BCCA Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using DOCEtaxel

**Protocol Code:** BRAVDOC

**Tumour Group:** Breast

**Contact Physician:** Dr. Karen Gelmon

**ELIGIBILITY:**
- First, second, or third line treatment of metastatic breast cancer patients with ECOG performance status 0, 1, or 2, and greater than 3 month life expectancy
- To continue after 8 cycles, a BCCA “Compassionate Access Program” request must be approved.

**TESTS:**
- Baseline: CBC & diff, platelets, liver enzymes
- Before each treatment: CBC & diff, platelets
- Before Cycle 4 and anytime if clinically indicated*: liver enzymes
  *See Precaution #5 for guidelines regarding hepatic dysfunction

**PREMEDICATIONS:**
- Dexamethasone 8 mg PO bid for 3 days, starting one day prior to each DOCEtaxel administration. Patient must receive minimum of 3 doses pre-treatment.
- Additional antiemetics not usually required.
- DOCEtaxel-induced onycholysis and cutaneous toxicity of the hands may be prevented by wearing frozen gloves starting 15 minutes before DOCEtaxel infusion until 15 minutes after end of DOCEtaxel infusion; gloves should be changed after 45 minutes of wearing to ensure they remain cold during the entire DOCEtaxel infusion.

**TREATMENT:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BCCA Administration Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOCEtaxel</td>
<td>100 mg/m²</td>
<td>IV in 250 mL* NS or D5W over 1 hour (see precaution #2) (use non-DEHP equipment)</td>
</tr>
</tbody>
</table>

* If 75 to 185 mg, use 250 mL bag. If greater 185 mg, use 500 mL bag.
Repeat every 21 days x 6 cycles. Discontinue if no response after 2 cycles.
If patient still receiving benefit after 6 cycles, further 2 cycles may be given.
DOSE MODIFICATIONS:

1. Hematological:

<table>
<thead>
<tr>
<th>ANC (x 10^9/L)</th>
<th>Platelets (x 10^9/L)</th>
<th>Dose</th>
<th>DOSE after Neutropenic Sepsis on DOCEtaxel</th>
</tr>
</thead>
<tbody>
<tr>
<td>greater than or equal to 1.5</td>
<td>greater than 90</td>
<td>100%</td>
<td>75%</td>
</tr>
<tr>
<td>1 to 1.4</td>
<td>70 to 90</td>
<td>75%</td>
<td>75%</td>
</tr>
<tr>
<td>less than 1</td>
<td>less than 70</td>
<td>delay</td>
<td>delay</td>
</tr>
</tbody>
</table>

2. Hepatic dysfunction:

<table>
<thead>
<tr>
<th>Alkaline Phosphatase</th>
<th>AST +/- or ALT</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 2.5 x ULN</td>
<td>and less than or equal to 1.5 x ULN</td>
<td>100%</td>
</tr>
<tr>
<td>2.5 to 5 x ULN</td>
<td>and 1.6 – 6 x ULN</td>
<td>75%</td>
</tr>
<tr>
<td>greater than 5 x ULN</td>
<td>or greater than 5 ULN</td>
<td>discuss with contact physician</td>
</tr>
</tbody>
</table>

ULN = upper limit of normal

PRECAUTIONS:

1. Fluid retention: Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.

2. Hypersensitivity: Reactions are common but it is not necessary to routinely initiate the infusion slowly. If slow initiation of infusion is needed, start infusion at 30 mL/h x 5 minutes, then 60 mL/h x 5 minutes, then 120 mL/h x 5 minutes, then complete infusion at 250 mL/h (for 500 mL bag, continue 250 mL/h for 5 minutes and then complete infusion at 500 mL/h). Refer to BCCA Hypersensitivity Guidelines.

3. Extravasation: DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BCCA Extravasation Guidelines.

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

5. Hepatic Dysfunction: DOCEtaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST) may lead to increased toxicity and usually requires a dose reduction. Baseline liver enzymes are recommended before cycle 1 and then if clinically indicated (eg, repeat liver enzymes prior to each treatment if liver enzymes are elevated, liver metastases are present or there is severe toxicity such as neutropenia). If liver enzymes are normal and there is no evidence of liver metastases or severe toxicity, check liver enzymes after 3 cycles (ie, at cycle 4). Note: this information is intended to provide guidance but physicians must use their clinical judgment when making decisions regarding monitoring and dose adjustments.
Call Dr. Karen Gelmon or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: N/A
Date revised: 1 Aug 2014 (non-PVC changed to non-DEHP)

References: