Generic Name:
Acalabrutinib
Trade Name:
Calquence
Company:
AstraZeneca
Notes:

As part of Project Orbis, a collaboration with the Australian Therapeutic Goods Administration and Health Canada, FDA approved a new indication for acalabrutinib to treat adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) as an initial or subsequent therapy.

The supplemental approval of acalabrutinib for patients with CLL or SLL was based on two randomized clinical trials that compared acalabrutinib to other standard treatments. The first clinical trial involved 535 patients with previously untreated CLL. Patients receiving acalabrutinib had a longer progression-free survival compared with patients receiving other standard treatments. The second clinical trial included 310 patients with previously treated CLL. Patients receiving acalabrutinib also had a longer progression-free survival than patients receiving other standard treatments.

The most common adverse effects were anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain. Patients may experience atrial fibrillation and flutter and should be monitored for symptoms of arrhythmias. Patients may experience serious infections and should be monitored and treated promptly. Patients should also be monitored for bleeding and managed appropriately. Patients may also experience low blood counts and should have blood work monitored regularly. Patients should be advised to use sun protection as other malignancies, such as skin cancers and other solid tumors, have occurred in patients taking the drug.

FDA advises health professionals to tell females of reproductive age to use effective contraception during treatment. Women who are pregnant or breastfeeding should not take acalabrutinib because it may cause harm to a developing fetus or newborn baby or cause delivery complications.

Medication Monitor Categories:
Supplemental Approvals