Ukoniq® (umbralisib) – Drug safety communication

- On February 3, 2022, the FDA announced that they are investigating a possible increased risk of death with TG Therapeutics' cancer medicine, Ukoniq (umbralisib), approved to treat two specific types of lymphomas (marginal zone lymphoma [MZL] and follicular lymphoma [FL]).

- The FDA determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine.

- Because of the seriousness of this safety concern and the similarities between the two types of cancer for which Ukoniq is approved and the type of cancer that was studied in the clinical trial, the FDA is alerting patients and health care professionals that they are re-evaluating this risk against the benefits of Ukoniq for its approved uses.

- The FDA conducted an initial review of data from UNITY, a phase 3, randomized, controlled clinical trial in patients with chronic lymphocytic leukemia (CLL). The trial is evaluating Ukoniq in combination with a monoclonal antibody drug that targets a specific protein called CD20 compared to the control arm in which patients received standard treatment.

    - The results showed a possible increased risk of death in patients receiving the combination of Ukoniq and the monoclonal antibody compared to the control arm.
    - Those receiving the combination of Ukoniq and the monoclonal antibody also experienced more serious adverse events than those in the control arm.
    - The UNITY trial was conducted in CLL patients, which is not an approved use but rather a use of this drug that is being studied; however, the FDA believes these findings have implications for its approved uses for MZL and FL.
    - In addition, trials of other medicines in the same PI3 kinase inhibitor class as Ukoniq have shown similar safety concerns.

- The FDA is continuing to evaluate the results from the UNITY trial. The FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq. The FDA is also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while we continue to review the UNITY findings.

- Health care professionals should review patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.

- Patients should talk to your health care professionals about the risks and benefits of Ukoniq or any concerns you may have, including about possible alternative treatments.