

## Jaypirca<sup>™</sup> (pirtobrutinib) – New drug approval

- On January 27, 2023, <u>Eli Lilly announced</u> the FDA approval of <u>Jaypirca (pirtobrutinib)</u>, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.
  - This indication is approved under accelerated approval based on response rate.
     Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- MCL is a rare blood cancer and a form of non-Hodgkin lymphoma. According to the <u>American Cancer Society</u>, about 5% of lymphomas are MCLs.
- Jaypirca is a highly selective, noncovalent (reversible) inhibitor of the enzyme BTK. BTK is a
  molecular target found across numerous B-cell leukemias and lymphomas including MCL.
- The efficacy of Jaypirca was established in BRUIN, a single-arm, open-label study in 120 patients with MCL. Jaypirca was continued until disease progression or unacceptable toxicity. Efficacy was based on overall response rate (ORR) and duration of response (DOR).
  - The ORR was 50% (95% CI: 41, 59).
  - The median DOR was 8.3 months (95% CI: 5.7, not estimable).
- Warnings and precautions for Jaypirca include infections, hemorrhage, cytopenias, atrial fibrillation and atrial flutter, second primary malignancies, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 15%) with Jaypirca use were fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, and bruising. Grade 3 or 4 laboratory abnormalities (≥ 10%) were decreased neutrophil count, decreased lymphocyte count, and decreased platelet count.
- The recommended dose of Jaypirca is 200 mg orally once daily until disease progression or unacceptable toxicity.
- Eli Lilly plans to launch Jaypirca in the coming weeks. Jaypirca will be available as a 50 mg and 100 mg tablet.



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