



## **Eagle Pharmaceuticals Receives Orphan Drug Designation for Lower Volume, Shorter Infusion Time Bendamustine Hydrochloride Product for Chronic Lymphocytic Leukemia and Indolent B-Cell Non-Hodgkin's Lymphoma**

July 8, 2014

Eagle Pharmaceuticals Inc. (Nasdaq:EGRX) ("Eagle" or "the Company") announced today that the United States Food and Drug Administration ("FDA") has granted orphan drug designation to bendamustine hydrochloride ("HCl"), a ready-to-dilute concentrate solution for injection that will be administered by infusion over 10 minutes after dilution in 50mL of sodium chloride ("saline") or a saline / dextrose mixture, for the treatment of chronic lymphocytic leukemia ("CLL") and indolent B-cell non-Hodgkin's lymphoma ("NHL").

Pursuant to the orphan drug designation, Eagle is eligible to receive tax incentives and Prescription Drug User Fee Act ("PDUFA") fee savings, and believes it may receive seven years of marketing exclusivity.

"We are pleased to have received orphan drug designation from the FDA as we advance the development pathway of bendamustine hydrochloride. We received tentative approval for our bendamustine hydrochloride ready-to-dilute (500mL) product on July 2<sup>nd</sup>, 2014. We believe the shorter infusion time afforded by this 50mL product will greatly benefit patients and healthcare providers alike in the treatment of CLL and NHL," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals Inc. "In the interim, we continue to advance the clinical trial for this low-volume, short infusion time bendamustine product."

The currently marketed bendamustine HCl product, Treanda, which is manufactured by Cephalon, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., is a lyophilized powder requiring reconstitution and dilution in 500mL of saline or a sodium chloride / dextrose mixture before administration over 30 minutes for CLL and 60 minutes for NHL.

Eagle is currently engaged in litigation defending a patent claim filed by Teva Pharmaceuticals in connection with our tentatively approved New Drug Application. The U.S. Patent and Trademark Office has issued patent 8,609,707 for Eagle's unique formulation of Bendamustine Hydrochloride Injection.

### **About Eagle**

Eagle Pharmaceuticals Inc. is a specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)(2) regulatory pathway. The Company develops products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. For further information: <http://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 "expect(s)," "feel(s)," "believe(s)," "will," "may," "intends," "anticipate(s)," "look forward," "upcoming," "plan" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to receive seven years of marketing exclusivity, tax incentives and PDUFA fee savings, the benefits of the 50mL bendamustine HCl infusion in the treatment of CLL and NHL, including the reduction in time to treat patients, our ability to obtain regulatory approval for bendamustine hydrochloride infusion in the treatment of CLL and NHL, the outcome of litigation filed by Teva regarding our NDA for bendamustine HCl, our ability to adequately enforce and protect our intellectual property and our ability to commercialize our product, if approved. 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 and when, if at all, we are able to receive seven years of marketing exclusivity, tax incentives and PDUFA fee savings; whether and when, if at all, bendamustine HCl infusion will receive final approval from FDA or equivalent foreign regulatory agencies and for which indications; the strength and enforceability of our intellectual property rights, whether bendamustine HCl infusion will be successfully marketed if approved; competition from other pharmaceutical and biotechnology companies; the development of, and our ability to take advantage of, the market for our therapeutic products; general economic conditions; 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.

Eagle Pharmaceuticals, Inc.  
David E. Riggs, 201-326 5300  
Chief Financial Officer  
E: [driggs@eagleus.com](mailto:driggs@eagleus.com)