Calquence® (acalabrutinib) – New indication

- On November 21, 2019, the FDA announced the approval of AstraZeneca's Calquence (acalabrutinib), for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

- Calquence is also approved for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

- CLL and SLL are cancers of lymphocytes, but they occur in different areas of the body. CLL occurs mainly in the blood and bone marrow, while SLL occurs mainly in the lymph nodes. Symptoms of CLL or SLL include low red blood cell counts, low platelet counts, fatigue, enlarged lymph nodes, and a higher risk of infection.

- The efficacy of Calquence for the treatment of CLL was demonstrated in two randomized, open-label, controlled studies. The indication for Calquence includes patients with SLL because it is the same disease. The first study, ELEVATE-TN, was conducted in 535 patients with previously untreated CLL. Patients received Calquence in combination with Gazyva® (obinutuzumab), Calquence monotherapy, or Gazyva in combination with chlorambucil. Efficacy was based on progression-free survival (PFS).

    - In the Calquence combination arm, risk of disease progression or death was reduced by 90% (hazard ratio [HR] 0.10; 95% CI: 0.06, 0.17; $p < 0.0001$) vs. Gazyva in combination with chlorambucil and in the Calquence monotherapy arm it was reduced by 80% (HR 0.20; 95% CI: 0.13, 0.30; $p < 0.0001$).
    - The median time to disease progression for patients treated with Calquence in combination with Gazyva or as a monotherapy has not yet been reached vs. 22.6 months (95% CI: 20, 28) for Gazyva in combination with chlorambucil.

- The second study, ASCEND, was conducted in 310 patients with relapsed or refractory CLL. Patients received Calquence monotherapy or an investigators choice of Zydelig® (idelalisib) plus a rituximab product or bendamustine plus a rituximab product.

    - In the Calquence arm, risk of disease progression or death was reduced by 69% (HR 0.31; 95% CI: 0.20, 0.49; $p < 0.0001$) vs. the investigator's choice comparator arm.
    - The median time to disease progression for patients treated with Calquence has not yet been reached vs. 16.5 months (95% CI: 14.0, 17.1) for the investigator's choice comparator arm.

- The recommended dose of Calquence for the treatment of CLL or SLL is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

    - Refer to the Calquence drug label for complete dosing recommendations for CLL, SLL, and MCL.
    - Refer to the Gazyva drug label for dosing recommendations when used in combination with Calquence.