Eagle Pharmaceuticals Receives Tentative FDA Approval for PEMFEXY (Pemetrexed Injection) Ready-to-Dilute

October 27, 2017

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) ("Eagle" or "the Company") today announced that the United States Food and Drug Administration ("FDA") has granted tentative approval for the Company's PEMFEXY™, a pemetrexed injection ready-to-dilute formulation for locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin; locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, as maintenance treatment; locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy as a single agent; and malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin.

"We are pleased to have received this tentative approval for PEMFEXY, which we believe offers a material benefit to healthcare providers. PEMFEXY fits well within our growing portfolio of oncology drugs, including BENDEKA®, bendamustine hydrochloride ready-to-dilute and rapid infusion, DOCETAXEL INJECTION, and fulvestrant, which is in development. We will work toward bringing this much needed drug to market as soon as the patent issues are resolved," stated Scott Tarriff, Chief Executive Officer.

"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. The tentative approval will be eligible for conversion to a final approval subject to the resolution of the current patent litigation between Eagle and Eli Lilly and Co.

"Our formulation does not require reconstitution, reducing the potential for dosing errors during mixing as well as the hazards of inhaling cytotoxic vapors that can occur when handling the powder form of the drug during preparation. We believe there is a need in the market for our improved formulation," concluded Tarriff.

Eagle submitted, and the FDA accepted for filing, its NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") for PEMFEXY ready-to-dilute in December 2016.

This NDA references ALIMTA®, the branded product manufactured by Eli Lilly and Co., which had annual U.S. sales of approximately $1.0 billion over the last twelve months.

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 such as "will," "may," "intends," "anticipate(s)," "plan," "enables," "potentially," "forecasted", "entitles," 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 conversion of Eagle's PEMFEXY NDA from a tentative approval to a final approval; the successful resolution of the existing patent litigation regarding Eagle's PEMFEXY product; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year December 2016, 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: the ability of Eagle to manufacture and commercialize its PEMFEXY product upon final approval; the formation of a market for Eagle's PEMFEXY product; and 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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