

BC Cancer Protocol Summary for Therapy for Metastatic Renal Cell Carcinoma Using Cabozantinib

Protocol Code

GUCABO

Tumour Group

Genitourinary

Contact Physician

Dr. C. Kollmannsberger

ELIGIBILITY:

- Metastatic renal cell carcinoma
- Any histology or IMDC risk group
- Second-line therapy after first-line tyrosine kinase inhibitor (SUNITinib, SORAFenib, or PAZOpanib)
OR
- Third-line therapy after first-line tyrosine kinase inhibitor and second-line immunotherapy
OR
- Third-line therapy after first-line immunotherapy and second-line tyrosine kinase inhibitor, or after everolimus (UGUEVER) or axitinib (UGUAXI) if intolerant to everolimus or axitinib
- Patients are eligible to receive everolimus (UGUEVER) OR axitinib (UGUAXIT) OR cabozantinib (GUCABO) but not sequential use of these agents except for intolerance or contraindications.

EXCLUSIONS:

- Pregnancy
- Uncontrolled hypertension

TESTS:

- Baseline: CBC, differential, platelets, sodium, potassium, creatinine, total protein, albumin, bilirubin, alkaline phosphatase, urine analysis, uric acid, TSH.
- Before each cycle: CBC, differential and platelets, urine analysis, creatinine, uric acid, ALT, bilirubin. TSH every other cycle or if clinically indicated.
- MUGA scan or echocardiogram if clinically indicated or if history of cardiac problems

PREMEDICATIONS:

Antiemetic protocol for moderate emetogenic chemotherapy protocols (see SCNAUSEA)

TREATMENT:

| Drug | Dose | BC Cancer Administration Guideline |
|--------------|-------|------------------------------------|
| cabozantinib | 60 mg | PO daily |

Duration: Continuous treatment, one cycle consists of 4 weeks of cabozantinib.
Dispense 30 day supply

DOSE MODIFICATIONS:

Reduce dose to 40 mg once daily for mild or moderate hepatic impairment. .

PRECAUTIONS:

1. **Diarrhea:** Consider dose reduction with severe diarrhea or short treatment breaks, if necessary.
2. **Drug Interaction:** Consider potential drug interactions with cytochrome P450 3A4 interacting agents.
3. **Hypertension:** cabozantinib can cause a rapid onset of high blood pressure. Temporary suspension of cabozantinib is recommended for patients with severe hypertension (greater than 200 mmHg systolic or greater than 110 mmHg diastolic). Treatment with cabozantinib may be resumed once hypertension is controlled (see also <http://www.hypertension.ca>). It is recommended that for at least the first 2 cycles of treatment patients monitor their blood pressure daily (home measurements, GP's office, etc.) and keep a journal of their blood pressure measurements that can be submitted to the physician.

Call Dr. Kollmannsberger or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

References:

1. Cella D, Escudier B, Tannir NM, et al. Quality Life outcomes for Cabozantinib versus everolimus in patients with metastatic renal cell carcinoma: METEOR Phase III Randomized Trial. J Clin Oncol. 2018; 36(8):757-764
2. Choueiri TK, Escudier B, Powles T, et al. METEOR investigators. Cabozantinib versus everolimus in advanced renal-cell carcinoma. N Engl J Med 2015; 373:1814-23.
3. Choueiri TK, Escudier B, Powles T, et al. METEOR investigators. Cabozantinib versus everolimus in advanced renal cell carcinoma (METEOR): final results from a randomized, open-label phase 3 trial. Lancet Oncol. 2016; 17(7):917-927