CMS Establishes Unique J-Code for BENDEKA® (bendamustine hydrochloride) Injection

November 2, 2016

Provides Access for Patients and Streamlined Reimbursement

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) and Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) announced today that the Centers for Medicare & Medicaid Services (CMS) has established a unique, product-specific billing code, or J-code (J9034), for BENDEKA® (bendamustine hydrochloride) Injection. The J-code will become effective on January 1, 2017.

The new J-code provides reimbursement coding clarity to outpatient facilities and physicians that administer BENDEKA, facilitating access for patients and Medicare, Medicaid and commercial insurance reimbursement.

“We are pleased that CMS recognized that the unique formulation and delivery mechanism offered by BENDEKA required separate recognition from other bendamustine products currently on the market. We expect the new J-code will provide greater access for patients, facilitate reimbursement and enable greater adoption of BENDEKA in the market,” said Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

“This is an important milestone for Teva as we continue to advance our bendamustine franchise with BENDEKA,” said Paul Rittman, Senior Vice President and General Manager, Teva Oncology. “We are committed to serving patients in need of this important therapy and are pleased that a unique J-code has been established to assist providers in obtaining reimbursement for BENDEKA.”

BENDEKA, a liquid, low-volume (50 mL) and short-time (10-minute) infusion formulation of bendamustine hydrochloride, was approved by the U.S. Food and Drug Administration (FDA) 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.

Under a February 2015 exclusive license agreement for BENDEKA, 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 and now is the most used bendamustine product. Please see Important Safety Information below including contraindication in patients with a known hypersensitivity (e.g., anaphylactic and anaphylactoid reactions) to bendamustine, polyethylene glycol 400, propylene glycol, or monothioglycerol.

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 Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,800 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2015 amounted to $19.7 billion. For more information, visit www.tevapharm.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.

Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products; competition for our specialty products, especially Copaxone® (which faces competition from orally-administered alternatives and a generic version); our ability to integrate Allergan plc's worldwide generic pharmaceuticals business ("Actavis Generics") and to realize the anticipated benefits of the acquisition (and the timing of realizing such benefits); the fact that following the consummation of the Actavis Generics acquisition, we are dependent to a much larger extent than previously on our generic pharmaceutical business; potential restrictions on our ability to engage in additional transactions or incur additional indebtedness as a result of the substantial amount of debt incurred to finance the Actavis Generics acquisition; the fact that for a period of time following the Actavis Generics acquisition, we will have significantly less cash on hand than previously, which could adversely affect our ability to grow; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from investments in our pipeline of specialty and other products; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents, confidentiality agreements and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2015 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statements or other information, whether as a result of new information, future events or otherwise.

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