NOW APPROVED

CABOMETYX™ (cabozantinib) tablets

60 mg | 40 mg | 20 mg

Join us to discuss a New Oral Treatment Option for Advanced RCC After Anti-Angiogenic Therapy

Register for this program today!*

Date: Saturday, October 1, 2016

Time: 7:15 AM

Location: Advances in Oncology Conference
Hyatt Regency ~ Regency Ballroom
1209 L Street
Sacramento, CA 95814

Presented by: Sachdev Thomas, MD

Hosted by: Exelixis, Inc.

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.

To RSVP for this program:

Please complete the information below and submit via one of the following channels:

E-mail: Exelixis@inventivhealth.com
Fax: 888-269-4201
Call: 972-692-2078

Full Name | Credentials | Title

Institution | City | State | Zip Code

Email Address | Phone

License Number (only if licensed in MA or MN) | Program 10 Meeting Code

*Program is intended for HCPs including: Oncologists, NPs, PAs, and RNs

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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 7.1% (3.1% 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 (≥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.

Minnesota, Vermont, the **Department of Defense,** and the **Department of Veterans Affairs** have restrictions on receiving in-kind benefits (eg, meals, valet parking) at company-sponsored events. You are accountable for understanding such restrictions and complying with them. If you are licensed in or affiliated with any of these states or federal agencies, Exelixis policies may restrict you from consuming any portion of the Exelixis-sponsored meal at this program or from receiving any other in-kind benefit from Exelixis (eg, valet parking) in connection with the program.

For all program attendees who receive Exelixis's in-kind benefits at this program, Exelixis will report the attendee's name and the value received as required by federal and state disclosure laws.

The meal cost may vary by event location and be up to $135 per person (exceptions may apply).

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