April 12, 2016

**Venclexta Approved for Lymphocytic Leukemia**

On April 11, 2016, AbbVie and Genentech received approval from the U.S. Food and Drug Administration (FDA) for Venclexta™ (venetoclax) for the second-line treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test. The recommended starting dose is 20mg once daily for seven days, which should be titrated weekly to the recommended dose of 400mg once daily. AbbVie and Genentech plan on launching Venclexta within a week. It will be available through a limited network of specialty pharmacies that does not include Accredo. Full prescribing information can be found at: [www.venclexta.com](http://www.venclexta.com)

- **At a Glance**
  - **Brand (Generic) Name:** Venclexta™ (venetoclax)
  - **Manufacturer:** AbbVie and Genentech
  - **Date Approved:** April 11, 2016
  - **Indication:** Second-line treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test
  - **Dosage Forms Available:** 10mg, 50mg and 100mg tablets
  - **Launch Date:** Venclexta is expected to be available within a week.
  - **Estimated Annual Cost:** Pricing information is not available at this time.
  - **Specialty Status:** Venclexta will be added to Express Scripts’ specialty drug list.
  - Chronic lymphocytic leukemia (CLL) is characterized by the build-up of abnormal white blood cells in the bone marrow and blood. Approximately 15,000 patients are diagnosed with CLL each year in the United States. About 10 percent of patients with CLL have 17p deletion, a chromosomal alteration, at diagnosis and 30 to 50 percent of patients with relapsed or refractory CLL have 17p deletion. Most patients with CLL with 17p deletion have a life expectancy of less than three years.
  - Venclexta is the first B-cell lymphoma 2 (BCL-2) inhibitor to gain FDA approval.
  - FDA approval was based on a clinical trial that showed that 80 percent of patients treated with Venclexta had a complete or partial response to therapy.
  - Venclexta was approved two months ahead of schedule under FDA’s accelerated approval, breakthrough therapy and priority review programs.
  - Venclexta has also been granted breakthrough therapy designations for use in combination with Rituxan® (rituximab – Genentech / Biogen) for the treatment of relapsed or refractory CLL and for the first-line treatment of acute myeloid leukemia (AML) with hypomethylating agents in patients who aren’t candidates to receive standard high-dose chemotherapy.