Cabometyx® (cabozantinib) – New indication

- On September 17, 2021, Exelixis announced the FDA approval of Cabometyx (cabozantinib), for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

- Cabometyx is also approved for:

  - Treatment of patients with advanced renal cell carcinoma (RCC)
  - First-line treatment of patients with advanced RCC in combination with Opdivo® (nivolumab)
  - Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib).

- Approximately 44,000 new cases of thyroid cancer will be diagnosed in the U.S. in 2021 and DTC make up about 90% of cases. DTC is typically treated with surgery followed by ablation of the remaining thyroid tissue with radioiodine, but approximately 5% to 15% of cases are resistant to radioiodine treatment.

- The approval of Cabometyx for the new indication was based on COSMIC-311, a randomized, double-blind, placebo-controlled study in patients with locally advanced or metastatic DTC that had progressed following prior VEGFR-targeted therapy and were radioactive iodine-refractory or ineligible. Patients were randomized to Cabometyx or placebo with supportive care until disease progression or unacceptable toxicity. The primary efficacy outcome measures were progression-free survival (PFS) and overall response rate (ORR). The primary analysis included 187 randomized patients. An updated analysis was performed and included 258 randomized patients.

  - In the primary analysis, median PFS was not reached for Cabometyx vs. 1.9 months for placebo (hazard ratio [HR] 0.22, 95% CI: 0.14, 0.35; $p < 0.0001$). ORR was 15% (95% CI: 7, 26) vs. 0% (95% CI: 0.0, 11), respectively ($p = 0.0281$).
  - In the updated analysis, median PFS was 11.0 months for Cabometyx vs. 1.9 months for placebo (HR 0.22, 95% CI: 0.15, 0.31). ORR was 18% (95% CI: 10, 29) vs. 0% (95% CI: 0.0, 11), respectively.

- For DTC, the recommended dosage of Cabometyx as a single agent for adult and pediatric patients 12 years of age and older with body surface area (BSA) greater than or equal to 1.2 m^2 is 60 mg orally once daily until disease progression or unacceptable toxicity. The recommended dosage in pediatric patients 12 years of age and older with BSA less than 1.2 m^2 is 40 mg once daily until disease progression or unacceptable toxicity.

  - Cabometyx treatment should be stopped at least 3 weeks prior to scheduled surgery, including dental surgery.
  - Cabometyx tablets should NOT be substituted with cabozantinib capsules (Cometriq®).

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— Refer to the Cabometyx drug label for dosing in RCC and HCC.

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