Eagle Pharmaceuticals and NorthShore University HealthSystem to Study Dantrolene Sodium for the Treatment of Concussion and Other Forms of Traumatic Brain Injury

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WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle") announced today a new research agreement with NorthShore University HealthSystem in Evanston, IL, focused on studying Eagle's RYANODEX ® (dantrolene sodium) for traumatic brain injury (TBI) in animal models.

"We are pleased to be partnering with NorthShore University HealthSystem, one of the top research institutes for the study of concussion and other forms of traumatic brain injury, or TBI, for which no drug treatments currently exist," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals. "We believe RYANODEX may have the potential to modulate some of these mechanisms, which may result in amelioration of neuron cell damage and death, commonly observed in TBI," Mr. Tarriff added.

TBI can acutely cause brain lesions that result in direct tissue damage that may prompt apoptotic cell mechanisms for several weeks post-injury, which may lead to worsened long-term outcomes. Disruption of certain intracellular mechanisms may affect cell functioning and survival.

NorthShore University HealthSystem has a long tradition and a profound commitment to advancing neuroscience discoveries that improve patient care and quality of life in traumatic brain injury. "Our research focuses on identifying and characterizing the mechanisms of cerebral concussions and other forms of traumatic brain injury and applying this knowledge to develop better methods to treat them. We are excited to complete this potentially ground-breaking study," said Julian E. Bailes, MD, Chairman of the Department of Neurosurgery at NorthShore and Co-Director of the NorthShore Neurological Institute.

Leading the study will be Adrian Hepner, M.D., Ph.D., Executive Vice President and Chief Medical Officer at Eagle, and John D. Finan, Ph.D., Research Scientist in the Department of Neurosurgery at NorthShore.

RYANODEX is currently approved for the treatment of malignant hyperthermia (MH) and for the prevention of MH in patients at high risk.

About Traumatic Brain Injury (TBI)

Traumatic Brain Injury, or TBI, often referred to as the "silent epidemic," contributes to worldwide death and disability more than any other traumatic injury. It's estimated that 69 million people worldwide sustain a TBI each year. According to the Centers for Disease Control and Prevention (CDC), about a third of TBIs occur in children.

TBI may result from an injury to the brain from an external force that jolts the brain. For example, TBI can occur from falls, being struck by an object, contact sports, motor vehicle accidents or shock waves, such as experienced during an explosion.

TBIs may be mild, moderate or severe based on whether a patient becomes unconscious, the duration of any unconsciousness and severity of other symptoms, such as bleeding in the brain. The effects of mild TBI, commonly referred to as concussion, include problems with thinking, remembering, and sleeping, as well as headaches or feeling tired or anxious. Moderate or more severe TBI can cause physical, cognitive, emotional, and behavioral changes which may persist for years even after treatment. Fifty percent of patients can experience declines within five years of injury.

Children are affected by TBI differently than adults. The CDC reports that an injury of any severity to the developing brain can disrupt a child's developmental trajectory and may result in restrictions in school and limited participation in activities, such as athletics.

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 TBI; expected FDA approval of the use of RYANODEX for the treatment of TBI the timing and level of success of a future launch of RYANODEX for the treatment of TBI; 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. 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.

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