Eagle Pharmaceuticals Reports Positive Outcome From FDA Meeting For RYANODEX For Exertional Heat Stroke NDA Submission

August 9, 2016

-- Hajj Study Results Sufficient for Human Data in Filing --

-- Hybrid Rule (Human and Animal Data) Reaffirmed --

-- Only Completion of Ongoing Animal Studies Required for Submission--

-- Eagle Purchases Royalty Rights to Ryanodex Portfolio --

Eagle Pharmaceuticals (“Eagle” or the “Company”) (NASDAQ:EGRX) today announced that the U.S. Food and Drug Administration ("FDA") has determined that no additional human safety and efficacy data is required for the submission of Eagle’s New Drug Application (“NDA”) for Ryanodex® for the treatment of exertional heat stroke (“EHS”), an investigational new indication for the product, further confirming that a hybrid development program comprised of clinical data from EHS patients and preclinical data from animal studies constitutes an adequate regulatory pathway for the NDA submission.

Eagle has also reduced its future Ryanodex royalty obligations to its licensing partner from 15% to 3% of net sales in exchange for $15 million in cash.

“We believe there is significant long-term value in our Ryanodex portfolio. Following our positive meeting with the FDA, we have an agreement for an NDA submission for EHS. We anticipate requesting priority review of the application and, if granted by the FDA, being the first to market with a potentially life-saving treatment for EHS as early as next year,” said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. “Furthermore, we believe the continued growth of the currently approved Malignant Hyperthermia indication and our plans to expand the Ryanodex label to include the potential treatment of Ecstasy and Methamphetamine intoxication will allow us to maximize the value of this product. Therefore, we increased our commitment to the portfolio by investing a portion of our cash to purchase substantially all of the royalty obligation owed on Ryanodex. This will allow us to increase the earnings potential of Ryanodex, benefitting shareholders for many years to come,” he added.

“We are pleased that the FDA recognized that our study during the Hajj last September, in combination with results from our ongoing animal studies, will provide adequate safety and efficacy data to complete our NDA submission. And, we are very grateful to the authorities of Saudi Arabia for their assistance in supporting the human study. We expect to complete our NDA filing upon successful conclusion of our animal work,” added Adrian Hepner, Executive Vice President and Chief Medical Officer.

The animal studies to support the NDA are currently underway. Upon successful completion of the animal studies, Eagle anticipates requesting priority review for its NDA submission. If approved, EHS would be the second indication for Ryanodex which is currently approved for the treatment of malignant hyperthermia (“MH") 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. Eagle is evaluating its option to submit a rolling NDA, as allowed by the fast track designation, which permits completed sections of an NDA to be submitted on an ongoing basis. Ryanodex is protected by two filed and five issued patents.

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. EHS is a leading cause of death in young athletes and non-combat related fatalities in the military.

In September 2015, Eagle completed its clinical study in EHS patients during the Hajj pilgrimage in 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 the use of Ryanodex with the current standard of care (“SOC”) showed substantial evidence of increased effectiveness in treating EHS than SOC alone, and that 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).

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. 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.

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; the satisfactory completion of studies to support the indication of Ryanodex for 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.

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