Jaypirca™ (pirtobrutinib) – New drug approval

- On January 27, 2023, Eli Lilly announced the FDA approval of Jaypirca (pirtobrutinib), 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 American Cancer Society, 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.