



Teva and Eagle Pharmaceuticals Announce NDA for Bendamustine Rapid Infusion Product Accepted for Filing

April 14, 2015

Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) and Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX) today announce that the New Drug Application (NDA) for a liquid bendamustine hydrochloride (HCl) rapid infusion product has been accepted for filing by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date for a decision on this NDA by the FDA is December 2015.

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. 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 is supported by data from a clinical trial 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.

"The rapid infusion bendamustine product, if approved, will be an important new treatment option for patients with CLL or indolent B-cell NHL that has progressed and their healthcare providers," said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "We look forward to continuing to work closely with the FDA through the review process, and to their decision on the NDA in December of this year."

"We are very pleased the FDA has accepted the rapid infusion bendamustine NDA for review," stated Paul Rittman, Vice President and General Manager, Teva Oncology. "Teva looks forward to the opportunity to bring this product to market, if approved, and we believe it represents an important and improved benefit to both patients and healthcare providers."

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 Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions to millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,000 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2014 amounted to \$20.3 billion. For more information, visit www.tevapharm.com.

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. Eagle currently markets RYANODEX[®] (dantrolene sodium) in the U.S. for the treatment of malignant hyperthermia. Additional information is available on the company's website at www.eagleus.com.

RYANODEX[®] is a registered trademark of Eagle Pharmaceuticals, Inc.

Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products; competition for our innovative products, especially Copaxone[®] (including competition from orally-administered alternatives, as well as from potential purported generic equivalents) and our ability to migrate users to our 40 mg/mL version; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance;

any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2014 and in our other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Eagle's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

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 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: 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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