Cabometyx® (cabozantinib) – Expanded indication

- On December 19, 2017, Exelixis announced the FDA approval of Cabometyx (cabozantinib) for the treatment of patients with advanced renal cell carcinoma (RCC).
    - Previously, Cabometyx was only approved for use in patients who have received prior anti-angiogenic therapy.
- RCC is one of the most common forms of cancer in the U.S. Approximately 30,000 patients in the U.S. require treatment, and an estimated 14,000 patients in the U.S. each year are in need of first-line treatment for advanced kidney cancer.
- Efficacy to support the expanded indication was based on data from a phase 2 trial of 157 patients with advanced RCC who have not received prior therapy. Patients were randomized to Cabometyx or Sutent® (sunitinib). The primary endpoint was progression free survival (PFS).
    - A statistically significant improvement in PFS was demonstrated with Cabometyx vs. Sutent (HR = 0.48; 95% CI: 0.31, 0.74, p = 0.0008).
    - The median PFS was 8.6 months for Cabometyx vs. 5.3 months with Sutent.
    - There was no difference in overall survival between the two groups (HR = 0.80; 95% CI: 0.53, 1.21).
- The recommended oral daily dose of Cabometyx is 60 mg.
    - Cabometyx should not be administered with food. Patients should not eat for at least 2 hours before and at least 1 hour after taking Cabometyx.
    - Cabometyx tablets should not be substituted with Cometriq™ (cabozantinib) capsules.