Eagle Pharmaceuticals Advances Novel and Proprietary Formulation of Fulvestrant Product Candidate EA-114; Company to Request Additional Meeting with U.S. Food and Drug Administration ("FDA")

May 4, 2020

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. ("Eagle" or the "Company") (NASDAQ: EGRX) today provided an update on its pilot clinical study to assess the unique characteristics of its fulvestrant product candidate, EA-114, which has the potential to enhance estrogen receptor ("ER") inhibition and improve patient outcomes.

"As discussed on our March 2nd earnings call, we have continued to refine our EA-114 program, collected additional pilot data, and are pleased with our progress. We have had two meetings with FDA and will request another meeting to discuss these data. With FDA's guidance, we hope to move ahead with our plans. We look forward to providing additional updates on the progress of this potential drug treatment for hormone-receptor ("HR")-positive advanced breast cancer," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"A substantial number of women with advanced HR-positive breast cancer receiving standard treatment experience early disease progression," said Adrian Hepner, Chief Medical Officer of Eagle Pharmaceuticals. "Low and inconsistent estrogen receptor inhibition often results in suboptimal treatment, which may lead to faster progression of the disease. Our research suggests that we may have a better approach."

About Fulvestrant

Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the FDA for the treatment of advanced hormone-related breast cancers. The therapeutic effect of fulvestrant involves its ability to competitively inhibit estrogen-stimulated cell division by binding to the ERs in cancer cells, which may reduce cancer cell proliferation.

Fulvestrant is indicated as a monotherapy treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy, or HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy, or as a combination therapy for the treatment of: (1) HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women, in combination with ribociclib, as initial endocrine based therapy or following disease progression on endocrine therapy, or (2) HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with palbociclib or abemaciclib, in women with disease progression after endocrine therapy.

About Breast Cancer

Breast cancer is the most commonly diagnosed cancer in women, with approximately 290,000 women diagnosed in the U.S. annually and more than 2.8 million breast cancer survivors in the U.S. today. HR-positive breast cancer is the most common clinical subtype, with the ER being expressed in approximately 75% of those diagnosed.

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 RYANODEX®, BENDEKA®, BELRAPZO®, and its 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 information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by the words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" or other similar terms or expressions. All statements other than statements of historical fact could be deemed forward looking, including, but not limited to, statements regarding Eagle's plans for clinical development of its fulvestrant product candidate, EA-114, including the reporting of results and timing of completion of the pilot study and its communications with the FDA; the potential benefits and efficacy of EA-114, including its ability to achieve a greater level of ER inhibition; and the potential for EA-114 to be a possible therapeutic option for HR-positive advanced breast cancer. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, but are not limited to, the uncertainty related to the impact of the COVID-19 pandemic on Eagle's clinical development plans for its product candidates, including EA-114; delay in or failure to obtain regulatory approval of Eagle's product candidates, including EA-114; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Eagle's product candidate and namely, unexpected concerns that may arise from additional data, analysis or results obtained during the pilot clinical study; that regulatory authorities may require additional information or further studies; as well as those risks and uncertainties described in the section titled "Risk Factors" section of Eagle's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 2, 2020 and its other subsequent filings with the Securities and Exchange Commission. All information in this press release speaks only as of the date of this press release, and Eagle undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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