FDA Does Not Grant Seven Year Orphan Drug Exclusivity for BENDEKA (bendamustine hydrochloride injection)

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-Eagle Believes the FDA is Required to Grant Exclusivity Based Upon Orphan Drug Designation Granted in 2014-

Eagle Pharmaceuticals, Inc. (Nasdaq:EGRX) ("Eagle" or the "Company") announced today that the U.S. Food and Drug Administration (FDA) has denied Eagle's request for seven years of orphan drug exclusivity in the U.S., for BENDEKA™ (bendamustine hydrochloride injection, or bendamustine HCl), a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine hydrochloride. BENDEKA was approved in December 2015 for the treatment of patients with chronic lymphocytic leukemia (CLL) and 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. Efficacy in CLL relative to first-line therapies other than chlorambucil has not been established.

Eagle believes that the FDA's decision is incorrect, and that BENDEKA was automatically entitled to orphan drug exclusivity for CLL and indolent B-cell NHL upon the drug's December 2015 approval. The FDA previously granted orphan drug designation for BENDEKA for both indications. Eagle is evaluating all options to challenge the FDA's decision.

Orphan drug designation is granted by the FDA Office of Orphan Products Development to novel drugs or biologics that treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. The designation typically provides the drug developer with a seven-year period of U.S. marketing exclusivity upon approval, as well as certain financial incentives that can help support its development.

The FDA currently requires sponsors of certain orphan designated drugs to make a "clinical superiority" demonstration as a condition to obtaining the seven-year exclusivity period upon approval. The FDA applies this requirement whenever the FDA has previously approved another drug of the same active moiety for the same indication.

In September 2014, DepoMed, Inc. (DepoMed) prevailed in litigation in federal district court in the District of Columbia, challenging the FDA's application of this clinical superiority demonstration requirement to its orphan-designated drug product, GRALISE™. DepoMed argued that the requirement violates the Orphan Drug Act, which automatically confers seven years of marketing exclusivity on orphan designated products upon approval. District Judge Ketanji Brown Jackson agreed with DepoMed's position, and ordered the FDA to recognize orphan drug exclusivity for GRALISE without requiring proof of "clinical superiority." While the FDA granted orphan drug exclusivity for GRALISE without a clinical superiority demonstration, it has continued to require the clinical superiority demonstration for other orphan designated drugs, such as BENDEKA.

Eagle believes that the FDA's rejection of orphan drug exclusivity for BENDEKA closely mirrors the decision that Judge Jackson overturned in the *DepoMed* litigation, and Eagle is evaluating all options to obtain a reversal of the FDA's BENDEKA decision at this time.

"We are disappointed with the agency's decision regarding orphan drug exclusivity for BENDEKA, which we believe to be incorrect," said Scott Tarriff, President and Chief Executive Officer. "With six Orange Book listed patents extending from 2026 through 2033, and additional pending patent applications, the market protection for BENDEKA is likely to be intact for many years. These patents will continue to be in effect beyond the seven years of exclusivity that would have been provided had the orphan drug exclusivity been granted. We believe the FDA's decision will have little to no impact on our bendamustine HCl business in the near term," concluded Tariff.

The following table lists the patents for liquid bendamustine hydrochloride (HCl) formulations:

U.S. Patent No.	Patent Expiration
8,609,707	8/11/2031
8,791,270*PED (Owned by Teva Pharmaceutical Industries, Ltd.)	7/12/2026
9,000,021	3/15/2033
9,034,908	3/15/2033
9,144,568	3/15/2033
9,265,831	1/28/2031

Under a February 2015 exclusive license agreement for BENDEKA, a subsidiary of Teva Pharmaceutical Industries, Ltd. is responsible for all U.S. commercial activities for the product including promotion and distribution. BENDEKA was launched by Teva in late January 2016. As previously announced, Eagle receives a 20% royalty on Teva's sales of BENDEKA.

Indications

BENDEKA 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.

BENDEKA 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: BENDEKA is contraindicated in patients with a known hypersensitivity (e.g., anaphylactic and anaphylactoid reactions) to bendamustine, polyethylene glycol 400, propylene glycol, or monothioglycerol.

Myelosuppression: Bendamustine hydrochloride caused severe myelosuppression (Grade 3-4) in 98% of patients in the two NHL studies. Three patients (2%) died from myelosuppression-related adverse reactions. Monitor leukocytes, platelets, hemoglobin (Hgb), and neutrophils frequently. Myelosuppression may require dose delays and/or subsequent dose reductions if recovery to the recommended values has not occurred by the first day of the next scheduled cycle.

Infections: Infection, including pneumonia, sepsis, septic shock, hepatitis and death has occurred. Patients with myelosuppression following treatment with BENDEKA are more susceptible to infections. Patients treated with Bendamustine hydrochloride are at risk for reactivation of infections including (but not limited to) hepatitis B, cytomegalovirus, Mycobacterium tuberculosis, and herpes zoster. Patients should undergo appropriate monitoring, prophylaxis, and treatment measures.

Anaphylaxis and Infusion Reactions: Infusion reactions to bendamustine hydrochloride have occurred commonly in clinical trials. Symptoms include fever, chills, pruritus, and rash. In rare instances severe anaphylactic and anaphylactoid reactions have occurred, particularly in the second and subsequent cycles of therapy. Monitor clinically and discontinue drug for severe (Grade 3-4) reactions. Ask patients about symptoms suggestive of infusion reactions after their first cycle of therapy. Consider measures to prevent severe reactions, including antihistamines, antipyretics, and corticosteroids in subsequent cycles in patients who have experienced Grade 1 or 2 infusion reactions.

Tumor Lysis Syndrome: Tumor lysis syndrome associated with bendamustine hydrochloride has occurred. The onset tends to be within the first treatment cycle with –bendamustine hydrochloride and, without intervention, may lead to acute renal failure and death. Preventive measures include vigorous hydration and close monitoring of blood chemistry, particularly potassium and uric acid levels. There may be an increased risk of severe skin toxicity when bendamustine hydrochloride and allopurinol are administered concomitantly.

Skin Reactions: Skin reactions have been reported with bendamustine hydrochloride treatment including rash, toxic skin reactions, and bullous exanthema. In a study of bendamustine hydrochloride (90 mg/m2) in combination with rituximab, one case of toxic epidermal necrolysis (TEN) occurred. TEN has been reported for rituximab. Cases of Stevens-Johnson syndrome (SJS) and TEN, some fatal, have been reported when bendamustine hydrochloride was administered concomitantly with allopurinol and other medications known to cause these syndromes. Where skin reactions occur, they may be progressive and increase in severity with further treatment. Monitor patients with skin reactions closely. If skin reactions are severe or progressive, withhold or discontinue BENDEKA.

Other Malignancies: There are reports of pre-malignant and malignant diseases that have developed in patients who have been treated with bendamustine hydrochloride, including myelodysplastic syndrome, myeloproliferative disorders, acute myeloid leukemia, and bronchial carcinoma. The association with BENDEKA therapy has not been determined.

Extravasation Injury: Extravasations resulting in hospitalizations from erythema, marked swelling, and pain have been reported with bendamustine hydrochloride. Assure good venous access prior to starting drug infusion and monitor the intravenous infusion site for redness, swelling, pain, infection, and necrosis during and after administration of BENDEKA.

Embryo-fetal Toxicity: Bendamustine hydrochloride can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid becoming pregnant while using BENDEKA.

Most Common Adverse Reactions:

• Adverse reactions (frequency >5%) during infusion and within 24 hours post-infusion are nausea and fatigue.

• 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 **BENDEKA Full Prescribing Information,** please visit: http://www.bendeka.com/PrescribingInformation.PDF

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.

Eagle's 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," "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 availability of drug exclusivities for BENDEKA, the ability of Eagle to successfully challenge the decision of the FDA, the impact of the FDA's decision on Eagle's bendamustine HCI business, Eagle's patent protection for BENDEKA, Teva's replacement of Treanda liquid with BENDEKA, difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials, and products licensed to third-parties for promotion and distribution; 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 year ended December 31, 2015, 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 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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