Eagle Pharmaceuticals Receives Tentative Approval for Patented, Ready-to-Dilute Bendamustine Hydrochloride Injection NDA

July 3, 2014

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) (“Eagle” or “the Company”) announced today that the United States Food and Drug Administration (“FDA”) has granted tentative approval to the Company’s New Drug Application (NDA) for patented Bendamustine Hydrochloride Injection, a ready-to-dilute concentrate solution (“bendamustine RTD”) for the treatment of Indolent B-cell non-Hodgkin lymphoma (NHL).

"Tentative approval" means that FDA has concluded that a drug product has met all required quality, safety and efficacy standards, but is not eligible for marketing in the U.S. because of existing patent protections or exclusivities. The tentative approval will convert to a final approval subject to the resolution of the current patent litigation on-going between Eagle and Teva Pharmaceutical Industries Ltd. (“Teva”), and the resolution or expiry of certain Orphan Drug exclusivities held by Teva.

“We are pleased to have achieved this critical milestone for our improved bendamustine RTD formulation, which we believe will benefit patients and healthcare providers alike,” stated Scott Tarriff, President and Chief Executive Officer. “In the interim, we continue to advance our clinical trial of our low-volume, short infusion time bendamustine product, which reduces the diluent volume from 500mL to 50mL and the infusion time to just ten minutes.”

The currently marketed bendamustine HCl product is a lyophilized powder requiring reconstitution and dilution in 500mL of saline or a sodium chloride / dextrose mixture before administration over 30 minutes for chronic lymphocytic leukemia and 60 minutes for NHL.

Eagle is currently engaged in litigation defending a patent claim filed by Teva regarding our tentatively approved NDA. 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 obtain final regulatory approval for bendamustine HCl infusion in the treatment of NHL and CLL, the outcome of litigation filed by Teva regarding our NDA for bendamustine HCl, the benefits of the 50mL bendamustine hydrochloride infusion in the treatment of NHL and CLL, including the reduction in time to treat patients, 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, bendamustine hydrochloride infusion will receive approval from FDA or equivalent foreign regulatory agencies and for which indications; the outcome of the litigation with Teva, 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.

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