FDA Grants Regular Approval to Cabometyx for First-Line Treatment of Advanced Renal Cell Carcinoma

New approval allows Cabometyx (cabozantinib) for first-line kidney cancer treatment.

December 19, 2017 By Food and Drug Administration (FDA)

On December 19, 2017, the Food and Drug Administration granted regular approval to cabozantinib (Cabometyx, Exelixis, Inc.) for treatment of patients with advanced renal cell carcinoma (RCC).

The FDA previously approved Cabometyx in 2016 for treatment of patients with advanced RCC who have received prior anti-angiogenic therapy. Today's approval provides for treatment in the first-line setting.

This approval was based on data from CABOSUN (NCT01835158), a randomized, open-label phase 2 multicenter study in 157 patients with intermediate and poor-risk previously untreated RCC. Patients received Cabometyx (n=79) 60 mg orally daily or sunitinib (N=78) 50 mg orally daily (4 weeks on treatment followed by 2 weeks off) until disease progression or unacceptable toxicity. Estimated median progression-free survival (as assessed by blinded independent radiology review committee) for patients taking Cabometyx was 8.6 months (95% CI: 6.8, 14.0) compared with 5.3 months (95% CI: 3.0, 8.2) for patients taking sunitinib (Hazard ratio 0.48; 95% CI: 0.31, 0.74; p=0.0008).

The most commonly reported (≥25%) adverse reactions in the Cabometyx clinical program are diarrhea, fatigue, nausea, decreased appetite, hypertension, palmar-plantar erythrodysesthesia, weight decreased, vomiting, dysgeusia, and stomatitis.

The most frequent grade 3-4 adverse reactions (≥5%) in patients treated with Cabometyx on CABOSUN were hypertension, diarrhea, hyponatremia, hypophosphatemia, PPE, fatigue, ALT increased, decreased appetite, stomatitis, pain, hypotension, and syncope.

The recommended dose of Cabometyx is 60 mg orally, once daily.

Cabozantinib is also approved for the treatment of medullary thyroid cancer and is marketed under the trade name Cometriq. Cometriq and Cabometyx have different formulations and are not interchangeable.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208692s002lbl.pdf.

FDA granted priority review to Cabometyx for this application. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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