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.