Bendeka™ (bendamustine) – New Warnings

- On February 9, 2017, the FDA approved new warnings to the Warnings and Precautions section of the Bendeka (bendamustine) drug label regarding hepatotoxicity and drug reaction with eosinophilia and systemic symptoms (DRESS).

- Bendeka is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with Rituxan® (rituximab) or a rituximab-containing regimen.
  - Efficacy for CLL relative to first line therapies other than Leukeran® (chlorambucil) has not been established.

- Bendamustine is also available as Treanda®. Treanda shares the same indications as Bendeka.
  - Both warnings, hepatotoxicity and DRESS, were added to the Treanda drug label in October 2016.

- Fatal and serious cases of liver injury have been reported with Bendeka.
  - Combination therapy, progressive disease or reactivation of hepatitis B were confounding factors in some patients.
  - Most cases were reported within the first three months of starting therapy.
  - Liver chemistry tests should be monitored prior to and during Bendeka therapy.

- Fatal and serious skin reactions have been reported with Bendeka treatment in clinical trials and post-marketing safety reports.
  - These skin reactions include the toxic skin reactions, Stevens-Johnson Syndrome, toxic epidermal necrolysis, and DRESS, and bullous exanthema and rash.
  - Events occurred when Bendeka was given as a single agent and in combination with other anticancer agents or allopurinol.
  - The skin reactions may be progressive and increase in severity with further treatment.
  - Patients with skin reactions should be monitored closely.
  - If skin reactions are severe or progressive, treatment with Bendeka should be withheld or discontinued.