Eagle Pharmaceuticals Granted Patent for PEMFEXY®

October 24, 2023

WOODCLIFF LAKE, N.J., Oct. 24, 2023 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the U.S. Patent and Trademark Office has granted the Company U.S. Patent No. 11,793,813 ("the '813 patent") entitled "Pemetrexed Formulations." Eagle has submitted the patent for listing in the U.S. Food and Drug Administration's Orange Book. [1] The '813 patent is directed to pemetrexed formulations, including the FDA-approved commercial formulation of PEMFEXY®.

The '813 patent will expire in 2036. This is the second patent to be listed in the Orange Book for PEMFEXY, and to date Eagle has not received any notice of a Paragraph IV certification for an application referencing PEMFEXY.

"The issuance of this patent is meaningful, as we continue to vigorously protect the commercial success of PEMFEXY and to add to the overall strength of our patent portfolio. PEMFEXY maintains a unique J-Code from CMS and sales remain strong, with a 24% share in the commercial (non-340B) pemetrexed market leaving the third quarter of 2023," stated Scott Tarriff, President and Chief Executive Office of Eagle.

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 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 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, and the company is focused on developing medicines with the potential to become part of the personalized medicine paradigm in cancer care. 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," "could," "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 with respect to: statements regarding the Company's expectations regarding the patent portfolio for PEMFEXY; the listing of patents for PEMFEXY in the FDA's Orange Book; the maintenance of a unique J-Code with CMS; and the sales of PEMFEXY and related market share. 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 post- COVID-19 environment and geopolitical factors such as the conflict in Ukraine; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates and successful compliance with FDA, European Medicines Agency and other governmental regulations applicable to product approvals; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; 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; 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; unexpected safety or efficacy data observed during clinical trials; clinical trial site activation or enrollment rates that are lower than expected; the risks inherent in drug development and in conducting clinical trials; unanticipated factors in addition to the foregoing that may impact the Company's financial and business projections and guidance and may cause the Company's actual results and outcomes to materially differ from its projections and guidance; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (the "SEC") on March 23, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 8, 2023 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.

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Public Relations for Eagle Pharmaceuticals, Inc.:
Faith Pomeroy-Ward
T: 817-807-8044
E: faith@eagleus.com

[1] Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)