SFDA

Safety Communication

[28/07/2022]

Possible Increased Risk of Death and Serious Adverse events with Copiktra (duvelisib) Use

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the results from a phase III clinical trial (DUO trial) showing a possible increased risk of death with duvelisib compared to Ofatumumab for leukemia and lymphoma treatment. The trial also found that duvelisib was associated with a higher risk of serious side effects, including infections, diarrhea, colitis, pneumonitis, skin adverse reactions, and increase liver enzyme levels.

The SFDA approved Copiktra (uvelisib), a PI3 kinase inhibitor, for the treatment of adults with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Duvelisib is also indicated for the treatment of adult patients with relapsed or refractory Follicular Lymphoma (FL) after at least two prior systemic therapies. Ofatumumab is a human monoclonal antibody approved for previously untreated chronic lymphocytic leukaemia (CLL) and Refractory CLL. Ofatumumab is intravenous infusion and should be administered under the supervision of a physician experienced in the use of cancer therapy while Duvelisib is administered orally.

DUO trial, is a phase 3, randomized, open-label trial involving 319 patients with CLL or SLL who had previously failed or stopped responding to therapy. With a median of 63 months follow-up, the final analysis of overall survival at 5 years showed a possible increased risk of death with duvelisib, with a hazard ratio of 1.09 (95% confidence interval [CI] 0.79, 1.51). Among the subpopulation of patients receiving at least two prior lines of therapy, the hazard ratio 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 duvelisib. The serious side effects included infections, diarrhea, inflammation of the intestine and lungs, skin reactions, and elevated liver enzyme levels in the blood.

Therefore, the SFDA advices healthcare professionals to consider the risks and benefits of continuing duvelisib in the context of other available treatments. In addition, healthcare professionals should inform patients to seek immediate medical care when they experience any of the aforementioned serious adverse events.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa