



Eagle Pharmaceuticals Granted Orphan Drug Designation for RYANODEX (dantrolene sodium) for Treatment of Organophosphate Exposure (Nerve Agents)

December 16, 2019

WOODCLIFF LAKE, N.J.--([BUSINESS WIRE](#))--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Food and Drug Administration ("FDA") has granted orphan drug designation (ODD) for RYANODEX[®] (dantrolene sodium) for the treatment of organophosphate exposure.

Organophosphates are a class of chemicals that include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophosphates may result in severe consequences, including brain damage and death. About 2,700 people in the United States are treated for accidental exposure to organophosphate pesticides every year. Additionally nerve agents are inexpensive and relatively easy to produce, even by small terrorist groups, and can be used to create mass casualties with small quantities.

Eagle is currently evaluating RYANODEX for the treatment of brain damage secondary to nerve agent exposure. If approved, RYANODEX would represent the first product available for this indication.

"We are delighted to have received orphan drug designation as we advance RYANODEX to treat brain damage secondary to nerve agent exposure and protect our military personnel and civilians in the event of a nerve agent attack," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

The mission of the FDA's Office of Orphan Products Development (OOPD) is to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000 people in the U.S. In fulfilling that task, the OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products. Orphan drug designation provides incentives for sponsors to develop products for rare diseases. These incentives may include a partial tax credit for certain clinical trial expenditures, the waiver of certain FDA user fees, and potential eligibility for seven years of orphan drug marketing exclusivity, if approved.

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty pharmaceutical company focused on developing and commercializing innovative and differentiated injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. 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 brain damage secondary to nerve agent exposure; expected FDA approval of the use of RYANODEX for the treatment of brain damage secondary to nerve agent exposure; the timing and level of success of a future launch of RYANODEX for the treatment of brain damage secondary to nerve agent exposure; 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. 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. 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.

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

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