



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

*After anti-angiogenic therapy

Date: Thursday, March 30, 2017

Time: 6:00 PM

Location: Le Papillon

410 Saratoga Avenue
San Jose, CA 95129

Presented by: Sachdev Thomas, MD

Hosted by: Jack Ciullo

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

Full Name	Credentials	Title	State	Zip Code
Institution		City	State	Zip Code
Email Address		Phone		
License Number (only if licensed in MA or MN)		Program 377		
		Meeting Code		



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IMPORTANT SAFETY INFORMATION

Hemorrhage: Severe hemorrhage occurred with CABOMETYX™. The incidence of Grade 3+ hemorrhagic events was 21% in CABOMETYX™-treated patients and 10% in everolimus-treated patients. Adverse hemorrhagic events were reported in 21% of CABOMETYX™-treated patients and 10% of everolimus-treated patients. Discontinue CABOMETYX™ in 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 GI perforations were reported in 0.9% of CABOMETYX™-treated patients. 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. Thrombotic events were reported in 7.3% of CABOMETYX™-treated patients and 2.5% of everolimus-treated patients. Pulmonary embolism occurred in 3.0% 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 Hypotensive Crisis: CABOMETYX™ treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (0.5% Grade 3+) of CABOMETYX™-treated patients and 7% (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+ diarrhea that cannot be managed with medical management. Discontinue CABOMETYX™ if Grade 3 diarrhea persists 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 6.2% of CABOMETYX™-treated patients and 0.6% 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 characterized by subcortical white matter edema, diagnosed by characteristic findings on MRI, occurred in 1.2% of CABOMETYX™-treated patients. Conduct 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 pregnant women. Advise pregnant women to use effective contraception during treatment with CABOMETYX™ and for 4 months after the last dose.

Adverse Reactions: The most commonly reported (≥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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