Eagle Pharmaceuticals Announces FDA Approval of Docetaxel Injection, Non-Alcohol Formula

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First and Only Alcohol-Free Formulation Approved in U.S.

Eagle Pharmaceuticals, Inc. (“Eagle” or “the Company”) (Nasdaq:EGRX) announced today that the U.S. Food and Drug Administration (“FDA”) has approved Docetaxel Injection, Non-Alcohol Formula for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer. Eagle entered into an exclusive licensing agreement with Teikoku Pharma USA Inc. in October 2015 to market, sell and distribute Docetaxel Injection in the U.S.

Docetaxel Injection is the first alcohol-free formulation approved in the U.S. Additional features of this product are:

- presents as one, pre-filled vial that does not require mixing;
- is available in three different dosages: 20mg/1ml, 80mg/4mL, and 160mg/8mL; and
- 24 hours of stability at final dilution strength.[1]

The need for an alcohol-free docetaxel gained visibility in June 2014 when the FDA issued a Drug Safety Communication warning patients that docetaxel may cause symptoms of alcohol intoxication after treatment. Manufacturers of docetaxel formulations for domestic use were subsequently required to revise their product labels to reflect alcohol content and include a drug safety warning. Some U.S. hospitals and clinics require patients to wait two or more hours after treatment with docetaxel before they can be released. This formulation of docetaxel was specifically developed to address these concerns.

“Docetaxel Injection addresses a compelling need in the docetaxel market. As the first alcohol-free formulation approved in the U.S., we believe the benefits of this novel formulation will provide an option for patients with alcohol sensitivity or a preference for an alcohol-free treatment. We are excited to add alcohol-free docetaxel to our growing portfolio of differentiated injectable products and believe it has the potential to improve the lives of patients, resolve concerns among health care professionals at hospitals and infusion centers, and ultimately drive value for Eagle stakeholders,” said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

Eagle expects to begin shipping Docetaxel Injection in January 2016. Eagle estimates that annual sales of generic docetaxel are approximately $75 million.

About Docetaxel

Docetaxel is a taxane product indicated for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

Docetaxel was originally developed by Sanofi and marketed under the Taxotere® brand. Since its patent expiration in 2011, several generics entered the market. The alcohol content of these docetaxel formulations, including Taxotere, ranges from 2.0 to 6.4 grams in a 200 mg dose[2].

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 “believes,” “potential,” “will,” “may,” “intends,” “anticipate(s),” “plan,” “enables,” “potentially,” “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 timing and level of success of a future launch of Docetaxel Injection, Non-Alcohol Formula; the success of Eagle’s commercial arrangement with Teikoku Pharma USA, Inc. and the parties’ ability to work effectively together; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; and other factors that are discussed in Eagle’s Annual Report on Form 10-K for the fiscal year ended September 30, 2014, 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: whether Eagle will be successful at commercializing the Docetaxel Injection, Non-Alcohol Formula product; whether Eagle and Teikoku will successfully perform each of their respective obligations under the license agreement; 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.

[1] Docetaxel Injection final dilution for infusion, if stored between 2 degrees C and 25 degrees C (36F and 77F) is stable for 24 hours in either 0.9% Sodium Chloride solution or 5% dextrose solution.

[2] FDA Drug Safety Communication: http://www.fda.gov/Drugs/DrugSafety/ucm401752.htm

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