CMS Establishes Unique J-Code for BELRAPZO™ (Bendamustine 500mL Hydrochloride Injection)

April 22, 2019

--Eagle's bendamustine 500mL hydrochloride injectable will be sold as BELRAPZO beginning June 3, 2019--

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. ("Eagle" or the "Company") (Nasdaq:EGRX) today announced that the Centers for Medicare & Medicaid Services (CMS) has established a unique, product-specific billing code, or J-code (J9036), for BELRAPZO ™ (bendamustine 500mL hydrochloride injection). The J-code will become effective on July 1, 2019. Eagle's bendamustine 500mL hydrochloride injectable will be sold as BELRAPZO beginning June 3, 2019.

"We launched our 500mL bendamustine hydrochloride injection, to address the need in the market for our unique formulation at a lower price point. The new J-code provides reimbursement coding clarity to outpatient facilities and physicians that will administer BELRAPZO, facilitating access for patients, and Medicare, Medicaid and commercial insurance reimbursement," said Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

About BELRAPZO

Indications

BELRAPZO is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL). Efficacy relative to first-line therapies other than chlorambucil has not been established.

BELRAPZO is indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Important Safety Information

Contraindication: BELRAPZO is contraindicated in patients with a history of a hypersensitivity reaction to bendamustine, polyethylene glycol 400, propylene glycol, or monothioglycerol. Reactions to bendamustine hydrochloride have included anaphylaxis and anaphylactoid reactions.

Myelosuppression: Delay or reduce dose. Restart treatment based on ANC and platelet count recovery. Complications of myelosuppression may lead to death.

Infections: Monitor for fever and other signs of infection or reactivation of infections and treat promptly.

Anaphylaxis and Infusion Reactions: Severe anaphylactic reactions have occurred. Monitor clinically and discontinue bendamustine hydrochloride. Pre-medicate in subsequent cycles for milder reactions.

Tumor Lysis Syndrome: Acute renal failure and death; anticipate and use supportive measures.

Skin Reactions: Discontinue for severe skin reactions. Cases of SJS, DRESS and TEN, some fatal, have been reported.

Hepatotoxicity: Monitor liver chemistry tests prior to and during treatment.

Other Malignancies: Pre-malignant and malignant diseases have been reported.

Extravasation Injury: Assure good venous access and monitor infusion site during and after administration.

Embryo-fetal toxicity: Fetal harm can occur when administered to a pregnant woman. Women should be advised to avoid becoming pregnant when receiving bendamustine hydrochloride.

Most Common Adverse Reactions:

- Most common non-hematologic adverse reactions for CLL (frequency ≥15%) are pyrexia, nausea, and vomiting.
- Most common non-hematologic adverse reactions for NHL (frequency ≥15%) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash, and stomatitis.
- Most common hematologic abnormalities (frequency ≥15%) are lymphopenia, anemia, leukopenia, thrombocytopenia, and neutropenia.

For BELRAPZO Full Prescribing Information, please visit:

www.belrapzo.com

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 BELRAPZO; the timing of effectiveness of the J-Code for BELRAPZO; the ability of the J-Code to provide reimbursement clarity; and the Company’s plans and ability to successfully commercialize BELRAPZO. 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 will incur unforeseen expenses or liabilities or other market factors; whether the Company can successfully advance BELRAPZO for the treatment of patients with chronic lymphocytic leukemia and for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen; difficulties or delays in manufacturing; whether the Company can continue to price BEPRAPZO competitively; 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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