

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 m² 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 m² 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[®]](#)).

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



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