## Venclexta® (venetoclax) – New warning

- On July 25, 2019, the FDA approved an update to the *Warnings and Precautions* section of the Venclexta (venetoclax) drug label, regarding increased mortality in patients with multiple myeloma when Venclexta is added to Velcade® (bortezomib) and dexamethasone.

- Venclexta is approved for:

  — The treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma
  — In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

- In a randomized trial in patients with relapsed or refractory multiple myeloma, the addition of Venclexta to bortezomib plus dexamethasone, a use for which Venclexta is not indicated, resulted in increased mortality.

  — Treatment of patients with multiple myeloma with Venclexta in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.