FDA Grants Eagle Seven Year Orphan Drug Exclusivity for BENDEKA (bendamustine hydrochloride injection)

July 9, 2018

Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) announced today that the U.S. Food and Drug Administration (FDA) has granted seven years of orphan drug exclusivity (ODE) in the U.S., for BENDEKA™ (bendamustine hydrochloride injection, or bendamustine HCI), a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride.

As a result, and consistent with the order issued by the U.S. District Court for the District of Columbia (the Court) on June 8, 2018, the FDA will not approve any drug applications referencing BENDEKA until the ODE expires in December 2022. Additionally, on July 7, 2018, the FDA filed a motion with the Court asking it to clarify that the order was not intended to affect applications referencing TREANDA®. Eagle continues to believe that an appropriate application of ODE would first allow generic TREANDA entrants in December 2022, rather than November 2019, and expects to vigorously defend the scope of its exclusivity grant.

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.

Eagle’s 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 “likely,” “will,” “may,” “can,” “could be,” “believe,” “intends,” “anticipate(s),” “plan,” “enables,” “potentially,” “entitles,” and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: the FDA’s ability to approve any drug applications referencing BENDEKA prior to December 2022; the Court’s response to the FDA’s motion; the ability of generic TREANDA products to enter the market prior to 2022; Eagle’s market protection for BENDEKA; successful compliance with FDA and other governmental regulations; and other factors that are discussed in Eagle’s Annual Report on Form 10-K for the year ended December 31, 2017, 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 Eagle’s management and/or board of directors will be effective in managing Eagle’s business, future growth and market protection, including with respect to BENDEKA; the Court’s response to the FDA’s motion; whether Eagle will maintain successful compliance with FDA and other governmental regulations; as well as the 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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