FDA Approves Jaypirca For Chronic Lymphocytic Leukemia

Nearly three quarters of treated patients experienced partial disease regression.

December 19, 2023 By Food and Drug Administration (FDA)

FDA grants accelerated approval to pirtobrutinib for chronic lymphocytic leukemia and small lymphocytic lymphoma

On December 1, 2023, the Food and Drug Administration granted accelerated approval to pirtobrutinib (Jaypirca, Eli Lilly and Company) for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

View full prescribing information for Jaypirca.

Efficacy was evaluated in BRUIN (NCT03740529], an open-label, international, single-arm, multicohort trial that included 108 patients with CLL or SLL previously treated with at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. Patients received a median of 5 prior lines of therapy (range: 2 to 11). 77% of patients discontinued the last BTK inhibitor for refractory or progressive disease. Pirtobrutinib was administered orally at 200 mg once daily and was continued until disease progression or unacceptable toxicity.

The main efficacy outcome measures were overall response rate (ORR) and duration of response (DOR), as assessed by an independent review committee using 2018 iwCLL criteria. The ORR was 72% (95% CI: 63, 80) and median DOR was 12.2 months (95% CI: 9.3, 14.7). All responses were partial responses.

The most common adverse reactions (≥ 20%), excluding laboratory terms, were fatigue, bruising, cough, musculoskeletal pain, COVID-19, diarrhea, pneumonia, abdominal pain, dyspnea, hemorrhage, edema, nausea, pyrexia, and headache. Grade 3 or 4 laboratory abnormalities in greater than 10% of patients were decreased neutrophil counts, anemia, and decreased platelet counts. Serious infections occurred in 32% of patients including fatal infections in 10% of patients. The prescribing information includes warnings and precautions for infections, hemorrhage, cytopenias, cardiac arrhythmias, and secondary primary malignancies.

The recommended pirtobrutinib dose is 200 mg orally once daily until disease progression or unacceptable toxicity.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review and orphan drug designation. FDA expedited programs are described in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

This announcement was published by the Food and Drug Administration on December 7, 2023.
