



Eagle Pharmaceuticals Receives Final FDA Approval for PEMFEXY™ (Pemetrexed for Injection)

February 10, 2020

-- Eagle has exclusive rights to commercialize product for four months beginning February 1, 2022 --

WOODCLIFF LAKE, N.J.--([BUSINESS WIRE](#))--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has received final approval from the U.S. Food and Drug Administration ("FDA") for its novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

"We are pleased to receive final approval from FDA and look forward to making PEMFEXY available to the patients who can benefit. Our initial market exclusivity for PEMFEXY represents a significant opportunity for Eagle and builds on the successes of our expanding presence in the oncology space," stated Scott Tarriff, Chief Executive Officer.

The conversion from tentative to a final approval follows the Company's settlement agreement reached with Eli Lilly and Company (NYSE: LLY) ("Lilly") on December 13, 2019. This agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXY into the market (equivalent to approximately a three-week supply of current ALIMTA utilization) on February 1, 2022, and a subsequent uncapped entry on April 1, 2022.

The Company received tentative approval for PEMFEXY in 2017, reflecting FDA's conclusion that the product met all required quality, safety and efficacy standards, but at the time was not eligible for marketing in the U.S. because of existing patent protections.

About PEMFEXY

PEMFEXY™ is 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.

About Eagle Pharmaceuticals, Inc.

Eagle is a pharmaceutical company focused on developing and commercializing innovative and differentiated injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. 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," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: the outcome of the review by the U.S. Department of Justice and the Federal Trade Commission of the settlement agreement; the timing of Eagle's PEMFEXY launch, if ever; the success, if any, of Eagle's marketing and sales efforts regarding PEMFEXY; and Eagle's ability to continue to expand in the oncology space. 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. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does 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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