Eagle Pharmaceuticals Announces Positive Type C Meeting with FDA for EA-114, an Estrogen Receptor Antagonist Used in the Treatment of Metastatic Breast Cancer in Post-Menopausal Women

August 29, 2023

Eagle plans to file a new drug application ("NDA") for EA-114 in 2024

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for all fulvestrant patients and provide the opportunity for a more personalized treatment
regimen in subpopulations, which represent over 50% of patients

WOODCLIFF LAKE, N.J., Aug. 29, 2023 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced a positive Type C meeting with the U.S. Food and Drug Administration ("FDA"). Eagle and the FDA agreed on a path forward to advance the clinical development of EA-114, an estrogen receptor antagonist used in the treatment of breast cancer in post-menopausal women. EA-114 has the potential to provide healthcare providers with a formulation that meaningfully optimizes the dosing regimen for all fulvestrant patients. Eagle currently anticipates filing a new drug application ("NDA") for EA-114 in 2024. If approved for all uses, EA-114 would allow physicians to provide a personalized treatment regimen to all patients, including specific sub-populations.

Over the course of five years and multiple studies, Eagle has dosed more than 800 people with the brand formulation of fulvestrant and multiple Eagle internally developed formulations. The Company's rigorous analysis of the data from these studies yielded significant insights which led Eagle to develop a novel formulation, EA-114, which if approved would optimize the dosing regimen of fulvestrant to allow for a more personalized treatment approach. EA-114 has the potential to improve treatment for all fulvestrant patients, including multiple subpopulations. These subpopulations collectively represent approximately half of the total patient population. EA-114 may additionally result in improved patient outcomes.

Eagle is committed to conducting the necessary clinical program to support approval of this novel formulation of fulvestrant. It is anticipated that EA-114 would be approved as a monotherapy and for use in combination with CDK4/6 inhibitors as described in the approved labeling for Faslodex®. According to IQVIA, products anticipated to be co-administered with EA-114 have had sales of $7 billion in the 12 months ending June 30th, 2023, and grew by 27% over the prior 12-month period.[1]

Eagle anticipates filing the NDA in 2024 while pursuing a label expansion for the subpopulations in parallel.

"We are very pleased that the Eagle team's perseverance, motivated by our desire to help breast cancer patients, has resulted in this novel formulation. We anticipate EA-114 being a very important part of a more personalized treatment regimen for post-menopausal metastatic breast cancer patients," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals. "Eagle is very proud that this development program has been created in-house by the company's formulation, clinical, and regulatory teams. We believe EA-114 has the potential to become an ever-increasing part of the personalized medicine paradigm in cancer care," concluded Tarriff.

Eagle continues to advance personalized medicine in the oncology sector by working to bring critically needed novel and complementary therapies to market. If approved, this will be Eagle's seventh internally developed NDA, highlighting the depth of Eagle's pipeline and its research and development capabilities in the area of medical oncology.

Eagle has filed a patent application pertaining to EA-114 and anticipates pursuing a robust patent portfolio over time. The Company believes EA-114 is eligible for a unique J-code from CMS under the current regulatory framework. In addition, Eagle believes EA-114, if the label expansion for subpopulations is approved, may be eligible for a period of regulatory exclusivity of three years and a separate period of potential patent protection, including potential patents eligible for listing in the Orange Book.

Currently, fulvestrant is indicated as monotherapy first-line endocrine treatment in post-menopausal women with hormone receptor-positive metastatic breast cancer (MBC) and in combination therapy to treat hormone receptor positive, advanced breast cancer in women whose breast cancer has spread or worsened after being treated with anti-estrogen medications.

Eagle intends to provide additional updates on the progress of the EA-114 development program for the sub-populations as discussions with the FDA progress.

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: the Company's ability to develop innovative medicines that address unmet medical needs; the potential development of EA-114; the Company's expectations for the design and timing of clinical trials and studies including with respect to enrollment, site selection, data meetings with regulatory agencies, and the timing thereof; the timing for filing a NDA for EA-114; the potential of EA-114 to offer unique or meaningful therapeutic benefits to patients and potentially

improving the treatment regimen for patients, and improving patient outcomes; the potential for regulatory exclusivity; the potential for an approved label expansion for subpopulations; the potential market size for EA-114 and potential sales associated therewith; the potential for a unique J-Code from CMS; and the Company's expectation to pursue a robust patent portfolio for EA-114, potential listing in the Orange Book and protections associated therewith. All 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@insiteconv.com

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

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[1] IQVIA SMART – US Edition Monthly.