

Lenvima® (lenvatinib) – New indication

- On August 15, 2018, the <u>FDA announced</u> the approval of <u>Lenvima (lenvatinib)</u>, for the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC).
- Lenvima is also approved for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer; and in combination with <u>Afinitor[®] (everolimus)</u> for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.
- According to the <u>American Cancer Society</u>, about 42,220 new cases of primary liver cancer and intrahepatic bile duct cancer will be diagnosed in 2018, and about 30,200 people will die from these cancers.
- The efficacy of Lenvima for the new indication was demonstrated in a non-inferiority study, which enrolled 954 patients with previously untreated, unresectable HCC. Patients were randomized to Lenvima or Nexavar[®] (sorafenib) until disease progression or unacceptable toxicity. The major efficacy outcome was overall survival (OS).
 - Lenvima was non-inferior to Nexavar for OS. The median OS was 13.6 months for Lenvima vs. 12.3 months for Nexavar (HR = 0.92 [95% CI: 0.79, 1.06]).
 - In addition, the progression-free survival was 7.3 months for Lenvima vs. 3.6 months for Nexavar (HR = 0.64 [95% CI: 0.55, 0.75]; p < 0.001).
 - The objective response rate was 41% for Lenvima vs. 12% for Nexavar (p < 0.001).
- The most common adverse reactions (≥ 20%) with Lenvima use in HCC 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 dosage of Lenvima for HCC is 12 mg for patients ≥ 60 kg or 8 mg for patients <
 60 kg and given orally once daily until disease progression or until unacceptable toxicity.



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