Generic Name:
Zanubrutinib
Trade Name:
Brukinsa
Company:
BeiGene USA
Notes:

FDA granted accelerated approval to zanubrutinib to treat adult patients with mantle cell lymphoma who have received at least one prior therapy.

A single-arm clinical trial of zanubrutinib 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 adverse effects for patients taking zanubrutinib were decreased neutrophil count, decreased platelet count, upper respiratory tract infection, decreased white blood cell count, decreased hemoglobin, rash, bruising, diarrhea. and cough. During treatment, patients should be monitored for hemorrhage, signs and symptoms of infection, cytopenias, and cardiac arrhythmias. Patients are advised to use sun protection if taking this therapy because there is a risk of other malignancies, including skin cancers.

FDA advises health professionals to tell females of reproductive age and males with a female partner of reproductive potential to use effective contraception during treatment. Women who are pregnant or breastfeeding should not take zanubrutinib because it may cause harm to a developing fetus or newborn baby.

Medication Monitor Categories:
New Drug Approvals