FDA Approves New Treatment for Mantle Cell Lymphoma

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FDA approves therapy to treat patients with relapsed and refractory mantle cell lymphoma supported by clinical trial results showing high response rate of tumor shrinkage

Today, the U.S. Food and Drug Administration granted accelerated approval to Brukinsa (zanubrutinib) capsules for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy.

“Mantle cell lymphoma usually responds well to initial treatment, but eventually returns or stops responding, and the cancer cells continue to grow. This is a life-threatening condition,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research. “Clinical trials showed that 84% of patients saw tumor shrinkage with this therapy. For patients whose disease relapses or becomes refractory, secondary therapies may be successful in providing another remission, and today’s approval will provide patients with another treatment option.”

Mantle cell lymphoma is a type of non-Hodgkin’s lymphoma representing 3-10% of all non-Hodgkin’s lymphomas in the United States. By the time it is diagnosed, mantle cell lymphoma has usually spread to the lymph nodes, bone marrow and other organs. In relapsed lymphoma, the disease reappears or grows again after a period of remission, while in refractory lymphoma, the disease does not respond to treatment or responds only briefly.

A single-arm clinical trial of Brukinsa included 86 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, 84% of patients had tumor shrinkage with a median duration of response (time between the initial response to therapy and subsequent disease progression or relapse) of 19.5 months. This trial was supported by an additional single-arm trial that included 32 patients, in which 84% of patients had tumor shrinkage with a median duration of response of 18.5 months.

Common side effects for patients taking Brukinsa were decreased neutrophil count (white blood cells that fight against infection), decreased platelet count (a component of blood whose function is to react to bleeding from blood vessel injury by clumping, initiating a blood clot), upper

respiratory tract infection, decreased white blood cell count, decreased hemoglobin (oxygen-carrying protein in red blood cells), rash, bruising, diarrhea and cough. During treatment, patients should be monitored for hemorrhage (bleeding), signs and symptoms of infection, cytopenias (decreased complete blood counts) and cardiac arrhythmias (irregular, rapid heart rate and abnormality in beating of the heart). Patients are advised to use sun protection if taking this therapy because there is a risk of other malignancies occurring including skin cancers. The FDA advises health care professionals to tell females of reproductive age and males with a female partner of reproductive potential to use effective contraception during treatment with Brukinsa. Women who are pregnant or breastfeeding should not take Brukinsa because it may cause harm to a developing fetus or newborn baby.

Brukinsa was granted Accelerated Approval, which enables the FDA to approve drugs for serious conditions to fill an unmet medical need based on a result that is reasonably likely to predict a clinical benefit to patients. Further clinical trials may be required to verify and describe Brukinsa's clinical benefit.

The FDA granted this application Breakthrough Therapy designation, which expedites the development and review of drugs that are intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. Brukinsa also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases. The FDA granted approval of Brukinsa to BeiGene USA Inc.

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