Eagle Pharmaceuticals' Exclusive Licensor Granted U.S. Patent for Dantrolene in the Treatment of Heat Stroke

April 1, 2014

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. ("Eagle") (NASDAQ:EGRX) announced today that the United States Patent and Trademark Office has granted Patent No. 8,685,460 for the treatment of heat stroke with Eagle's dantrolene sodium for injectable suspension ("dantrolene"). The patent issued today expires in 2023. Eagle's dantrolene formulation for the treatment of Exertional Heat Stroke (EHS) was granted Orphan Drug designation by the Food and Drug Administration on September 25, 2012.

Eagle is currently developing dantrolene in this new EHS indication. The company filed an NDA in January 2014 for Ryanodex® (dantrolene sodium-for injectable suspension) in the treatment of Malignant Hyperthermia ("MH") which was granted a priority review and has a PDUFA date of July 22, 2014. Ryanodex for the treatment of MH has also received Orphan Drug designation.

EHS is one of the top three causes of sudden death among student athletes and is a leading cause of non-combat death within the U.S. Military. Currently, there are no FDA approved drugs for the treatment of EHS. The current standard of care in treating heat stroke patients is aggressive cooling e.g. through icing and intravenous hydration. It is estimated that there are 30,000 cases of heat stroke every year in the U.S. Scott Tarriff, Eagle's CEO, said, "This is the fourth patent issued to Eagle regarding Ryanodex. Eagle now has 11 patents owned, licensed or issued covering its pipeline and an additional 10 patents filed with the U.S. patent office."

About Exertional Heat Stroke

EHS is a state of extreme hyperthermia that occurs when heat generated by exercise in warm climates results in an elevated body temperature (above 104° F) due to failed thermoregulation that occurs when the body produces or absorbs more heat than it dissipates. Extreme temperature elevation and the resulting metabolic crisis can become a medical emergency that can result in disability or death.

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 "expect(s)," "feel(s)," "believe(s)," "will," "may," "intends," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the benefits of (dantrolene sodium)- for injectable suspension in critical care situations, including the reduction in time to treat patients, the reduction in drug volume, our ability to obtain regulatory approval for Ryanodex in MH, our ability to adequately enforce and protect our intellectual property and our ability to commercialize our product, if approved. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether and when, if at all, Ryanodex will receive final approval from FDA or equivalent foreign regulatory agencies and for which indications; the strength and enforceability of our intellectual property rights, whether Ryanodex will be successfully marketed if approved; competition from other pharmaceutical and biotechnology companies; the development of, and our ability to take advantage of, the market for our therapeutic products; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our Prospectus filed with the Securities and Exchange Commission on February 13, 2014, and our other periodic and interim reports filed from time to time with the 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.

ABOUT EAGLE

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)-(2) regulatory pathway. The company develops products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products.

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