Eagle Pharmaceuticals Receives Complete Response Letter from FDA on KANGIO (RTU bivalirudin) Application

March 18, 2016

Eagle Pharmaceuticals, Inc. (NASDAQ: EGRX) (“Eagle” or the “Company”) today announced that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its KANGIO™ (bivalirudin injection), 505(b)(2) New Drug Application for a ready-to-use (“RTU”), stable liquid intravenous formulation of 5 mg/mL bivalirudin in a 50-mL vial intended for use as an anticoagulant in patients: (1) undergoing percutaneous coronary intervention (“PCI”) with use of glycoprotein IIb/IIIa inhibitor, (2) undergoing PCI with, or at risk of, heparin-induced thrombocytopenia (“HIT”) and thrombosis syndrome (“HITTS”), and/or (3) with unstable angina undergoing percutaneous transluminal coronary angioplasty (“PTCA”).

The FDA issues Complete Response Letters to communicate that their initial review of an application is complete; however, they cannot approve the application in its present form and request additional information. In its letter to Eagle, the FDA requested further characterization of bivalirudin-related substances in the drug product. Eagle will work directly with the FDA to determine an appropriate path forward to address the comments.

“We are evaluating the FDA’s response and will work closely with the agency to better understand and address their comments regarding Kangio,” said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. “We remain committed to Kangio as an important new formulation of bivalirudin for intravenous use, offering multiple benefits for patients and care givers,” concluded Tarriff.

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: our response to the FDA’s Complete Response Letter on Kangio; any future approval of Kangio by the FDA; any future commercial market acceptance of Kangio; difficulties or delays in manufacturing; the enforceability or defense of intellectual property rights by or against third parties; the outcome of clinical studies; the availability and pricing of third party sourced products and materials, and products licensed to third-parties for promotion and distribution; 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, whether Eagle will adequately evaluate and respond to the FDA’s Complete Response Letter on Kangio; whether the FDA will ultimately approve Kangio; whether the market will accept Kangio, if approved; and other 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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