

Clinical Review of CABOMETYX: A Treatment Standard for Advanced Renal Cell Carcinoma*

*After anti-angiogenic therapy

Date: Wednesday, July 12, 2017

Presented by: Nancy Moldawer, RN, MSN

Time: 6:00 PM

Cedars-Sinai Medical Center
Los Angeles, CA

Location: Il Fornaio

Hosted by: Marsha Sokoloff

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Register for this program today!

Program is intended for healthcare professionals including: Oncologists, NPs, PAs and RNs.

Program is not intended for non-healthcare professionals, including guests or spouses.

Indication:

CABOMETYX™ 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.

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

REGISTRATION:

1. RSVP to
Marsha Sokoloff
415-734-0690
msokoloff@exelixis.com
2. Or Register Online at <http://bit.ly/2te4HZZ>
3. Or you may complete the registration form below and fax it to 888-269-4201

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	Program 421		
License Number (only if licensed in MA or MN)	Meeting Code		

IMPORTANT SAFETY INFORMATION

Hemorrhage: Severe hemorrhage occurred with CABOMETYX™. The incidence of Grade ≥ 3 hemorrhagic events was 2.1% in CABOMETYX™-treated patients and 1.6% in everolimus-treated patients. Fatal hemorrhages also occurred in the cabozantinib clinical program. Do not administer CABOMETYX™ to patients that have or are at risk for severe hemorrhage.

Gastrointestinal (GI) Perforations and Fistulas: Fistulas were reported in 1.2% (including 0.6% anal fistula) of CABOMETYX™-treated patients and 0% of everolimus-treated patients. GI perforations were reported in 0.9% of CABOMETYX™-treated patients and 0.6% of everolimus-treated patients. Fatal perforations occurred in the cabozantinib clinical program. Monitor patients for symptoms of fistulas and perforations. Discontinue CABOMETYX™ in patients who experience a fistula that cannot be appropriately managed or a GI perforation.

Thrombotic Events: CABOMETYX™ treatment results in an increased incidence of thrombotic events. Venous thromboembolism was reported in 7.3% of CABOMETYX™-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.9% of CABOMETYX™-treated patients and 0.3% of everolimus-treated patients. Events of arterial thromboembolism were reported in 0.9% of CABOMETYX™-treated patients and 0.3% of everolimus-treated patients. Fatal thrombotic events occurred in the cabozantinib clinical program. Discontinue CABOMETYX™ in patients who develop an acute myocardial infarction or any other arterial thromboembolic complication.

Hypertension and Hypertensive Crisis: CABOMETYX™ treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥ 3) of CABOMETYX™-treated patients and 71% (31% Grade ≥ 3) of everolimus-treated patients. Monitor blood pressure prior to initiation and regularly during CABOMETYX™ treatment. Withhold CABOMETYX™ for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX™ at a reduced dose. Discontinue CABOMETYX™ for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX™ if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

Diarrhea: Diarrhea occurred in 74% of patients treated with CABOMETYX™ and in 28% of patients treated with everolimus. Grade 3 diarrhea occurred in 11% of CABOMETYX™-treated patients and in 2% of everolimus-treated patients. Withhold CABOMETYX™ 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 CABOMETYX™ at a reduced dose. Dose modification due to diarrhea occurred in 26% of patients.

Palmar-Plantar Erythrodysesthesia Syndrome (PPES): PPES occurred in 42% of patients treated with CABOMETYX™ and in 6% of patients treated with everolimus. Grade 3 PPES occurred in 8.2% of CABOMETYX™-treated patients and in <1% of everolimus-treated patients. Withhold CABOMETYX™ in patients who develop intolerable Grade 2 PPES or Grade 3 PPES until improvement to Grade 1; resume CABOMETYX™ at a reduced dose. Dose modification due to PPES occurred in 16% of patients.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in the cabozantinib clinical program. Perform an evaluation for RPLS in any patient presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX™ in patients who develop RPLS.

Embryo-fetal Toxicity: CABOMETYX™ can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX™ and for 4 months after the last dose.

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

Drug Interactions: Strong CYP3A4 inhibitors and inducers: Reduce the dosage of CABOMETYX™ if concomitant use with strong CYP3A4 inhibitors cannot be avoided. Increase the dosage of CABOMETYX™ if concomitant use with strong CYP3A4 inducers cannot be avoided.

Lactation: Advise a lactating woman not to breastfeed during treatment with CABOMETYX™ and for 4 months after the final dose.

Reproductive Potential: Contraception—Advise females of reproductive potential to use effective contraception during treatment with CABOMETYX™ and for 4 months after the final dose. Infertility — CABOMETYX™ may impair fertility in females and males of reproductive potential.

Hepatic Impairment: Reduce the CABOMETYX™ dose in patients with mild (Child-Pugh score [C-P] A) or moderate (C-P B) hepatic impairment. CABOMETYX™ is not recommended for use in patients with severe hepatic impairment.

Please see full Prescribing Information

<https://hcp.cabometyx.com/downloads/CABOMETYXUSPI.pdf>

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