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

Protocol Code
USMAVVVIS

Tumour Group
Skin and Melanoma

Contact Physician
Dr. Kerry Savage

ELIGIBILITY:
- Metastatic basal cell carcinoma
- Locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy
- Referral to medical oncologists
- ECOG 0 to 2
- 18 years and older
- A BCCA “Compassionate Access Program” request with appropriate clinical information for each patient must be approved prior to treatment
- Registration of the prescribing physician, dispensing pharmacists and patients with the ERIVEDGE Pregnancy Prevention Program (www.erivedge.ca)

EXCLUSIONS:
- Pregnant or at risk of becoming pregnant
- Breastfeeding

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: AST, ALT, bilirubin, sodium, potassium

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BCCA Administration Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>vismodegib</td>
<td>150 mg once daily</td>
<td>PO</td>
</tr>
</tbody>
</table>

- 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.

Date activated: 1 Oct 2014

Date revised:

REFERENCES: