Court Issues Decision in Favor of Eagle Pharmaceuticals Granting Seven Year Orphan Drug Exclusivity for BENDEKA (bendamustine hydrochloride injection)

June 11, 2018

--Generic TREANDA entry now not expected until December 2022--

-- Further Protects Longevity of BENDEKA franchise --

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) ("Eagle" or the "Company") announced today that the U.S. District Court for the District of Columbia (the Court) has issued a decision requiring the FDA to grant seven years of orphan drug exclusivity (ODE) in the U.S., for BENDEKA™ (bendamustine hydrochloride injection, or bendamustine HCl), a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride.

As a result of the Court's decision, the FDA will not be able to approve any drug applications referencing BENDEKA until the ODE expires in December 2022. Moreover, the Company now does not expect generic TREANDA ® entrants into the market until 2022, rather than November 2019.

"We are delighted with the court's decision to grant orphan drug exclusivity for BENDEKA, further extending the longevity of this important product," said Scott Tarriff, Chief Executive Officer. "With thirteen Orange Book listed patents extending from 2026 through 2033, and additional pending patent applications, the market protection for BENDEKA is likely to be intact for many years. We also believe it will provide for continued profitability and building long-term value for Eagle," concluded Tariff.

Orphan drug exclusivity is granted by the FDA Office of Orphan Products Development to drugs or biologics that treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. The designation typically provides the drug developer with a seven-year period of U.S. marketing exclusivity upon approval, bars FDA from approving any other application (ANDA, 505(b)(2) or "full" NDA or BLA) for the same drug for the same orphan disease, and offers certain financial incentives that can help support its development.

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 ability of generic TREANDA products to enter the market prior to 2022; Eagle's market protection for BENDEKA; the commercial success of Eagle's commercial portfolio, including BENDEKA; successful compliance with FDA and other governmental regulations; the ability of Eagle to deliver sustained shareholder value over time; 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; whether the FDA will comply with the Court's decision; 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.

Investor Relations for Eagle Pharmaceuticals, Inc:
Lisa M. Wilson, 212-452-2793
President
lwilson@insitecony.com