Eagle Pharmaceuticals Receives FDA Approval for Additional Indication for PEMFEXY® in Combination with Pembrolizumab and Platinum Chemotherapy

December 19, 2022

-- Additional indication is for the initial treatment of patients with metastatic, non-squamous, non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations --

-- Represents the fifth indication for PEMFEXY, a ready-to-use liquid with a unique J-code approved to treat non-squamous non-small cell lung cancer and mesothelioma --

WOODCLIFF LAKE, N.J., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") announced today that the U.S. Food and Drug Administration ("FDA") has approved an additional indication for PEMFEXY® (pemetrexed injection) in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic, non-squamous, non-small cell lung cancer ("NSCLC") with no EGFR or ALK genomic tumor aberrations. Eagle's approved PEMFEXY (pemetrexed injection) is a ready-to-dilute ("RTD") novel liquid intravenous formulation developed to eliminate the reconstitution step of the Listed Drug ("LD"), ALIMTA®.

"With this fifth indication, PEMFEXY is now approved for all of the same indications as ALIMTA, and we believe it allows for key advantages such as eliminating the need for reconstitution. Since its initial launch in February 2022, PEMFEXY has been an important addition to Eagle's hospital and acute care product portfolio, and we are pleased to bring this treatment option to patients undergoing chemotherapy. At the same time, we also believe that Eagle is well positioned to capture the commercial opportunity that PEMFEXY represents," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

Effective October 1, 2022, the Company amended its agreement to reduce future royalties related to PEMFEXY profits from 25% to a range of 0% to 12.5% based on aggregate profits achieved in exchange for a one-time payment of $15 million.

In February 2020, Eagle received approval from the FDA of its New Drug Application for PEMFEXY, following the settlement agreement of patent litigation with Eli Lilly and Company (NYSE: LLY) in December 2019. The agreement provided for a release of all claims by the parties and allowed 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.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include vasopressin, PEMFEXY®, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM® (Japan), and BYFAVO® and BARHEMSYS® through its wholly owned subsidiary Acacia Pharma Inc. Eagle's oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. 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," "future," "belief," "guidance," "opportunity," "advantages," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, the commercial potential of PEMFEXY and Eagle's ability to capture its commercial opportunity; future profits and royalties related to PEMFEXY sales; and the potential of Eagle's products candidates to address underserved therapeutic areas across multiple disease states. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company'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 and uncertainties include, but are not limited to: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; whether the Company will incur unforeseen expenses or liabilities or other market factors; delay in or failure to obtain regulatory approval of the Company's product candidates and successful compliance with FDA, European Medicines Agency and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates, including its fulvestrant product; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the outcome of litigation involving any of its products or that may have an impact on any of its products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in drug development and in conducting clinical trials; and those risks and uncertainties identified in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 8, 2022, the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022, June 30, 2022 and September 30, 2022, filed with the SEC on May 9, 2022, August 9, 2022, and November 9, 2022, filed with the SEC on August 9, 2022, and its other subsequent filings with the SEC. Readers are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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