Kepivance® (palifermin) – Label Update

- On July 1, 2016, the FDA approved a safety update for Kepivance (palifermin) pertaining to the risk of exacerbated mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of allogeneic hematopoietic stem cell support.
    - The following information was added to the *Limitations of Use* section of the *Indications and Usage* section of the label: Kepivance was not effective in decreasing the incidence of severe mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of allogeneic hematopoietic stem cell support.
- Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of autologous hematopoietic stem cell support. Kepivance is indicated as supportive care for preparative regimens predicted to result in ≥ WHO Grade 3 mucositis in the majority of patients.
    - The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies.
    - Kepivance is not recommended for use with melphalan 200 mg/m^2 as a conditioning regimen.
- In a study of patients with hematologic malignancies undergoing allogeneic transplantation, the incidence of WHO grade 3 and 4 mucositis was nominally higher in patients treated with Kepivance (81%) vs. placebo (73%).
- In addition, the *Dosage and Administration* section was updated with the following: Administer the last 3 doses of Kepivance after myelotoxic therapy is complete. Administer the first of these doses on the day of hematopoietic stem cell infusion after the infusion is completed, and at least 7 days after the most recent administration of Kepivance.
    - Previously, the label stated more than 4 days after the most recent administration of Kepivance.