



Eagle Pharmaceuticals Announces Positive Results of Pre-clinical Study Conducted to Evaluate Effects of RYANODEX in Acute Radiation Syndrome (ARS)

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--Eagle to explore ARS indication to treat individuals exposed to high doses of radiation such as nuclear power plant leakage or nuclear weapons; additional research ongoing to evaluate hematopoietic syndrome in certain cancer patients undergoing radiation therapy--

WOODCLIFF LAKE, N.J.--([BUSINESS WIRE](#))--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced positive results of a proof-of-concept (POC) study in a Total-Body Radiation Animal Model. The objective of the study was to evaluate the efficacy of intravenous administration of RYANODEX[®] to prevent or mitigate Acute Radiation Syndrome (ARS) in a total body irradiated C57BL/6 male mouse hematopoietic model.

Animals in each treatment group received a well-characterized, high-dose of radiation to their whole body and also received randomly-assigned RYANODEX in different treatment modalities. In this study, the RYANODEX treatment group had overall less mortality post-treatment than non-treated animals with ARS. Additional details will be provided when available.

Based on the study results to date, Eagle intends to further explore an investigational indication for RYANODEX for the treatment of hematopoietic syndrome in individuals exposed to high doses of radiation, such as nuclear power plant leakage or nuclear weapons. Due to its nature, this indication is likely to be developed under the U.S. Food and Drug Administration's "Animal Rule".

The Company plans to conduct further research for treatment of post-irradiation hematopoietic syndrome, which could include treating the hematological side effects in certain cancer patients undergoing radiation therapy.

"This initial data provides the basis for better characterization of the underlying mechanisms of ionizing-radiation bone marrow suppression and the radioprotective effects of RYANODEX," said Adrian Hepner MD, Chief Medical Officer of Eagle.

"We believe these study data support further investigation of RYANODEX as a therapy in patients with ARS exposed to high doses of radiation. We plan to focus additional research efforts in specific cancer populations undergoing radiation therapy, a significant area of unmet medical need and look forward to reporting our progress," said Scott Tarriff, Chief Executive Officer of Eagle.

About Acute Radiation Syndrome

Acute Radiation Syndrome (ARS), also known as radiation toxicity or radiation sickness, is an acute medical condition caused by irradiation of the whole body (or a significant portion of the body), by a high dose of penetrating radiation in a short period of time, generally minutes. The leading cause of ARS is depletion of pluripotent cells in specific tissues. ARS generally follows a predictable clinical course and is characterized by signs and symptoms that are manifestations of cellular deficiencies and the reactions of various tissues and organs to ionizing radiation. High-dose ionizing radiation exposures to the whole or substantial parts of the body often result in life-threatening injuries, primarily to those radiosensitive, self-renewing tissues, but most markedly to the hematopoietic systems. The survival rate of patients with the hematopoietic syndrome decreases with increasing radiation exposure. The primary cause of death is the destruction of the bone marrow, resulting in infection and hemorrhage.

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," 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: Eagle's ability to advance RYANODEX in the treatment of ARS; Eagle's plans to continue to evaluate the data with respect to RYANODEX in the treatment of ARS; and Eagle's plans to conduct further research with respect to RYANODEX in the treatment of ARS. 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 Company can successfully advance its product candidates, including RYANODEX; the risks inherent in the early stages of drug development and in conducting pre-clinical studies and clinical trials; the possibility that the study results with respect to RYANODEX in the treatment of ARS may be inaccurate or incomplete; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the U.S. Securities and Exchange Commission (SEC) on February 26, 2018 and its other 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.

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