BC Cancer Protocol Summary for the Treatment of Metastatic or Locally Advanced Basal Cell Carcinoma Using Vismodegib

Protocol Code	*SMAVVIS*
Tumour Group	*Skin and Melanoma*
Contact Physician	*Dr. Kerry Savage*

ELIGIBILITY:

Patients must have:

- Metastatic basal cell carcinoma, or
- Locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy
- Referral to medical oncologists
- Registration of the prescribing physician, pharmacy, dispensing pharmacists and patients with the ERIVEDGE Pregnancy Prevention Program (www.erivedge.ca)

EXCLUSIONS:

- Pregnant or at risk of becoming pregnant (see EPPP requirements)
- Breastfeeding
- Age less than 18 years

TESTS:

- Baseline (required before first treatment): CBC & diff, platelets, creatinine. If female of child-bearing potential: pregnancy test (blood) or evidence of hysterectomy
- Every 4 weeks (required before treatment): CBC and diff, platelets; if female of childbearing potential: pregnancy test (blood)
- As clinically indicated: ALT, bilirubin, sodium, potassium

PREMEDICATIONS:

- Antiemetic protocol for low emetogenicity (see SCNAUSEA). Antiemetics are not usually required.

Activated: 1 Oct 2014 Revised: 1 Jan 2022 (Eligibility and exclusions clarified, protocol code revised, CAP requirement removed)

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
vismodegib	150 mg once daily	PO

- Repeat every 4 weeks (1 cycle= 4 weeks) until disease progression or unacceptable toxicity develops.

DOSE MODIFICATIONS:

Treatment may be interrupted up to 4 weeks based on individual tolerability.

PRECAUTIONS:

1. **Teratogenicity**: If vismodegib is taken during pregnancy, it may cause severe birth defects or death to the fetus. Vismodegib should never be used by females who are pregnant or who could become pregnant while taking the drug. Even a single dose taken by a pregnant woman may cause birth defects.

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

REFERENCES:

1. Sekulic A, Migden MR, Oro AE, et al. Efficacy and safety of vismodegib in advanced basal-cell carcinoma. N Engl J Med 2012;366(23):2171-9.