Eagle Pharmaceuticals Commences Pivotal Study for Fulvestrant

December 7, 2017

Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or “the Company”) today announced that it has begun dosing subjects in its pivotal study for the Company’s fulvestrant formulation intended 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 with palbociclib for the treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression after endocrine therapy.

This pharmacokinetic and safety pivotal study is an open label trial in which healthy female volunteers across multiple U.S. sites will be randomized 1:1 to receive either the Company’s fulvestrant formulation or the reference drug Faslodex®. The Company anticipates dosing its last subject during the first half of 2018, with study completion within twelve months, and an expected NDA filing in the fourth quarter of 2018.

“We began dosing the first cohort of subjects in our pivotal study fulvestrant trial on November 30th, following guidance from the U.S. Food and Drug Administration (FDA) regarding the study design. We believe our fulvestrant formulation holds the potential to be a best-in-class treatment option for thousands of patients,” stated Scott Tarriff, Chief Executive Officer.

“Our innovative formulation, if approved, could offer multiple potential benefits compared to the current branded fulvestrant product, Faslodex. Our formulation allows the therapy to be administered at the recommended dose with one intramuscular injection instead of two high-viscosity intramuscular injections, and in far less time – seconds instead of minutes. In addition, it does not contain castor oil, and our formulation’s lower viscosity allows for administration with a 23-gauge needle, which is 25% thinner than the current needle required to administer Faslodex,” added Tarriff.

Faslodex, manufactured by AstraZeneca, generated worldwide sales of $925 million in the twelve months ended September 30, 2017.

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 such as “will,” “may,” “intends,” “anticipate(s),” “plan,” “enables,” “potentially,” “forecasted”, “entitles,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events, including, but not limited to: the successful completion of Eagle’s pivotal Phase III trial of fulvestrant; and other factors that are discussed in Eagle’s Annual Report on Form 10-K for the year December 2016, and its other filings with the U.S. Securities and Exchange Commission. All of 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: the ability of Eagle to manufacture and commercialize its Pemetrexed product upon final approval; the formation of a market for Eagle’s Pemetrexed product; 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.

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