## Cabometyx® (cabozantinib) – New indication

- On January 14, 2019, Exelixis announced the FDA approval of Cabometyx (cabozantinib) tablets, for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib).
    - Cabometyx is also approved for the treatment of patients with advanced renal cell carcinoma.
- HCC is the most common form of liver cancer and the fastest-rising cause of cancer-related death in the U.S.
- The approval of Cabometyx's new indication was based on CELESTIAL, a study in in patients with HCC who had previously received Nexavar and had Child Pugh Class A liver impairment. Patients were randomized to receive Cabometyx or placebo until disease progression or unacceptable toxicity. The primary efficacy outcome measure was overall survival (OS). Additional outcome measures were progression-free survival (PFS) and objective response rate (ORR).
    - Median OS was 10.2 months (95% CI: 9.1, 12.0) with Cabometyx vs. 8.0 months (95% CI: 6.8, 9.4) with placebo (HR 0.76, 95% CI: 0.63, 0.92; p = 0.0049).
    - Median PFS was 5.2 months (95% CI: 4.0, 5.5) with cabozantinib vs. 1.9 months (95% CI: 1.9, 1.9) with placebo (HR 0.44, 95% CI: 0.36, 0.52; p < 0.0001).
    - ORR was 4% (95% CI: 2.3, 6.0) with cabozantinib vs. 0.4% (95% CI: 0.0, 2.3) with placebo (p = 0.0086).
- In addition to the new indication, the *Warnings and Precautions* section of the labeling was updated to include proteinuria, osteonecrosis of the jaw, and wound complications.
- The recommended dosage of Cabometyx for both indications is 60 mg orally once daily without food until disease progression or unacceptable toxicity.
    - Cabometyx should be administered at least 1 hour before or at least 2 hours after eating.
    - Cabometyx tablets should not be substituted with Cometriq® (cabozantinib) capsules.