Eagle is currently conducting animal studies to further support the safety and efficacy of Ryanodex for the treatment of EHS. The Prescription Drug User Fee Act (PDUFA) review clock will begin once the complete NDA has been submitted.

The FDA provides designation of a drug as a Fast Track product if it is intended for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. This provision is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved drug product can reach the market expeditiously.

Ryanodex is protected by two filed and five issued patents.

"With no drug indicated for the treatment of EHS, initiation of the NDA submission process marks an important step forward in our efforts to make a meaningful difference in the lives of people affected by this potentially life-threatening condition. We look forward to working closely with the FDA towards the goal of making Ryanodex available to these patients as soon as possible," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

Results of the clinical study demonstrated that the use of Ryanodex in addition to the current standard of care ("SOC") showed substantial evidence of increased effectiveness in treating EHS than SOC alone, and that the safety profile of Ryanodex in EHS patients was consistent with the known and well characterized safety profile of Ryanodex for the currently approved indications. The current SOC for the treatment of EHS is limited to body cooling by physical methods (e.g., water immersion, evaporative cooling) and supportive measures (e.g., IV fluids, respiratory support, cardiac monitoring).

Additional information regarding the clinical study in EHS patients and its outcomes can be found in Eagle's press release dated December 17, 2015.

About Exertional Heat Stroke

Exertional Heat Stroke ("EHS") is a rare, 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. EHS cases are also observed in construction workers, firefighters, military personnel, and farmers. There is no currently approved drug product for the treatment of EHS.

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.

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.

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").

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 and phrases such as "will," "may," "intends," "anticipate(s)," "plan," "enables," "potential," "entitles," "optimistic" "could" "look forward" 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: the safety and efficacy of RYANODEX for the treatment of EHS; the successful outcome of any animal studies to support the use of RYANODEX for the treatment of EHS; the timing of an FDA review and subsequent approval for the EHS indication for RYANODEX; the likelihood of FDA approval of the use of RYANODEX for the treatment of EHS; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the fiscal year ended September 30, 2014, 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 the FDA will ultimately approve RYANODEX for the treatment of EHS; whether our studies will support the safety and efficacy of RYANODEX for the treatment of EHS; and 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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