



Eagle Pharmaceuticals Successfully Completes Clinical Treatment Portion of Its Safety and Efficacy Study of RYANODEX for Exertional Heat Stroke

October 6, 2015

First Exertional Heat Stroke Study of Its Kind Conducted in Saudi Arabia during the Hajj Pilgrimage

Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX) ("Eagle" or the "Company") today announced that the Company has successfully completed the clinical treatment portion of its safety and efficacy study to evaluate RYANODEX® (dantrolene sodium for injectable suspension) for Exertional Heat Stroke ("EHS"). The first of its kind study was conducted from September 22-27, 2015 at the Hajj pilgrimage in Saudi Arabia. Due to the unpredictable and sudden nature of EHS, the study was conducted in an emergency and acute-care medical setting.

In this study, 34 EHS patients were randomized to receive current standard of care ("SOC") treatment or SOC plus RYANODEX. Based on preliminary study results, participants who received RYANODEX in combination with the SOC showed no significant drug-related adverse events. The Company believes this patient cohort is a sufficient number of subjects to enable assessment of a clinically meaningful treatment effect of RYANODEX in EHS. Eagle expects to complete the clinical data analysis during the fourth quarter of 2015.

"The goal of this study is to collect clinically meaningful data that will support establishing the safety and efficacy of RYANODEX for the treatment of EHS, potentially expanding the indication of this FDA approved product," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "We worked closely with the Saudi health authorities and the Saudi medical community to implement this novel and challenging study, and are extremely pleased with their commitment to supporting our efforts. The data is currently under analysis, and we will be meeting with the FDA shortly to discuss next steps and look forward to providing additional information in due course."

About the Study

The main protocol inclusion criteria required that eligible study patients showed hallmark clinical features of EHS, including the following:

- Subjects between 18-45 years of age, and believed to have experienced exertional physical activity within the previous 24 hours;
- Presence of neurological impairment, which was evaluated using the Glasgow Coma Scale;
- Core body temperature of 104 degrees Fahrenheit or greater; and
- Tachycardia (at least 100 heart beats per minute)

A total of 34 EHS patients were randomized in a 1:1 ratio to receive either standard of care (SOC), which consists of body cooling by physical methods (e.g. cold water immersion, cold water mist, ice packs application) and supportive measures, or SOC plus RYANODEX.

Over the course of the study, patients were evaluated for changes in core body temperature, and neurological, renal, respiratory and cardiac functions. The Company is currently finalizing data collection and generating the study databases.

About RYANODEX

Indication

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").

About Exertional Heat Stroke

Exertional Heat Stroke is a rare 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 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.

RYANODEX® is a registered trademark of Eagle Pharmaceuticals, Inc.

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," "intends," "anticipate(s)," "plan," "enables," "potentially," "entitles," 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; FDA approval of the use of RYANODEX for the treatment of EHS; the anticipated issuance by the USPTO of additional patents related to Eagle's products in 2015; 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 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; the timing of issuance by the USPTO of additional patents to Eagle related to its products, if at all; 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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