Eagle Pharmaceuticals Completes NDA Submission for Ryanodex for Exertional Heat Stroke to FDA

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-Ryanodex could offer a new standard of care for this serious and life-threatening condition-

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) ("Eagle" or "the Company") today announced that it has completed the submission of its 505(b)(2) New Drug Application (NDA) for Ryanodex® for the treatment of exertional heat stroke (EHS) to the U.S. Food and Drug Administration (FDA). There is no currently approved drug treatment for EHS. Due to the life-threatening nature of EHS and the unmet need for an effective drug treatment for EHS, Eagle has requested Priority Review of this NDA for Ryanodex. If granted, as anticipated, a Prescription Drug User Fee Act (PDUFA) date for a decision on the NDA would be July 2017; otherwise the Company anticipates approval later in 2017.

"If approved, Ryanodex for EHS would be the first drug therapy for athletes, our military and active individuals affected by this severe, life-threatening condition that can potentially cause long-term neurological impairment and organ damage. Ryanodex could offer a new standard of care in the treatment of EHS when combined with traditional cooling methods," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

EHS is a rare, sudden, and unpredictable medical condition characterized by severe hyperthermia and neurological dysfunction. EHS constitutes a medical emergency, mostly affecting young, active and otherwise healthy individuals. Treatment delay can result in major complications including brain damage, organ failure and death. Today, the treatment for EHS is limited to body cooling by physical methods (i.e. water immersion, ice-packs, water misting), and supportive measures including intravenous (IV) fluids and respiratory support. Under normal physiologic conditions, an individual's average brain temperature is approximately 0.9°C higher than core body temperature. Changes of less than 1°C can result in functional alterations in various areas of the nervous system. Consequently, individuals whose core body temperature rises above 104°F (40°C), which is common with individuals experiencing EHS, risk severe organ dysfunction, and long-term disability. Approximately 30% of EHS survivors have persistent neurologic complications despite the use of aggressive cooling.

"We look forward to working with the FDA in its review process. If approved, we aim to bring Ryanodex to market for the treatment of heat stroke as early as this summer. This would be Eagle's most significant self-launched product to date. We are actively aligning resources to build commercial strength for our launch and driving awareness of EHS to support its successful commercialization," added David Pernock, President and Chief Commercial Officer of Eagle Pharmaceuticals.

The NDA is seeking approval of Ryanodex for the treatment of patients with exertional heat stroke, which is one of the most severe forms of heat stroke. Eagle's Ryanodex for the treatment of exertional heat stroke has previously been granted Orphan Drug designation by the FDA, and therefore may be eligible for seven years of exclusivity upon approval. Ryanodex is protected by two filed and five issued patents. Ryanodex for the treatment of EHS has also been granted Fast Track designation.

The NDA is supported by data from animal work completed in December 2016 and a clinical trial in EHS patients completed following the Hajj pilgrimage in 2015. The studies supported the product's known and well-characterized safety profile and demonstrated that administration of Ryanodex in addition to body cooling showed substantial evidence of increased clinically meaningful effectiveness in treating patients with EHS, compared to body cooling alone.

"Our innovative formulation of dantrolene sodium has unique properties that may allow Eagle's low-volume high-concentration Ryanodex formulation, with its simple, rapid reconstitution and fast administration to be a potentially suitable therapy for the treatment of EHS in emergency settings," added Adrian Hepner, MD, PhD, Chief Medical Officer of Eagle Pharmaceuticals.

Information regarding Eagle's pivotal animal study can be found in Eagle's press release dated December 13, 2016. Additional information regarding Eagle's human clinical study and its outcomes can be found in Eagle's press release dated December 17, 2015.

About EHS

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.

Currently, there is no approved drug product for the treatment of EHS, one of the most severe form of heat-related illness, characterized by core body temperature of 104° F (40° C) or greater and significant neurological dysfunction. EHS 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 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 such as "will," "may,", "believe," "intends," "anticipate(s)," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: Eagle's ability to gain successful FDA approval of the Ryanodex for exertional heat stroke and the impact, if any of such approval; the timing and level of success of a future launch of Ryanodex for exertional heat stroke; difficulties

or delays in manufacturing; the availability and pricing of third party sourced products and materials; the strength of the patent portfolio protecting Ryanodex and the ability of Eagle to defend against third party attempts to design around or invalidate those patents; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; the commercial success of Eagle's commercial portfolio, including Ryanodex for exertional heat stroke once launched; the ability of Eagle to deliver sustained shareholder value over time; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the 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's management and/or board of directors will be effective in managing Eagle's business and future growth, as well as the 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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