

US FDA approves expanded use of BeiGene's blood cancer drug

The oral drug, Brukinsa, in combination with Roche's Gazyva was approved to treat relapsed or refractory follicular lymphoma in patients who have received at least two prior lines of treatment.

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The U.S. Food and Drug Administration has granted accelerated approval for the expanded use of BeiGene's combination drug to treat certain patients with a type of blood cancer, the health

regulator said on Thursday.



The oral drug, Brukinsa, in combination with Roche's Gazyva was approved to treat relapsed or refractory follicular lymphoma in patients who have received at least two prior lines of treatment.

The U.S. wholesale acquisition cost for Brukinsa comes at \$15,066 for a 30-day supply, the company said, adding that the drug is priced similarly for all indicated uses.

Follicular lymphoma is a form of cancer that starts in the white blood cells. About six new cases of the cancer are reported in the U.S. per 100,000 people annually, according to government data.

Brukinsa belongs to the same class of drugs as AbbVie's Imbruvica, which target a type of protein called Bruton's tyrosine kinase (BTK) and inhibit the proliferation of malignant B-cells.

Other treatment options for patients with relapsed or refractory follicular lymphoma include cell therapies such as Novartis' Kymriah and Gilead Sciences' Yescarta.

Brukinsa's approval was based on data from a mid-stage study in which the drug's combination with Gazyva helped destroy or significantly reduce cancerous tumors in patients, compared to Gazyva alone.

Brukinsa is approved in the United States to treat four other types of blood cancers and generated global sales of \$1.3 billion last year.

BeiGene said a confirmatory late-stage study was underway, which was needed to secure full U.S. approval.

T.D. Cowen analyst Yaron Werber estimates Brukinsa's peak annual sales in the range of \$3 billion to \$4 billion. (Reporting by Sriparna Roy, Sneha S K and Mariam Sunny in Bengaluru; Editing by Devika Syamnath and Shounak Dasgupta)

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