Eagle Pharmaceuticals Resubmits NDA for RYANODEX for Exertional Heat Stroke

January 9, 2020

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle") today announced that the Company has resubmitted its New Drug Application ("NDA") for RYANODEX ® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS"), in addition to body cooling, to the U.S. Food and Drug Administration ("FDA"). Eagle believes that this submission addresses the Complete Response Letter received in July 2017. A Prescription Drug User Fee Act ("PDUFA") date of six months is anticipated for this class of resubmissions.

"We are pleased to have resubmitted our NDA for EHS and we look forward to continuing to work with the FDA over the course of its review," stated Scott Tarriff, Chief Executive Officer.

About EHS

EHS is one of the most severe forms of heat-related illness. This rare, sudden and unpredictable disorder is characterized by core body temperature of 104° F (40° C) or greater and significant neurological dysfunction, such as sudden changes in behavior, seizures or coma.

EHS constitutes a medical emergency, and carries high rates of morbidity and mortality. The central nervous system is very sensitive to hyperthermia, which may lead to severe neurologic complications and permanent brain damage.

EHS is mostly seen in young people undergoing intense 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 outdoor workers, firefighters, and military personnel.

About RYANODEX

RYANODEX® (dantrolene sodium) for injectable suspension is indicated for the treatment of malignant hyperthermia 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.

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

About Eagle Pharmaceuticals, Inc.

Eagle is a pharmaceutical company focused on developing and commercializing innovative and differentiated injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. 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 "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," 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 success of the resubmission in addressing the Complete Response Letter; the timing of FDA approval, if received, of the use of RYANODEX for the treatment of EHS; the anticipated PDUFA date for this class of resubmissions; the timing and level of success of a future launch of RYANODEX for the treatment of EHS; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; and the commercial success of Eagle's commercial portfolio, including RYANODEX. 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 use of RYANODEX for the treatment of EHS will be approved by FDA; whether the Company can successfully market and commercialize RYANODEX for the treatment of EHS; and other factors that are discussed in Eagle's filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does 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.

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

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