Eagle Pharmaceuticals Submits NDA for Ready-to-Use Bivalirudin to FDA

May 20, 2015

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) has submitted a 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its novel ready-to-use bivalirudin product ("RTU bivalirudin").

This product is a stable liquid intravenous formulation of bivalirudin, the same active ingredient as in The Medicine Company's Angiomax ® (bivalirudin). U.S. sales of Angiomax were approximately $600M for the twelve months ended December 31, 2014.

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, and/or (3) with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA). RTU bivalirudin is intended for use with aspirin.

"Our RTU bivalirudin product contains the same active ingredient and is dosed as an IV solution at the same dose and rate as Angiomax," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "Furthermore, our liquid formulation will allow for immediate administration, with no reconstitution nor initial dilution required, reducing work flow and the risk of dosing errors. We believe these attributes of our formulation can be clinically significant in critical care situations. We look forward to continuing to work closely with the FDA through the review process."

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: acceptance for filing by the FDA of the NDA for 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, and/or (3) with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA); success in gaining timely FDA approval of the RTU bivalirudin product for the treatment of these patients; 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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