

# Clinical Review of CABOMETRYX: A Treatment Standard for Advanced Renal Cell Carcinoma\*

\*After anti-angiogenic therapy

**Date:** Wednesday, October 4, 2017

**Presented by:** Nitin Rohatgi, MD, MBA

**Time:** 6:30 PM

Sutter Medical Groups, Medical Director,  
Breast Cancer Program  
Sacramento, CA

**Location:** Le Pappilon

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## Register for this program today!

Program is intended for healthcare professionals including: Oncologists, NPs, PAs, RNs, Pharmacists, Medical Assistants.  
Program is not intended for non-healthcare professionals, including guests or spouses.

### Indication:

CABOMETRYX™ is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

Please see Important Safety Information on the following page and full Prescribing Information at this presentation and at <https://cabometryx.com/downloads/cabometryxuspi.pdf>.

Contact your local sales representative if you have any questions regarding this program.

### REGISTRATION:

1. RSVP to  
**Jack Ciullo**  
925-890-2999  
jciullo@exelixis.com
2. Or Register Online at <http://bit.ly/2hKijLQ>
3. Or you may complete the registration form below and fax it to 888-269-4201

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## Important Safety Information

### WARNINGS AND PRECAUTIONS

- **Severe hemorrhage** occurred with CABOMETRYX. Grade  $\geq 3$  hemorrhagic events occurred in 2.1% of CABOMETRYX patients vs 1.6% of everolimus patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETRYX to patients that have or are at risk for severe hemorrhage.
- **Gastrointestinal (GI) perforations and fistulas** were reported. Fistulas were reported in 1.2% (with 0.6% anal fistula) of CABOMETRYX patients vs 0% of everolimus patients. GI perforations were reported in 0.9% of CABOMETRYX patients vs 0.6% of everolimus patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms. Discontinue CABOMETRYX in patients who experience a fistula that cannot be appropriately managed or a GI perforation.
- **Thrombotic events** increased with CABOMETRYX. Venous thromboembolism (7.3% CABOMETRYX vs 2.5% everolimus), pulmonary embolism (3.9% CABOMETRYX vs 0.3% everolimus), and arterial thromboembolism events (0.9% CABOMETRYX vs 0.3% everolimus) were reported. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETRYX in patients who develop an acute myocardial infarction, cerebral infarction, or other serious arterial thromboembolic complication.
- **Hypertension and hypertensive crisis** occurred with CABOMETRYX. Treatment-emergent hypertension increased with CABOMETRYX. Hypertension was reported in 37% (15% grade  $\geq 3$ ) of CABOMETRYX patients vs 7.1% (3.1% grade  $\geq 3$ ) of everolimus patients. Monitor blood pressure prior to initiation and regularly during CABOMETRYX treatment. Withhold CABOMETRYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETRYX at a reduced dose. Discontinue CABOMETRYX for hypertensive crisis or severe hypertension that cannot be controlled with antihypertensive therapy or medical management.
- **Diarrhea** occurred in 74% (11% grade 3) of CABOMETRYX patients vs 28% (2% grade 3) of everolimus patients. Withhold CABOMETRYX in patients who develop intolerable grade 2 diarrhea or grade 3-4 diarrhea that cannot be managed with standard antidiarrheal treatments until improvement to grade 1; resume CABOMETRYX at a reduced dose.
- **Palmar-plantar erythrodysesthesia (PPES)** occurred in 42% (8.2% grade 3) of CABOMETRYX patients vs 6% (<1% grade 3) of everolimus patients. Withhold CABOMETRYX in patients who develop intolerable grade 2 PPES or grade 3 PPES until improvement to grade 1; resume CABOMETRYX at a reduced dose.
- **Reversible posterior leukoencephalopathy syndrome (RPLS)**, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETRYX in patients who develop RPLS.
- **Embryo-fetal toxicity** may be associated with CABOMETRYX. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during CABOMETRYX treatment and for 4 months after the last dose.

### ADVERSE REACTIONS

- The most commonly reported ( $\geq 25\%$ ) adverse reactions were diarrhea, fatigue, nausea, decreased appetite, PPES, hypertension, vomiting, weight decreased, and constipation.

### DRUG INTERACTIONS

- Avoid **strong CYP3A4 inhibitors**. Reduce the dosage of CABOMETRYX if concomitant use with strong CYP3A4 inhibitors cannot be avoided.
- Avoid **strong CYP3A4 inducers**. Increase the dosage of CABOMETRYX if concomitant use with strong CYP3A4 inducers cannot be avoided.

### USE IN SPECIFIC POPULATIONS

- Advise a **lactating** woman not to breastfeed during CABOMETRYX treatment and for 4 months after the final dose.
- In patients with mild to moderate **hepatic impairment**, reduce the CABOMETRYX dosage. CABOMETRYX is not recommended for use in patients with severe hepatic impairment.

Please see accompanying full Prescribing Information at <https://cabometryx.com/downloads/cabometryxuspi.pdf>.

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