Bendeka Approved for Chronic lymphocytic leukemia (CLL) and Indolent B-cell non-Hodgkin lymphoma

Eagle Pharmaceuticals and Teva received U.S. Food and Drug Administration (FDA) approval for Bendeka™ (bendamustine) injection for intravenous use on Dec. 8, 2015. Bendeka has two indications: for patients who have chronic lymphocytic leukemia (CLL) and for patients who have indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab. For CLL, the recommended dose is 100mg/square meter of body surface area (m²) per day on the first two days of each 28-day treatment cycle for up to six cycles. Recommended dosing for patients with NHL is up to eight cycles of 120mg/m² per day on the first two days of 21-day treatment cycles. Treatments are given as 10-minute intravenous (IV) infusions of Bendeka mixed with 50mL of IV fluid. Complete prescribing information may be accessed at: http://www.bendeka.com/PrescribingInformation.PDF.

At a Glance

- **Brand (Generic) Name:** Bendeka™ (bendamustine)
- **Manufacturer:** Eagle Pharmaceuticals and Teva
- **Date Approved:** Dec. 8, 2015
- **Indication:** To treat chronic lymphocytic leukemia (CLL) and to treat indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab (Rituxan® - Genentech) or a rituximab-containing regimen
- **Dosage Forms Available:** 4mL multi-dose vials containing 100mg of bendamustine
- **Launch Date:** First quarter 2016
- **Estimated Annual Cost:** Pricing information is not yet available.
- **Specialty Status:** Bendeka will be added to Express Scripts’ specialty drug list.
- **Teva will market Bendeka in the United States.**
- **Bendamustine, an alkylating drug, was first approved by FDA in 2008 as Cephalon’s Treanda®, which also treats CLL and NHL. However, Treanda must be infused over longer times and in larger volumes.**
- **Almost all (98%) of NHL patients receiving Bendeka in clinical trials experienced severe myelosuppression, which is the decreased ability of bone marrow to produce blood cells. During Bendeka therapy, blood counts should be watched closely. Doses may need to be reduced or delayed if blood counts do not reach adequate levels before the next scheduled treatment cycle.**