Eagle Pharmaceuticals' RTU Bivalirudin NDA Accepted for Filing

July 23, 2015

WOODCLIFF LAKE, N.J., Jul 23, 2015 (BUSINESS WIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) today announced that the 505(b)(2) New Drug Application (NDA) for its novel ready-to-use bivalirudin product ("RTU bivalirudin") has been accepted for filing by the U.S. Food and Drug Administration (FDA).

This 505(b)(2) NDA requests FDA approval of Eagle's RTU bivalirudin product for the treatment of 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 and thrombosis syndrome, or (3) with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA).

"We look forward to the FDA's decision on this NDA in March 2016 and, if approved, intend to launch our RTU bivalirudin product the following day," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "We expect our RTU liquid formulation will be well received due to its multiple differentiating features. We look forward to continuing to work closely with the FDA through the review process.

Eagle's RTU bivalirudin product, which contains the same active ingredient as Angiomax, is administered as an IV solution at the same dose and rate. Eagle's liquid formulation will allow for immediate administration, with no reconstitution nor initial dilution required, reducing work flow and the risk of dosing errors.

Eagle's intellectual property pertaining to RTU bivalirudin includes two issued patents and an additional patent pending at the U.S. Patent and Trademark Office.

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.

Angiomax® is a registered trademark of The Medicines Company.

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: success in gaining timely FDA approval of the RTU bivalirudin product for the treatment of 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 and thrombosis syndrome, or (3) with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA); the timing and level of success of a future launch of the RTU bivalirudin product; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; 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 September 30, 2014, 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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SOURCE: Eagle Pharmaceuticals, Inc.