Eagle Pharmaceuticals Reports Positive Results from Pivotal Animal Study Supporting the Efficacy of RYANODEX for Exertional Heat Stroke

December 13, 2016

-- Animal study conducted under the Animal Rule met primary efficacy endpoint --

--Ryanodex-treated animals showed a greater proportion of subjects achieving reversal of heat stroke/hypermetabolic crisis --

-- Animal Studies constitute an essential portion of the NDA submission --

Eagle Pharmaceuticals ("Eagle" or the "Company") (NASDAQ:EGRX) today announced positive results from its pivotal animal study conducted under the Animal Rule[1], for Ryanodex® for the treatment of Exertional Heat Stroke ("EHS"), an investigational new indication for the product. Due to the rare and unpredictable nature of EHS, the animal work is an essential part of the hybrid development program in support of the efficacy of Ryanodex for the treatment of EHS. The hybrid program is comprised of safety and efficacy data from a human study in EHS patients, and efficacy data from an established animal model. Both components are necessary to fulfill the NDA submission requirements. Eagle previously filed human safety and efficacy clinical data as part of the rolling NDA submission.

The study results indicated that 58.3% of animals treated with Ryanodex in addition to the Standard of Care ("SOC" [efficient cooling and supportive measures]) achieved reversal of the induced heat stroke/hypermetabolic crisis (HS/HC), the primary efficacy endpoint, compared to only 9.1% of animals treated with SOC alone. The robust and clinically meaningful treatment difference in favor of Ryanodex was statistically significant (p value= 0.0272).

"We believe that Ryanodex has the potential to offer tremendous value to patients, caregivers and shareholders over a long horizon. Eagle could be the first to market with a potentially life-saving treatment for EHS, if approved by the FDA, as early as mid-2017. We are committed to ensuring that the right resources are in place to support the success of the product," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"The positive data from our animal work further supports the efficacy data from our human clinical study, which we completed at the end of 2015. The clinical and nonclinical components of our development program provide adequate safety and efficacy data to complete our NDA submission. We anticipate completing the NDA filing as soon as possible," added Adrian Hepner, Executive Vice President and Chief Medical Officer.

Study Design and Outcomes

Data from Eagle's prior nonclinical studies in an established and well characterized model in the Malignant Hyperthermia ("MH") susceptible swine provided the basis for the design of the pivotal animal study, which was agreed to by the FDA, to support the efficacy of Ryanodex for the treatment of EHS in humans.

The GLP study was a randomized, blinded, controlled trial, in which study animals included in the pre-specified primary analysis of the primary efficacy endpoint received either Ryanodex in addition to SOC immediately after crisis onset, or SOC-only immediately after crisis onset.

A dose of 2 mg/kg of Ryanodex (dantrolene sodium) for injectable suspension was administered via bolus IV injection at onset of the induced heat stroke/hypermetabolic crisis (HS/HC). This is the same dosage level used in Eagle's human clinical safety and efficacy study conducted during the Hajj in 2015.

The study data showed that only 9.1% (1 of 11) of animals treated with SOC only achieved reversal of the crisis, compared to 58.3% (7 of 12) animals treated with Ryanodex in addition to SOC (p=0.0272).

In September 2015, Eagle completed its clinical study in EHS patients during the Hajj pilgrimage in the Kingdom of Saudi Arabia. The study was conducted at the Emergency Departments of four hospitals in the Makkah region of Saudi Arabia. Due to the life-threatening, unpredictable and sudden nature of EHS, it was necessary to conduct the study in a 'real world' emergency and acute-care medical setting.

Study results demonstrated that administration of Ryanodex in addition to the current standard of care ("SOC") showed substantial evidence of increased effectiveness in treating patients with EHS, compared to SOC alone. In addition, 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).

Ryanodex is currently approved for the treatment of Malignant Hyperthermia and for the prevention of MH in patients at high risk.

Eagle's Ryanodex for the treatment of EHS has previously been granted fast track designation and orphan drug designation by the FDA. Ryanodex is protected by two filed and five issued patents.

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

About 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 and non-combat related fatalities in the military. 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. EHS is the most severe form of heat-related illness, characterized by core body temperature of 104° F (40° C) or greater and significant neurological dysfunction. It 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.

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.

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").

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 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: the earnings potential and long-term value of Ryanodex; 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 December 31, 2015, 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 Eagle will generate earnings and realize long-term value from Ryanodex; 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.

[1] FDA Guidance for Industry 'Product Development Under the Animal Rule' (October 2015)

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