



## Teva and Eagle Pharmaceuticals Announce Commercial Availability of BENDEKA™ (bendamustine hydrochloride) Injection

January 28, 2016

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) and Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) announced today the commercial availability of BENDEKA™, (bendamustine hydrochloride) injection, a liquid, low-volume (50 mL) and short-time 10-minute infusion formulation of bendamustine. BENDEKA is approved 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.

"With the launch of BENDEKA, Teva furthers our commitment to providing treatment options for patients with these rare forms of cancer," said Paul Rittman, Senior Vice President and General Manager, Teva Oncology. "We believe BENDEKA represents an important benefit to both patients and healthcare providers, and are pleased it is now available. Based on the product profile, we expect BENDEKA to replace TREANDA® liquid."

"We are pleased to announce that Teva has shipped Bendeka injection per our exclusive license agreement with them, and that the product will be in the hands of health care professionals and patients alike, as scheduled," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

Under a February 2015 exclusive license agreement for BENDEKA, Teva is responsible for all U.S. commercial activities for the product including promotion and distribution.

### Indications for BENDEKA and TREANDA (bendamustine hydrochloride) Injection

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

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 for BENDEKA and TREANDA

**Contraindication:** Patients with a known hypersensitivity (e.g., anaphylactic and anaphylactoid reactions) to bendamustine. BENDEKA is also contraindicated in patients with a known hypersensitivity to polyethylene glycol 400, propylene glycol, or monothio glycerol.

**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 bendamustine hydrochloride 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 prior to administration.

**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 of 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/m<sup>2</sup>) 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 or TREANDA.

**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 either BENDEKA or TREANDA 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 either BENDEKA or TREANDA.

**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 either BENDEKA or TREANDA.

**Most Common Adverse Reactions:**

- The most common non-hematologic adverse reactions for CLL (frequency  $\geq 15\%$ ) are pyrexia, nausea, and vomiting.
- The most common non-hematologic adverse reactions for NHL (frequency  $\geq 15\%$ ) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash, and stomatitis.
- The most common hematologic abnormalities for both indications (frequency  $\geq 15\%$ ) are lymphopenia, anemia, leukopenia, thrombocytopenia, and neutropenia.
- During BENDEKA infusion and within 24 hours post-infusion, adverse reactions (frequency  $>5\%$ ) are nausea and fatigue

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

For **TREANDA Full Prescribing Information**, please visit: [http://www.treanda.com/pdf/TREANDA\\_final\\_PI.pdf](http://www.treanda.com/pdf/TREANDA_final_PI.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 to millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,000 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 2014 amounted to \$20.3 billion. For more information, visit [www.tevapharm.com](http://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](http://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® (including competition from orally-administered alternatives, as well as from generic equivalents such as the recently launched Sandoz product) and our ability to continue to migrate users to our 40 mg/mL version and maintain patients on that version; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities (such as our pending acquisitions of Allergan's generic business and Rimsa), or to consummate and integrate acquisitions; 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 the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; 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; 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 generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; 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, 2014 and in our other filings with the U.S. Securities and Exchange Commission.*

**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: 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 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 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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