Generic Name:
Lenvatinib
Trade Name:
Lenvima
Company:
Eisai Inc.
Notes:

FDA has approved lenvatinib capsules for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).

Approval was based on an international, multicenter, randomized, open-label, noninferiority trial conducted in 954 patients with previously untreated, metastatic or unresectable HCC.

Patients were randomized (1:1) to receive lenvatinib (12 mg orally once daily for patients with a baseline body weight of ?60 kg and 8 mg orally once daily for patients with a baseline body weight of <60 kg) or sorafenib (400 mg orally twice daily). Treatment continued until radiological disease progression or unacceptable toxicity.

The trial demonstrated that lenvatinib was noninferior but not statistically superior to sorafenib for overall survival and a statistically significant improvement in progression-free survival compared with sorafenib. The overall response rate was higher for the lenvatinib arm compared with sorafenib (41% vs. 12% per mRECIST and 19% vs. 7% per RECIST 1.1).

The most common adverse reactions observed in the lenvatinib-treated patients with HCC (?20%) in order of decreasing frequency were hypertension, fatigue, diarrhea, decreased appetite, arthralgia/myalgia, decreased weight, abdominal pain, palmar-plantar erythrodysesthesia syndrome, proteinuria, dysphonia, hemorrhagic events, hypothyroidism, and nausea.

The recommended lenvatinib dosages for patients with HCC are the following: 12 mg orally once daily in patients 60 kg or greater actual body weight or 8 mg orally once daily in patients less than 60 kg actual body weight.

Medication Monitor Categories:
Supplemental Approvals