

You are cordially invited to attend an educational presentation at PRIMO titled:

# CABOMETYX® + OPDIVO® : A Combination Treatment for 1L Patients With Advanced Renal Cell Carcinoma

## OBJECTIVES

Describe the efficacy, safety/tolerability, and dosing information for CABOMETYX + OPDIVO in first-line aRCC in various risk groups

Understand the primary analysis, the 4-year minimum follow-up, exploratory quality of life, and sites of metastasis data in the CHECKMATE-9ER trial

Outline the recommended dosing approach and adverse event management in patients receiving CABOMETYX + OPDIVO



### PRESENTED BY:

**Sandy Liu, MD**

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Irvine, CA



### DATE & TIME:

Friday, February 7, 2025  
11:15 AM - 12:00 PM HST



### LOCATION:

Alohilani Resort Waikiki Beach  
Room: Stingray  
2490 Kalākaua Ave  
Honolulu, HI 96815

### TO RSVP:

Register Online at: <https://sphase.info/exe01354>

Session is Non-CME



Due to changes in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code, beginning 1/1/2022, Alcoholic Beverages will no longer be provided by Exelixis, Inc.

### INDICATIONS

CABOMETYX (cabozantinib), in combination with nivolumab, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

CABOMETYX is indicated for the treatment of patients with advanced RCC.

### IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

**Hemorrhage:** Severe and fatal hemorrhages occurred with CABOMETYX. Discontinue CABOMETYX for Grade 3-4 hemorrhage and before surgery. Do not administer to patients who have a recent history of hemorrhage, including hemoptysis, hematemesis, or melena.

Please see Important Safety Information on the following page and full Prescribing Information provided or at <https://www.cabometryx.com/downloads/CABOMETRYXUSPI.pdf>.

Please note: Your e-mail address is required for registration. The information you provide will only be used to facilitate your attendance at this program.

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

Acceptance of a meal provided by Exelixis is an in-kind benefit and requires participants to be present for the entirety of this educational program. Participants attending virtual programs are encouraged to be on their webcam for the entirety of the program\* to ensure attendance and participation.

\*Does not apply to product theater programs.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

**Perforations and Fistulas:** Fistulas, including fatal cases, and gastrointestinal (GI) perforations, including fatal cases, occurred in CABOMETYX patients. Monitor for signs and symptoms and discontinue in patients with Grade 4 fistulas or GI perforation.

**Thrombotic Events:** CABOMETYX increased the risk of thrombotic events. Fatal thrombotic events have occurred. Discontinue CABOMETYX in patients who develop an acute myocardial infarction or serious arterial or venous thromboembolic events.

**Hypertension and Hypertensive Crisis:** CABOMETYX can cause hypertension including hypertensive crisis. Monitor blood pressure regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled; when controlled, resume at a reduced dose. Permanently discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy or for hypertensive crisis.

**Diarrhea:** Diarrhea may be severe. Monitor and manage patients using antidiarrheals as indicated. Withhold CABOMETYX until improvement to  $\leq$  Grade 1, resume at a reduced dose.

**Palmar-Plantar Erythrodysesthesia (PPE):** Withhold CABOMETYX until PPE resolves or decreases to Grade 1 and resume at a reduced dose for intolerable Grade 2 PPE or Grade 3 PPE.

**Hepatotoxicity:** CABOMETYX in combination with nivolumab can cause hepatic toxicity with higher frequencies of Grades 3 and 4 ALT and AST elevations compared to CABOMETYX alone. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider withholding CABOMETYX and/or nivolumab, initiating corticosteroid therapy, and/or permanently discontinuing the combination for severe or life-threatening hepatotoxicity.

**Adrenal Insufficiency:** CABOMETYX in combination with nivolumab can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold CABOMETYX and/or nivolumab and resume CABOMETYX at a reduced dose depending on severity.

**Proteinuria:** Monitor urine protein regularly during CABOMETYX treatment. For Grade 2 or 3 proteinuria, withhold CABOMETYX until improvement to  $\leq$  Grade 1 proteinuria; resume CABOMETYX at a reduced dose. Discontinue CABOMETYX in patients who develop nephrotic syndrome.

**Osteonecrosis of the Jaw (ONJ):** Perform an oral examination prior to CABOMETYX initiation and periodically during treatment. Advise patients regarding good oral hygiene practices. Withhold CABOMETYX for at least 3 weeks prior to scheduled dental surgery or invasive dental procedures. Withhold CABOMETYX for development of ONJ until complete resolution, resume at a reduced dose.

**Impaired Wound Healing:** Withhold CABOMETYX for at least 3 weeks prior to elective surgery. Do not administer for at least 2 weeks after major surgery and until adequate wound healing. The safety of resumption of CABOMETYX after resolution of wound healing complications has not been established.

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS):** RPLS can occur with CABOMETYX. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue CABOMETYX in patients who develop RPLS.

**Thyroid Dysfunction:** Thyroid dysfunction, primarily hypothyroidism, has been observed with CABOMETYX. Assess for signs of thyroid dysfunction prior to the initiation of CABOMETYX and monitor for signs and symptoms during treatment.

**Hypocalcemia:** Monitor blood calcium levels and replace calcium as necessary during treatment. Withhold and resume at reduced dose upon recovery or permanently discontinue CABOMETYX depending on severity.

**Embryo-Fetal Toxicity:** CABOMETYX can cause fetal harm. Advise pregnant women of the potential risk to fetus. Verify pregnancy status and advise use of effective contraception during treatment and for 4 months after last dose.

### ADVERSE REACTIONS

The most common ( $\geq 20\%$ ) adverse reactions are:

CABOMETYX as a single agent: diarrhea, fatigue, PPE, decreased appetite, hypertension, nausea, vomiting, weight decreased, and constipation.

CABOMETYX in combination with nivolumab: diarrhea, fatigue, hepatotoxicity, PPE, stomatitis, rash, hypertension, hypothyroidism, musculoskeletal pain, decreased appetite, nausea, dysgeusia, abdominal pain, cough, and upper respiratory tract infection.

### DRUG INTERACTIONS

**Strong CYP3A4 Inhibitors:** If coadministration with strong CYP3A4 inhibitors cannot be avoided, reduce the CABOMETYX dosage. Avoid grapefruit or grapefruit juice.

**Strong CYP3A4 Inducers:** If coadministration with strong CYP3A4 inducers cannot be avoided, increase the CABOMETYX dosage. Avoid St. John's wort.

### USE IN SPECIFIC POPULATIONS

**Lactation:** Advise women not to breastfeed during CABOMETYX treatment and for 4 months after the final dose.

**Hepatic Impairment:** In patients with moderate hepatic impairment, reduce the CABOMETYX dosage. Avoid CABOMETYX in patients with severe hepatic impairment.

Please see accompanying full [Prescribing Information](#) for additional important safety information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.

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For all program attendees who receive 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.

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 **CABOMETYX**® + **OPDIVO**  
(cabozantinib) tablets (nivolumab)