FDA Approves Venclexta for Certain Types of Leukemia and Lymphoma

Study found Venclexta plus Gazyva (obinutuzumab) delayed disease progression in previously untreated patients.

May 15, 2019 By Food and Drug Administration (FDA)

On May 15, 2019, the Food and Drug Administration approved Venclexta (venetoclax; AbbVie Inc. and Genentech Inc.) for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Approval was based on CLL14 (NCT02242942), a randomized (1:1), multicenter, open label, actively controlled trial of venetoclax in combination with obinutuzumab (VEN+G) versus obinutuzumab in combination with chlorambucil (GClb) in 432 patients with previously untreated CLL with coexisting medical conditions.

The major efficacy outcome was progression-free survival (PFS) assessed by an independent review committee. The trial demonstrated a statistically significant improvement in PFS for patients who received VEN+G compared with those who received GClb (HR 0.33; 95% CI: 0.22, 0.51; $p<0.0001$). Median PFS was not reached in either arm after a median follow-up duration of 28 months. The overall response rate was 85% in VEN+G arm compared to 71% in GClb arm, $p=0.0007$. The trial also demonstrated statistically significant improvements in rates of minimal residual disease negativity (less than one CLL cell per 10^4 leukocytes) in bone marrow and peripheral blood. Overall survival data were not mature at this analysis.

In CLL/SLL, the most common adverse reactions (≥ 20%) for venetoclax when administered with obinutuzumab, rituximab, or as monotherapy were neutropenia, thrombocytopenia, anemia, diarrhea, nausea, upper respiratory tract infection, cough, musculoskeletal pain, fatigue, and edema.

View full prescribing information for VENCLEXTA for recommended starting and ramp-up dosages.

FDA used the Real-Time Oncology Review and Assessment Aid Pilot Program for this application and granted priority review as well as orphan drug and breakthrough therapy designations. Approval was granted 3.7 months ahead of the PDUFA date. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

This announcement was originally published on the Food and Drug Administration website.
