FDA Approves Jaypirca Targeted Therapy for Mantle Cell Lymphoma

Jaypirca (pirtobrutinib) is a highly selective kinase inhibitor that utilizes a novel binding mechanism.

January 31, 2023 By Food and Drug Administration (FDA)

FDA grants accelerated approval to pirtobrutinib for relapsed or refractory mantle cell lymphoma

On January 27, 2023, the Food and Drug Administration (FDA) granted accelerated approval to pirtobrutinib (Jaypirca, Eli Lilly and Company) for relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.

Efficacy was evaluated in BRUIN (NCT03740529), an open-label, multicenter, single-arm trial of pirtobrutinib monotherapy that included 120 patients with MCL previously treated with a BTK inhibitor. Patients had a median of 3 prior lines of therapy, with 93% having 2 or more prior lines. The most common prior BTK inhibitors received were ibrutinib (67%), acalabrutinib (30%), and zanubrutinib (8%); 83% had discontinued their last BTK inhibitor due to 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 measures were overall response rate (ORR) and duration of response (DOR), as assessed by an independent review committee using Lugano criteria. The ORR was 50% (95% CI: 41, 59) with a complete response rate of 13%. The estimated median DOR was 8.3 months (95% CI: 5.7, NE), and the estimated DOR rate at 6 months was 65.3% (95% CI: 49.8, 77.1).

The most common adverse reactions (≥15%) in patients with MCL were fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, and bruising. Grade 3 or 4 laboratory abnormalities in ≥10% of patients were decreased neutrophil counts, lymphocyte counts, and platelet counts. The prescribing information includes warnings and precautions for infections, hemorrhage, cytopenias, atrial fibrillation and flutter, and second primary malignancies.

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

View full prescribing information for Jaypirca.

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 fast track designation. FDA expedited programs are described in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics. The application also was granted orphan drug designation.

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.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE’s Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

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http://beta.docker.cancerhealth.com/blog/fda-approves-jaypirca-targeted-therapy-mantle-cell-lymphoma