



New Patent Issued for Eagle Pharmaceuticals' Bendamustine Rapid Infusion Product

May 19, 2015

Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX) ("Eagle" or the "Company") today announced that the United States Patent and Trademark Office ("USPTO") has granted U.S. Patent No. 9,034,908, which pertains to the use of the bendamustine hydrochloride (HCl) formulation administered in a 50mL bag within ten minutes (the "rapid infusion" product). The patent issued today expires in March 2033.

The U.S. Food and Drug Administration ("FDA") recently accepted for filing Eagle's New Drug Application (NDA) for the rapid infusion bendamustine product. This NDA requests FDA approval of the rapid infusion bendamustine HCl product for the treatment of patients with chronic lymphocytic leukemia (CLL) and patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. The Prescription Drug User Fee Act (PDUFA) goal date for a decision on this NDA by the FDA is December 13, 2015.

"Today's patent issuance further strengthens our intellectual property for our rapid infusion bendamustine product, and we anticipate additional patent issuances going forward," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "We look forward to the PDUFA date for the rapid infusion bendamustine product in December, and if approved we believe the additional milestone and royalty payments will expedite our ability to deliver long term, sustainable growth."

This product candidate has received Orphan Drug Designations for both CLL and indolent B-cell NHL, and therefore may be eligible for seven years of exclusivity upon approval.

The NDA for Eagle's rapid infusion bendamustine product is supported by [data from clinical trials](#) completed in November 2014, which demonstrated that the rapid infusion bendamustine HCl product can be administered in ten minutes in a low-volume, 50 mL admixture.

In February 2015, Eagle and Teva Pharmaceutical Industries Ltd. entered into an exclusive license agreement for the rapid infusion bendamustine product. Teva will be responsible for all U.S. commercial activities for the product including promotion and distribution. Eagle has responsibility for obtaining all regulatory approvals, conducting post-approval clinical studies, if required, and initially supplying drug product to Teva.

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: the anticipated issuance by the USPTO of additional patents related to Eagle's products in 2015; success in gaining timely FDA approval of the rapid infusion bendamustine product for the treatment of patients with CLL and patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen; the timing and level of success of a future launch of the rapid infusion bendamustine product by Teva; the success of Eagle's commercial arrangement with Teva and the parties' ability to work effectively together; 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: the timing of issuance by the USPTO of additional patents to Eagle related to its products, if at all; whether the FDA will ultimately approve Eagle's NDA for the rapid infusion bendamustine product for the treatment of patients with CLL and patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen; whether Teva will be successful at commercializing the rapid infusion bendamustine product; whether Eagle and Teva will successfully perform each of their respective obligations under the exclusive license agreement; 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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