

You are cordially invited to attend an educational presentation Practical Recommendations in Immuno & Molecular Oncology (PRIMO) titled:

Understanding Differentiated Thyroid Cancer (DTC) and Treatment Considerations for CABOMETYX[®] (cabozantinib)

CABOMETYX is indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

OBJECTIVES

Review the indication and Important Safety Information for CABOMETYX

Review the COSMIC-311 clinical trial data, dosing, and administration for CABOMETYX

Present a case and review treatment of a hypothetical patient with progressive radioactive iodine-refractory (RAI-R) DTC

PRESENTED BY:

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DATE & TIME:

Thursday, February 8, 2024
9:00 AM - 9:45 AM HT



LOCATION:

The Royal Sonesta Kaua'i Resort Lihue
3610 Rice St
Lihue, HI 96766
Room: Puna Ballroom | Nawiliwili Room

TO RSVP:

Register Online at: <https://sphase.info/exe00919>



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.

INDICATION

CABOMETYX is indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

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.

Patients should be assessed for signs of thyroid dysfunction prior to the initiation of CABOMETYX and monitored for signs and symptoms of thyroid dysfunction during CABOMETYX treatment. Thyroid function testing and management of dysfunction should be performed as clinically indicated.

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.

Pediatric Use: Monitor open growth plates in adolescent patients (12 years and older with DTC). Consider interrupting or discontinuing CABOMETYX if abnormalities occur.

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 or call 1-800-FDA-1088.

Minnesota, Vermont, the Department of Defense, the Department of Veterans Affairs, and certain other states and institutions have restrictions on receiving in-kind benefits (e.g., meals, valet parking) at company-sponsored events. You are accountable for understanding and complying with such restrictions. If you are licensed in or affiliated with any of these states, federal agencies, or institutions, 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 (e.g., valet parking) in connection with the program.

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.

This program is not certified for Continuing Medical Education credit.