Calquence® (acalabrutinib) – New formulation approval

- On August 5, 2022, AstraZeneca announced the FDA approval of AstraZeneca's Calquence (acalabrutinib) tablet, for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy, and for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
    - Calquence was previously approved as a capsule formulation for the same indications.
- Calquence tablet can be taken with gastric acid-reducing agents, including proton pump inhibitors, antacids and H2-receptor antagonists.
- The ELEVATE-PLUS trials showed Calquence capsule and tablet formulations are bioequivalent, indicating the same efficacy and safety profile can be expected with the same dosing strength and schedule.
- The recommended dose of Calquence as monotherapy is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.
    - Calquence may also be used in combination with Gazyva® (obinutuzumab) for previously untreated CLL or SLL. Refer to the Calquence and Gazyva drug labels for dosing and administration information.
- AstraZeneca's launch plans for Calquence tablet are pending. Calquence will be available as a 100 mg tablet.