



Eagle Pharmaceuticals, Inc. Granted Final FDA Approval for Bendamustine Hydrochloride Ready-to-Dilute Solution in a 500ml Admixture

May 16, 2018

-- Eagle to ship 500ml admixture product immediately --

Eagle Pharmaceuticals, Inc. ("Eagle" or "the Company") (Nasdaq:EGRX) today announced that the U.S. Food and Drug Administration (FDA) has granted final approval for Eagle's ready-to-dilute (RTD) bendamustine hydrochloride (HCl) solution in a 500ml admixture 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. Eagle's bendamustine HCl injection does not require reconstitution and is administered as a 500ml admixture over 30 or 60 minutes.

"This approval expands our bendamustine product offering, is complementary to BENDEKA[®], and enables us to provide value to a cost-conscious segment of the market that we are uniquely positioned to fill. We intend to launch our ready-to-dilute product with our internal sales force. Based upon our view of the market, we anticipate over time achieving up to a 12% market share, increasing our overall profitability," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

Eagle has 13 U.S. patents covering different bendamustine formulations and methods.

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 and phrases such as "anticipated," "forward," "will," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "anticipate," "intend" 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 Company's ability to successfully ship, market, and sell its bendamustine HCl 500ml solution; the Company's forecasted market penetration for Eagle's bendamustine HCl 500ml solution; and the Company's ability to continue to deliver value over the long term. 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 Company will incur unforeseen expenses or liabilities or other market factors; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of our products or that may have an impact on any of our products, successful compliance with FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions; the strength and enforceability of our intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the timing of product launches; the successful marketing of our products; the risks inherent in the early stages of drug development and in conducting clinical trials; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the U.S. Securities and Exchange Commission (SEC) on February 26, 2018 and its other filings with the SEC. 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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