Calquence approved to treat CLL, SLL

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(HealthDay)—The U.S. Food and Drug Administration has granted supplemental approval to Calquence (acalabrutinib) for treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma

(SLL), the agency announced Thursday.

Calquence was initially approved in 2017 for treatment of adults with previously treated mantle cell lymphoma. It is now approved as a new treatment option or as an initial or subsequent therapy for adults with CLL or SLL. The latest approval of Calquence is part of Project Orbis, a collaboration among the FDA, the Australian Therapeutic Goods Administration, and Health Canada. Through Project Orbis, oncology drug applications can be concurrently submitted for review among the FDA and its international partners, according to Richard Pazdur, M.D., director of the FDA Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA Center for Drug Evaluation and Research.

The supplemental approval was based on two randomized, clinical trials. The first trial involved 535 patients with previously untreated CLL and the second involved 310 patients with previously treated CLL. In both trials, progression-free survival was longer among patients who received Calquence versus those who received other standard treatments.

The most commonly reported side effects of Calquence include anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain. Patients taking Calquence can experience atrial fibrillation and should be monitored for symptoms of arrhythmias. Patients should also be monitored for serious infections and bleeding and should be treated promptly if bleeding or infection occur. Clinicians should also monitor patients' blood work regularly to check for low blood counts, and they should inform patients to use sun protection because other malignancies, including skin cancer, have occurred in patients taking Calquence.

Approval was granted to AstraZeneca.

More information: More Information