Venclexta® (venetoclax) – Expanded indication

- On June 8, 2018, Genentech announced the FDA approval of Venclexta (venetoclax), for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.
    - This approval also allows for combination therapy with Rituxan® (rituximab).
    - Previously, Venclexta was approved for the treatment of patients with CLL with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy.
    - The previous indication has been updated and converted from accelerated approval to full approval.
- CLL is the most common type of adult leukemia. Although signs of CLL may disappear for a period of time after initial treatment, the disease is considered incurable and many people will require additional treatment. In CLL, the cancer primarily occurs in the blood and bone marrow. SLL is similar to CLL, but primarily occurs in the lymph nodes.
    - In 2018, it is estimated there will be more than 20,000 new cases of CLL diagnosed in the U.S.
- The efficacy and safety of Venclexta in combination with Rituxan were evaluated in the MURANO open-label study of 389 patients with CLL who had received at least one prior therapy. Patients were randomized to Venclexta + Rituxan (VEN+R) or bendamustine + Rituxan (B+R). Efficacy was based on progression-free survival (PFS). The median follow-up for PFS was 23.4 months (range: 0 to 37.4+ months).
    - PFS was not reached in the VEN+R group vs. 18.1 months (95% CI: 15.8, 22.3) in the B+R group (HR = 0.19 [95% CI: 0.13, 0.28]; $p < 0.0001$).
    - The overall response rate was 92% in the VEN+R group vs. 72% in the B+R group. Median overall survival had not been reached in either arm after a median follow up of 22.9 months.
- The most common adverse reactions (≥ 20%) with Venclexta in combination with Rituxan use were neutropenia, diarrhea, upper respiratory tract infection, fatigue, cough, and nausea.
- Refer to the Venclexta drug label for specific dosing instructions.