Copiktra® (duvelisib) – Drug safety communication

- On June 30, 2022, the FDA announced a warning that results from a clinical trial show a possible increased risk of death with Secura Bio's Copiktra (duvelisib) compared to Arzerra® (ofatumumab) for treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

- In 2018, Copiktra was approved for treatment of adult patients with relapsed or refractory CLL or SLL after at least two prior therapies. The information on survival or risk of death was limited, and the FDA required longer follow-up from the clinical trial to gain more information.

- To evaluate the long-term safety of Copiktra, the FDA required Secura Bio to submit the final 5-year survival results from the DUO trial. DUO is a Phase 3, randomized, open-label study evaluating Copiktra (a PI3K inhibitor) vs. Arzerra (a CD20-directed cytolytic monoclonal antibody) in 319 patients with relapsed or refractory CLL or SLL who received at least one prior line of therapy.

    - With a median of 63 months follow-up, the final overall survival results showed a possible increased risk of death with Copiktra, with a hazard ratio (HR) of 1.09 (95% CI: 0.79, 1.51).
    - Among the subpopulation of patients receiving at least two prior lines of therapy – the FDA approved use – the HR was 1.06 (95% CI: 0.71, 1.58).
    - In addition to the risk of death, the incidence of deaths due to adverse events, serious adverse events, Grade ≥ 3 adverse events, and treatment modifications due to adverse events were higher among patients receiving Copiktra.

- The safety findings for Copiktra were similar for other medicines in the same PI3 kinase inhibitor class, which were discussed at an advisory committee meeting in April 2022.

- The FDA plans to hold a future public meeting to discuss the findings from the clinical trial and whether Copiktra should continue to be prescribed for patients.

- Patients should talk to their health care professional about the risks and benefits of receiving Copiktra.

- Health care professionals should consider the risks and benefits of continuing Copiktra in the context of other available treatments. Patients receiving Copiktra should be advised of the possible increased risk of death and higher risk of serious adverse events.