Eagle Pharmaceuticals Announces Enrollment of Additional Exertional Heat Stroke Patients at the 2019 Hajj Pilgrimage

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WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. (“Eagle” or the “Company”) (Nasdaq: EGRX) today provided an update on the Company’s program for RYANODEX ® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke (“EHS”). Eagle is investigating RYANODEX for EHS in addition to current standard of care, which is comprised of body cooling and supportive measures. There is currently no approved drug product for the treatment of EHS.

Over the course of the development program, Eagle has met with the U.S. Food and Drug Administration (“FDA”) multiple times to determine an appropriate path forward for regulatory approval of RYANODEX since returning from the 2018 Hajj and to address the Complete Response Letter received from FDA in 2017.

As a result of this dialogue with FDA, Eagle conducted an additional controlled clinical study in EHS patients during the 2019 Hajj pilgrimage held from August 9-14 in Saudi Arabia. The Company enrolled 10 additional patients at the 2019 Hajj, bringing the total number of patients recruited in 2015, 2018 and 2019 to 41.

Eagle has submitted a plan to FDA that proposes reviewing the data collectively for all 41 patients. If FDA agrees with this plan, Eagle plans to resubmit the New Drug Application (“NDA”) for EHS.

The rare, sudden, and unpredictable nature of EHS presents significant difficulty and challenges in prospectively identifying patients for participation in a clinical study. The studies had similar designs, inclusion criteria, and efficacy endpoints, and were all conducted in the same “real-world” emergency setting.

“Eagle and FDA continue to discuss a path forward for support of the expanded indication of EHS. Once these discussions yield a definitive outcome, we will provide a further update,” stated Scott Tarriff, Chief Executive Officer.

The NDA filed for EHS has Orphan Drug, Priority Review and Fast-Track designations.

RYANODEX is protected by patents through 2025.

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 mostly 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 outdoor workers, firefighters, and military personnel. EHS is characterized by severe hyperthermia and neurological dysfunction, such as sudden changes in behavior, seizures or coma.

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 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 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 "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; FDA approval of the use of RYANODEX for the treatment of EHS; the timing and level of success of a future launch of RYANODEX for the treatment of EHS; the successful development and completion of additional clinical studies 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, if and when launched. 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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