Jaypirca® (pirtobrutinib) – New indication

- On December 1, 2023, Eli Lilly announced the FDA approval of Jaypirca (pirtobrutinib), for the treatment of adult patients 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.
    - 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.
- Jaypirca is also approved for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
- The approval of Jaypirca for the new indication was based on BRUIN, an open-label, single-arm, multicohort study in patients with CLL/SLL. Efficacy was based on 108 patients with CLL/SLL treated with Jaypirca who were previously treated with at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. Efficacy was established based on overall response rate (ORR) and duration of response (DOR).
    - The ORR was 72% (95% CI: 63, 80).
    - The median DOR was 12.2 months (95% CI: 9.3, 14.7).
- The recommended dose of Jaypirca for both MCL and CLL/SLL is 200 mg orally once daily until disease progression or unacceptable toxicity.