



Eagle Pharmaceuticals' Pemetrexed NDA Accepted for Filing by the FDA

February 28, 2017

Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or "the Company") today announced that the 505(b)(2) New Drug Application (NDA) for its novel Pemetrexed Injection, 25 mg/mL has been accepted for filing by the U.S. Food and Drug Administration (FDA). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of October 30, 2017 to complete its review of the NDA.

This 505(b)(2) NDA requests FDA approval of Eagle's ready-to-dilute (RTD) Pemetrexed Injection 25 mg/mL product for the treatment of Locally Advanced or Metastatic Nonsquamous Non-Small Cell Lung Cancer, and Mesothelioma (in combination with cisplatin).

"We are pleased that our Pemetrexed Injection NDA has been accepted for filing with the FDA. We look forward to the FDA's decision in October 2017, and intend to work closely with the FDA through the review process," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

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," "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 impact, if any, of Eagle's success in gaining timely FDA approval of the RTU pemetrexed product; the timing and level of success of a future launch of the RTU pemetrexed product; the effectiveness of Eagle's IP in differentiating its RTU pemetrexed product from other pemetrexed products' IP; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; the commercial success of Eagle's commercial portfolio, including RTU pemetrexed once launched; 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, 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 whether Eagle's management and/or board of directors will be effective in managing Eagle's business and future growth, 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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