



Eagle Pharmaceuticals Announces Positive Initial Results of Animal Study Exploring Use of Ryanodex in MDMA (Ecstasy) Induced Hyperthermia Conducted at the National Institutes of Health

October 31, 2016

-- Ryanodex-treated animals experienced a greater decrease in brain temperature from peak temperature values, compared to animals in the control group --

- Brain temperature in Ryanodex-treated animals returned to baseline --

Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX) ("Eagle" or the "Company") today announced initial results from the preclinical study conducted by Eagle at the National Institute on Drug Abuse ("NIDA")/National Institutes of Health ("NIH") exploring the use of Ryanodex® in the treatment of hyperthermia related to MDMA ("Ecstasy") intoxication. The study was conducted in the summer of 2016 utilizing a well-characterized animal model.

"The initial results of this study are very encouraging and consistent with the results of our clinical work with Ryanodex for the treatment of Exertional Heat Stroke. The current standard of care ("SOC") for drug-induced hyperthermia is limited to body cooling by physical methods and supportive measures such as intravenous fluids, respiratory support and cardiovascular monitoring. We believe that the use of Ryanodex in conjunction with the current standard of care, to reduce elevated body and brain temperature resulting from the use of MDMA, may offer an additional therapeutic benefit to patients, compared with SOC alone," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"These positive results bring us one step closer to addressing the serious, and often life threatening, consequences of body and brain hyperthermia associated with intoxication from illicit psychostimulant drugs," stated Adrian Hepner, Executive Vice President and Chief Medical Officer. "We anticipate meeting with the FDA in the near future to discuss the overall development program for Ryanodex for the treatment of drug-induced hyperthermia," he added.

Initial Study Results

Initial results show that Ryanodex-treated animals experienced a greater decrease in brain temperature, after reaching peak temperature values, compared to animals in the control group. Over time, mean brain temperature percent change from peak value was higher in the Ryanodex group.

Mean Brain Temperature Percent Decrease from Peak Values

Minutes Post-Dose	Ryanodex-Treated Animals n=5 ¹	Control-Treated Animals n=5 ¹
30	24%	16%
60	46%	33%
90	61%	42%
120	74%	48%

¹ Each animal was treated twice, and received either Ryanodex or control vehicle at each separate study period, acting as its own control.

In addition, brain temperature in Ryanodex-treated animals returned to the baseline value (recorded immediately prior to MDMA administration), at approximately 140 minutes post-treatment, while brain temperature in control-treated animals did not return to baseline values over the course of the experiment.

Study Design

The effect of Ryanodex on MDMA-induced hyperthermia was evaluated in a rodent animal model following a well-established protocol, where MDMA was administered to the experimental rat during social interaction with another rat. This condition mimics the human use of the drug, commonly used in dance clubs and rave parties, which result in potentiation of the hyperthermic effect of MDMA. Ryanodex or the control vehicle were administered when temperature showed a clear acceleration, approximately 90 minutes after administration of MDMA. A total of 5 rats were included in the experiment. Each experimental animal received MDMA twice, and received either Ryanodex or the control vehicle after the first or second MDMA administration, allowing for comparison of data obtained from the same animals treated with Ryanodex and the control treatment.

Brain Hyperthermia

Body and brain hyperthermia are one of the leading causes of severe morbidity and death in MDMA (Ecstasy) and Methamphetamine intoxication. In 2011, the last year for which data is available, 125,000 emergency room visits were related to Ecstasy and Methamphetamine use. Methamphetamines are the fourth most reported illicit drug in emergency room visits following cocaine, marijuana, and heroin. And, according to the Drug Abuse Warning Network ("DAWN"), the number of emergency room visits involving Ecstasy among patients younger than 21 increased 128 percent between 2005 and 2011.

MDMA (Ecstasy)

3,4-methylenedioxy-methamphetamine (MDMA), commonly known as "Ecstasy" or "Molly", is an illicit, synthetic drug that alters a user's mood and perception. MDMA increases the activity of three brain chemicals: dopamine, norepinephrine and serotonin. It is chemically similar to both stimulants and hallucinogens, producing feelings of increased energy, pleasure, emotional warmth, and distorted sensory and time perception. MDMA can also affect the body's ability to regulate temperature, leading to a spike in brain and overall body temperature that can result in organ damage, permanent

disability and even death.

MDMA is a Schedule I drug under the Controlled Substances Act. Schedule I drugs have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

About NIDA

The National Institute on Drug Abuse (“NIDA”) at the National Institutes of Health (NIH) supports most of the world’s research on drug abuse and addiction. Its mission is to advance science on the causes and consequences of drug use and addiction and to apply that knowledge to improve individual and public health. Additional information can be found at www.drugabuse.gov.

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,” “intends,” “anticipate(s),” “plan,” “enables,” “potentially,” “entitles,” 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: timing of clinical studies and preclinical studies; results of clinical studies and preclinical studies; the utility of Ryanodex® in the treatment of hyperthermia related to MDMA (“Ecstasy”) Methamphetamine intoxication or exertional heat stroke (EHS), the likelihood of obtaining FDA approved indications for the use of Ryanodex® in the treatment of hyperthermia related to MDMA (“Ecstasy”) Methamphetamine intoxication or exertional heat stroke (EHS); difficulties or delays in manufacturing; the enforceability or defense of intellectual property rights by or against third parties; the availability and pricing of third party sourced products and materials, and products licensed to third-parties for promotion and distribution; the establishment of a commercial market for Ryanodex® for hyperthermia related to MDMA or Methamphetamine intoxication or for EHS; 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 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 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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