FDA Approves New Treatment for Adults With Mantle Cell Lymphoma

Mantle cell lymphoma is a rare and fast-growing type of non-Hodgkin lymphoma.

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The U.S. Food and Drug Administration today granted accelerated approval to Calquence (acalabrutinib) for the treatment of adults with mantle cell lymphoma who have received at least one prior therapy.

“Mantle cell lymphoma is a particularly aggressive cancer,” said Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research. “For patients who have not responded to treatment or have relapsed, Calquence provides a new treatment option that has shown high rates of response for some patients in initial studies.”

Mantle cell lymphoma is a rare and fast-growing type of non-Hodgkin lymphoma and, according to the National Cancer Institute at the National Institutes of Health, represents 3 to 10 percent of all non-Hodgkin lymphoma cases in the U.S. Mantle cell lymphoma is a cancer of the lymph system, which is part of the body’s immune system and is made up of lymph tissue, lymph nodes, the spleen, thymus, tonsils and bone marrow. By the time mantle cell lymphoma is diagnosed, it usually has spread to the lymph nodes, bone marrow and other organs.

Calquence is a kinase inhibitor that works by blocking an enzyme needed by the cancer to multiply and spread.

Calquence was approved using the Accelerated Approval pathway, under which the FDA may approve drugs for serious conditions where there is unmet medical need and a drug is shown to have certain effects that are reasonably likely to predict a clinical benefit to patients. Further study is required to verify and describe anticipated clinical benefits of Calquence and the sponsor is currently conducting this trial.

Today’s approval of Calquence was based on data from a single-arm trial that included 124 patients with mantle cell lymphoma who had received at least one prior treatment. The trial measured how many patients experienced complete or partial shrinkage of their tumors after treatment (overall response rate). In the trial, 81 percent of patients had a complete or partial response (40 percent complete response, 41 percent partial response).

Common side effects of Calquence include headache; diarrhea; bruising; fatigue and muscle pain (myalgia); and reduced levels of red blood cells (anemia), platelets (thrombocytopenia) and neutrophils (neutropenia) in the blood.

Serious side effects include bleeding (hemorrhage), infections and irregular heartbeat (atrial fibrillation). Additional cancers, known as second primary malignancies, have occurred in some patients taking Calquence. Women who are breastfeeding should not take Calquence because it may cause harm to a newborn baby.

The FDA granted this application Priority Review and Breakthrough Therapydesignations. Calquence also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the accelerated approval of Calquence to AstraZeneca Pharmaceuticals LP.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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