FDA Approves Cabozantinib for Hepatocellular Carcinoma

Median progression-free survival 5.2 months in cabozantinib arm versus 1.9 months in placebo arms.

January 14, 2019 By Food and Drug Administration (FDA)

On January 14, 2019, the Food and Drug Administration approved cabozantinib (CABOMETYX, Exelixis, Inc.) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

Approval was based on CELESTIAL (NCT01908426), a randomized (2:1), double-blind, placebo-controlled, multicenter trial in patients with HCC who had previously received sorafenib and had Child Pugh Class A liver impairment. Patients were randomized to receive cabozantinib 60 mg orally once daily (n=470) or placebo (n=237) until disease progression or unacceptable toxicity.

The primary efficacy measure was overall survival (OS); additional outcome measures were progression-free survival (PFS) and overall response rate (ORR), as assessed by investigators per RECIST 1.1. Median OS was 10.2 months (95% CI: 9.1,12.0) for patients receiving cabozantinib and 8 months (95% CI: 6.8, 9.4) for those receiving placebo (HR 0.76; 95% CI: 0.63, 0.92; p=0.0049). respectively (HR 0.44; 95% CI: 0.36, 0.52; p<0.001). ORR was 4% (95% CI: 2.3, 6.0) in the cabozantinib arm and 0.4% (95% CI: 0.0, 2.3) in the placebo arm.

The most common adverse reactions in ≥ 25% of patients who received cabozantinib in clinical trials, in order of decreasing frequency, are diarrhea, fatigue, decreased appetite, palmar-plantar erythrodysesthesia, nausea, hypertension, and vomiting.

The recommended cabozantinib dose is 60 mg orally, once daily at least one hour before or 2 hours after eating.

View full prescribing information for CABOMETYX.

FDA granted this application orphan drug designation. Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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This announcement originally appeared on the Food and Drug Administration website.
