

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

Protocol Code

GUAXIT

Tumour Group

Genitourinary

Contact Physician

Dr. C. Kollmannsberger

ELIGIBILITY:

- Metastatic renal cell carcinoma
- Any histology or IMDC risk group
- After failure of first-line tyrosine kinase inhibitor therapy (SUNItinib, SORAFenib, or PAZOpanib) OR after failure of first-line immunotherapy OR
- Intolerance or contraindication to everolimus (UGUEVER)*

* Patients are eligible to receive everolimus (UGUEVER) OR aXitinib (UGUAXIT) but not sequential use of these agents except for intolerance or contraindications.

EXCLUSIONS:

- Pregnancy
- Significant cardiovascular disease and/or LVEF less than 40%
- 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 low emetogenic chemotherapy protocols (see [SCNAUSEA](#))

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
aXitinib	5 mg twice daily May escalate to maximum of 10 mg twice daily	PO

Note: 4 weeks of treatment comprise 1 cycle.

DOSE MODIFICATIONS:

May reduce dose to 2 to 4 mg twice daily if needed for toxicity management.

PRECAUTIONS:

1. **Diarrhea:** Consider dose reduction with severe diarrhea or short treatment breaks, if necessary.
2. **Hepatic dysfunction:** Consider a 50% dose reduction with moderate hepatic impairment (Child-Pugh class B).
3. **Drug Interaction:** Consider potential drug interactions with cytochrome P450 3A4 interacting agents.
4. **Hypertension:** aXitinib can cause a rapid onset of high blood pressure. Temporary suspension of aXitinib is recommended for patients with severe hypertension (greater than 200 mmHg systolic or greater than 110 mmHg diastolic). Treatment with aXitinib 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:

Motzer RJ, et al. Axitinib versus sorafenib as second-line treatment for advanced renal cell carcinoma: overall survival analysis and updated results from a randomised phase 3 trial. *Lancet Oncol* 2013;14:552-62.

APPENDIX – Renal Cell Carcinoma Funding Algorithm

