



Eagle Pharmaceuticals Reports Positive Outcomes from Clinical Trial of Bendamustine HCl Product Delivered via Low-Volume, Rapidly Infused Admixture

November 10, 2014

Data indicate that Eagle's Bendamustine HCl Product, Rapidly Infused in a Low Volume Admixture, is Bioequivalent to Teva's In-Market Branded Product (Treanda®)

Safety Profile of Eagle's Product is Comparable to Treanda

USPTO has Allowed Eagle's Product Patent for Low-Volume, Short Infusion Time Administration

Eagle Pharmaceuticals, Inc. (NASDAQ:EGRX) ("Eagle" or the "Company") today announced positive results from a recently-conducted clinical trial of its bendamustine hydrochloride ("HCl") product, in which the dose was delivered in a 50mL admixture in ten minutes (the "rapidly infused product") versus a 500mL admixture in the 60-minute infusion required for Treanda® (bendamustine HCl).

In this study, Eagle's rapidly infused product was found to be bioequivalent to Treanda, which was the primary endpoint of the study. The incidence and profile of adverse events, both infusion-related and general, for the rapidly infused product was comparable to Treanda. This is particularly important because the rapidly infused product delivers the same amount of active ingredient as Treanda but with a lower admixture volume, which enables the Eagle product to be administered more quickly.

Eagle received tentative approval for this formulation in July 2014. The positive data supports that the product can be delivered in this new low-volume infusion.

Eagle received orphan drug designation for its rapidly infused product for chronic lymphocytic leukemia ("CLL") and indolent B-cell non-Hodgkin's lymphoma ("NHL") on July 2, 2014.

"We are very excited about these results, and intend to file these data with the FDA as soon as possible," said Scott Tarriff, President and Chief Executive Officer. "We look forward to our pre-NDA meeting with the FDA in mid-December.

"We believe the shorter infusion time afforded by the 50mL admixture will greatly benefit cancer patients and healthcare providers alike, and our goal is to bring our rapidly infused product to market as soon as possible," Tarriff concluded.

This open-label, randomized, crossover, Phase I clinical trial was designed to compare bioequivalence of Eagle's rapidly infused product and Treanda, and to assess the safety and tolerability of the rapidly infused product. The study evaluated 81 patients with a histologically-confirmed diagnosis of solid tumors and hematologic malignancies for which no curative or standard therapy is appropriate.

The treatment phase, pharmacokinetic assessments, infusion-related safety assessments and bioequivalence evaluation are complete in all 81 patients. The overall safety assessment is complete in over 80% of subjects and will conclude on November 17th.

On September 16, 2014, Cephalon, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., filed a motion to dismiss all claims against Eagle concerning alleged infringement of U.S. Patent No. 8,445,524. Cephalon recently filed a second lawsuit in the District of Delaware alleging that Eagle's bendamustine product infringes Cephalon's newly-issued U.S. Patent No. 8,791,270. That case remains pending.

Eagle also confirmed that the U.S. Patent and Trademark Office ("USPTO") has allowed a patent covering administration of its bendamustine HCl product candidate in a low volume admixture with a shorter infusion time. This is the second patent allowed for this product. Eagle continues to execute its strategy to further strengthen its intellectual property surrounding this and its other products and product candidates.

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. The Company'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.

Treanda® is a registered trademark of Cephalon, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

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 "expect(s)," "feel(s)," "believe(s)," "will," "may," "intends," "anticipate(s)," "look forward," "upcoming," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the timing of future events related to the ongoing development and potential benefits of the bendamustine HCl low-volume, shorter infusion time product candidate. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether the FDA will allow our NDA for approval of our bendamustine product and when such approval might be granted; our ability to successfully complete the overall safety assessment for the bendamustine HCl rapidly infused product candidate on time, if at all, and whether the results of the safety assessment will establish the safety of the product or demonstrate an adverse safety profile; the strength and enforceability of our intellectual property rights; the outcome of pending litigation; and the other risk factors contained in our Prospectus filed with the Securities and Exchange Commission on February 13, 2014, and our other periodic and interim reports filed from time to time with the 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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