Calquence® (acalabrutinib) – New indication, accelerated approval converted to traditional approval

- On January 17, 2025, AstraZeneca announced the FDA approval of Calquence (acalabrutinib), **in combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT)**.

- In addition to the new indication, the FDA converted Calquence's accelerated approval to a traditional (full) approval for treatment of adult patients with MCL who have received at least one prior therapy.

- Calquence is also approved for treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

- The approval of Calquence for the new indication was based on ECHO, a randomized, double-blind, placebo-controlled study in 598 patients who were ≥ 65 years of age and who had no intention for transplant. Patients were randomized to Calquence plus bendamustine and rituximab (Calquence plus BR) or placebo plus BR. The major efficacy outcome was progression-free survival (PFS).

    — Median PFS was 66.4 months for Calquence plus BR vs. 49.6 months for placebo plus BR (hazard ratio 0.73, 95% CI: 0.57, 0.94; p = 0.016).
    — The overall response rate was 91% (95% CI: 87, 94) for Calquence plus BR vs. 88% (95% CI: 84, 91) for placebo plus BR.

- For patients with previously untreated MCL, the recommended dosage of Calquence is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

- Refer to the Calquence drug label for dosing for its other indications.