Eagle Pharmaceuticals Commences Dosing in Pilot Study for Novel Estrogen Receptor Antagonist Product Candidate

December 9, 2019

--Product has potential to achieve greater inhibition of estrogen receptors and better outcomes for patients with ER-positive breast cancer--

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that the Company has commenced dosing in a pilot clinical study to assess the unique characteristics of its fulvestrant product candidate, which has the potential to enhance estrogen receptor ("ER") inhibition and improve patient outcomes. The results of the pilot study will inform the design of the Company's pivotal trial, which Eagle expects to commence in 2020.

"We are pleased that dosing is underway in our pilot study, and look forward to gathering data to determine the design of our future pivotal study in estrogen receptor positive breast cancer patients. We believe there is a sizable patient population who could benefit from our product's differentiated characteristics, and we look forward to expanding our portfolio of oncology assets," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

About Fulvestrant

Fulvestrant, an estrogen receptor antagonist with no agonist properties, is approved by the U.S. Food and Drug Administration for the treatment of advanced hormone-related breast cancers. The therapeutic effect of fulvestrant relies on its ability to inhibit ERs in cancer cells by binding to and downregulating, or blocking, the ER in breast cancer cells. Recent studies have shown that higher residual ER availability is associated with early disease progression.

Fulvestrant is indicated as a monotherapy treatment of hormone receptor (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. Hormone receptor-positive (HR+) 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 specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle's strategy is to utilize the FDA's 505(b)(2) regulatory pathway. 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 "will," "expected," "we believe," "committed," "plan," "promise," "may," "enables," "potential," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events, including: the Company's plans with respect to the commercial availability of fulvestrant; the Company's plans and ability to successfully develop and commercialize its novel fulvestrant product candidate; the favorable outcome of the Company's pilot study to evaluate the pharmacokinetics and safety of its fulvestrant product candidate and intention to conduct a subsequent clinical trial, including the timing of such clinical trials; and the efficacy of the Company's fulvestrant product candidate, including the ability to achieve a greater level of estrogen receptor inhibition. All 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. Such risks include, but are not limited to: whether the Company can successfully advance fulvestrant for the treatment of cancer patients; whether Eagle's studies will support the safety and efficacy of fulvestrant for the treatment of cancer patients; whether the FDA will ultimately approve fulvestrant for the treatment of cancer patients; whether the Company will incur unforeseen expenses or liabilities or other market factors; the effect of competitive factors and Eagle's reactions to those factors; the pace and extent of market adoption of Eagle's products and technologies; uncertainty in the process of obtaining regulatory approval or clearance for Eagle's products; the success of Eagle's growth strategies; timing and achievement of product development milestones; the outcome of ongoing or future litigation; the impact and benefits of market development; Eagle's ability to protect its intellectual property; dependence upon third parties; unexpected new data, safety and technical issues; market conditions; other risks inherent to drug development and commercialization; and other risks described in Eagle's filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do 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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