



FDA Grants Fast Track Designation to RYANODEX for Treatment of Exertional Heat Stroke; Fast Track Designation Highlights Serious, Unmet Medical Need that Exists for Patients with EHS

February 1, 2016

Eagle Pharmaceuticals ("Eagle" or the "Company") (NASDAQ:EGRX) today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track designation to its RYANODEX® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS"), an investigational new indication for the product.

The FDA's Fast Track program facilitates the development and review of drugs intended to treat serious conditions and address an unmet medical need. A drug development program with Fast Track designation is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval to get important new drugs to the patient earlier.

"We are very encouraged by the FDA's Fast Track designation, which is an acknowledgement of the seriousness of EHS and the current lack of a drug treatment. EHS is a leading cause of death in young athletes and non-combat related fatalities in the military yet no drug products exist on the market today to treat this devastating and potentially fatal condition. This Fast Track designation will enable us to work more closely with the FDA and expedite our program to make RYANODEX available to medical practitioners, and potentially expand the product's label to include EHS as an authorized second indication," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"We look forward to meeting with the FDA to review the results of our clinical trial and determining next steps for this important development program," concluded Tarriff.

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; 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.

For Eagle Pharmaceuticals
Investor Relations
In-Site Communications
Lisa M. Wilson, 212-452-2793