FDA approves new drug for chronic lymphocytic leukemia, small lymphocytic lymphoma

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The U.S. Food and Drug Administration has approved zanubrutinib (Brukinsa), a next-generation BTK inhibitor, for the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.

The approval was based on data from the phase 3 ALPINE trial, a head-to-head comparison of BTK inhibitors. Patients were randomly assigned to zanubrutinib or ibrutinib. Ibrutinib is a first-generation BTK inhibitor and the current standard treatment.

Jennifer R. Brown, M.D., Ph.D., from Dana-Farber Cancer Institute in Boston, led the ALPINE trial that found zanubrutinib-treated patients had a longer progression-free survival (PFS) at 29.6 months of follow-up (79.5 versus 67.3 percent). Furthermore, patients taking zanubrutinib had a lower rate of treatment discontinuation (26.3 versus 41.2 percent), including for heart disorders and cardiac events. The rate of atrial fibrillation or atrial flutter was lower with zanubrutinib (5.2 percent) versus ibrutinib (13.3 percent).

The FDA reported that the most common adverse reactions seen with zanubrutinib were a decrease in neutrophil count, upper respiratory tract infection, decrease in platelet count, hemorrhage, and musculoskeletal pain.

"I am encouraged that zanubrutinib has been approved for adults with chronic lymphocytic leukemia and small lymphocytic lymphoma and optimistic that many patients across the country will benefit from this approval," Brown said in a statement. "Our findings also found that zanubrutinib led to fewer side effects and adverse events than ibrutinib, leading to a better quality of life for patients."

Approval of Brukinsa (zanubrutinib) was granted to BeiGene.

More information: More Information