Venclexta® (venetoclax) – Expanded indication

- On May 16, 2019, Roche announced the FDA approval of Venclexta (venetoclax), for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
    - Previously, Venclexta was approved for the treatment of adult patients with CLL or SLL, with or without 17p deletion, who have received at least one prior therapy.
- Venclexta is also approved in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
- The expanded indication for Venclexta was based on the CLL14 open-label study enrolling 432 patients with previously untreated CLL with coexisting medical conditions. Patients received Venclexta in combination with Gazyva® (obinutuzumab) (VEN+G) or Venclexta in combination with Leukeran® (chlorambucil) (GClb). The major efficacy outcome was progression-free survival (PFS).
    - VEN+G produced a durable and significant reduction in the risk of disease worsening or death (PFS) vs. GCIb (HR 0.33; 95% CI: 0.22, 0.51; $p < 0.0001$).
    - In addition, overall response rate was 85% for the VEN+G group vs. 71% for the GCIb group.
    - At the time of analysis, median overall survival (OS) had not been reached. The median duration of follow-up for OS was 28 months.
- The most common adverse reactions (≥ 20%) with Venclexta when given in combination with Gazyva or Rituxan® (rituximab) or as monotherapy in CLL/SLL were neutropenia, thrombocytopenia, anemia, diarrhea, nausea, upper respiratory tract infection, cough, musculoskeletal pain, fatigue, and edema.
- For CLL/SLL Venclexta dosing begins with a 5-week ramp-up schedule to the recommended daily dose of 400 mg. Refer to the Venclexta prescribing information for further dosing instructions when administered in combination with Gazyva, Rituxan, or as monotherapy.
- Refer to the Venclexta prescribing information for additional dosing recommendations and for use in AML.