Lenvima® (lenvatinib) – New indication

- On August 15, 2018, the FDA announced the approval of Lenvima (lenvatinib), 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 Afinitor® (everolimus) for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.

- According to the American Cancer Society, 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.