BCCA Protocol Summary for Palliative Therapy for Malignant Melanoma with Brain Metastases Using Temozolomide

**Protocol Code**

SMAVTMZ

**Tumour Group**

Melanoma

**Contact Physician**

Dr. Vanessa Bernstein

**ELIGIBILITY:**

- Malignant melanoma with brain metastasis
- ECOG less than or equal to 3
- Adequate renal function
- Life expectancy of 12 weeks or longer

**EXCLUSIONS:**

- Pregnant or breast feeding women

**TESTS:**

- Baseline: CBC and differential, platelets, creatinine, glucose (patients on corticosteroids)
- Before each treatment: CBC and differential, platelets
- If clinically indicated: creatinine, glucose

**PREMEDICATIONS:**

- ondansetron 8 mg given 30 minutes prior to each dose of temozolomide at the discretion of the treating physician

**TREATMENT:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose*</th>
<th>BCCA Administration Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>temozolomide</td>
<td>200 mg/m² <strong>once daily for 5 days (days 1 to 5)</strong></td>
<td>PO at bedtime</td>
</tr>
</tbody>
</table>

* round dose to nearest 5 mg

** For patients who had received prior chemotherapy for metastatic melanoma, start with dose level -1 and then increase to dose level 0 if tolerable (see Dose Levels table below).

- Repeat every 28 days to a maximum of 8 cycles
- Discontinue for clinical or radiographic progression.
DOSE MODIFICATIONS:

Dose Levels

<table>
<thead>
<tr>
<th>Drug</th>
<th>Temozolomide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose Level 0</td>
<td>200 mg/m² * once daily for 5 days (days 1 to 5)</td>
</tr>
<tr>
<td>(Starting Dose)</td>
<td></td>
</tr>
<tr>
<td>Dose Level –1</td>
<td>150 mg/m² * once daily for 5 days (days 1 to 5)</td>
</tr>
<tr>
<td>Dose Level –2</td>
<td>100 mg/m² * once daily for 5 days (days 1 to 5)</td>
</tr>
<tr>
<td>Dose Level –3</td>
<td>Discontinue temozolomide</td>
</tr>
</tbody>
</table>

* round dose to nearest 5 mg

1. Hematological

<table>
<thead>
<tr>
<th>ANC (x10^9/L)</th>
<th>Platelets (x10^9/L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>greater than or equal to 1.5 and greater than or equal to 100</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>less than 1.5 or less than 100</td>
<td>Delay*</td>
<td></td>
</tr>
</tbody>
</table>

* Perform weekly CBC, maximum of 3 times.

- If ANC recovers to greater than or equal to 1.5 x 10^9/L and platelets recover to greater than or equal to 100 x 10^9/L, re-start temozolomide at one level reduced dose.
- If the hematologic toxicity developed at 100 mg/m², re-start with 100 mg/m² upon recovery.
- Dose reductions below 100 mg/m² are not permitted. Temozolomide should be discontinued for repeated grade 3 or 4 hematologic toxicity (ANC less than 1 x 10^9/L, platelets less than 50 x 10^9/L) at the 100 mg/m² dose.

PRECAUTIONS:

1. Neutropenia: Fever or other evidence of infection must be assessed promptly and treated aggressively.

Call Dr. Vanessa Bernstein or tumour group delegate at (250) 519-5500 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: 1 July 2010

Date revised: 01 Jun 2017 (Contact physician updated)
References: