FDA approves venetoclax for chronic lymphocytic leukemia

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(HealthDay)—Venetoclax (VENCLEXTA) has been approved to treat adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma, the U.S. Food and Drug Administration announced yesterday.

Data from CLL14, a randomized, multicenter, open-label, actively controlled trial, provided the basis for approval. CLL14 involved 432 patients with previously untreated CLL and coexisting medical conditions who were randomly assigned to venetoclax plus obinutuzumab (VEN+G) or obinutuzumab plus chlorambucil (GClb). The researchers observed a statistically significant improvement in progression-free survival for patients who received VEN+G compared with those who received GClb (hazard ratio, 0.33). Overall response was 85 percent in patients who received VEN+G and 71 percent in those who received GClb.

VENCLEXTA is available in 10-, 50-, and 100-mg tablets. Dosing begins with a five-week ramp-up, and the FDA advises clinicians to consult the manufacturer prescribing information for the full ramp-up schedule.

When administered with obinutuzumab, with rituximab, or as monotherapy, the most commonly reported adverse reactions of venetoclax included neutropenia, thrombocytopenia, anemia, diarrhea, nausea, upper respiratory tract infection, cough, musculoskeletal pain, fatigue, and edema. The manufacturer prescribing information also warns of the potential risk for tumor lysis syndrome during the ramp-up phase and directs clinicians to advise patients of the signs and symptoms.

Approval was granted to AbbVie and Genentech.

More information: More Information