FDA investigating possible increased risk of death with lymphoma medicine Ukoniq (umbralisib)

Consider risks and benefits of continued use versus other treatments

2-3-2022 FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. We 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 this drug is approved and the type of cancer that was studied in the clinical trial, we are alerting patients and health care professionals that we are re-evaluating this risk against the benefits of Ukoniq for its approved uses.

We are continuing to evaluate the results from the clinical trial called UNITY. FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq. We have also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while we continue to review the UNITY findings. We will communicate our final conclusions and recommendations when we have completed our review or have more information to share.

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.

Ukoniq is a prescription medicine approved in February 2021 to treat adults with marginal zone lymphoma (MZL) when the disease has returned or it did not respond to prior treatment with at least one specific type of medicine. Ukoniq is also approved to treat adults with follicular lymphoma (FL) when the disease has returned or it did not respond to at least three prior treatments. Both MZL and FL are slow-growing cancers that start in white blood cells called lymphocytes, which are part of the body's immune system. Ukoniq, which is in a class of medicines called PI3 kinase inhibitors, works by blocking the action of an abnormal protein that signals cancer cells to multiply, which helps stop their spread. The medicine is available as a tablet to take by mouth.

We 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, we believe these findings have implications for its approved uses for MZL and FL. In addition, clinical trials of other medicines in the same PI3 kinase inhibitor class as Ukoniq have shown similar safety concerns.

We urge health care professionals and patients to report side effects involving Ukoniq or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Health care professionals, patients, and consumers can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Related Information

National Cancer Institute: Lymphoma

National Cancer Institute: Chronic Lymphocytic Leukemia

The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective

Think It Through: Managing the Benefits and Risks of Medicines

Advisory Committees: Critical to the FDA's Product Review Process