

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

Protocol Code:

BRAVDOC7

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
- Poor tolerance to high doses of dexamethasone used for BRAVDOC
- Patients unable to tolerate BRAVDOC
- For other indications, or for more than 4 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 3 and any time if clinically indicated*: liver enzymes
See Precaution #5 for guidelines regarding hepatic dysfunction

PRE & POST MEDICATIONS:

- Dexamethasone 8 mg po 1 hour prior to DOCEtaxel treatment.
- Antiemetics not usually required.

TREATMENT:

| Drug | Dose | BCCA Administration Guideline |
|--------------------|----------------------|--|
| DOCEtaxel (weekly) | 36 mg/m ² | IV in 250 mL* NS or D5W over 1 hour (see precaution #2) (use non-DEHP equipment) |

*If 30 to 74 mg, use 100 mL bag and run over 30 mins. If 75 to 185 mg, use 250 mL bag and run over 1 hour. See escalation of infusion rate under Hypersensitivity in PRECAUTIONS section.

Repeat weekly for 6 weeks followed by 2 weeks rest (1 cycle = 8 weeks) x 4 cycles (32 weeks)
Discontinue if no response after 1 cycle (8 weeks).

DOSE MODIFICATIONS:

1. Hematological:

| ANC (x 10 ⁹ /L) | Platelets (x 10 ⁹ /L) | Dose | Dose after Neutropenic Sepsis on DOCEtaxel |
|------------------------------|----------------------------------|-------|--|
| greater than or equal to 1.5 | greater than 90 | 100% | 75% |
| 1 to 1.4 | 70 to 90 | 75% | 75% |
| less than 1.0 | less than 70 | delay | delay |

2. Hepatic Dysfunction:

| Alkaline Phosphatase | | AST and/or ALT | Dose |
|----------------------|-----|---------------------------------|--------------------------------|
| less than 2.5 x ULN | And | less than or equal to 1.5 x ULN | 100% |
| 2.5 to 5 x ULN | And | 1.6 to 5 x ULN | 75% |
| greater than 5 x ULN | Or | greater than 5 x ULN | Discuss with contact physician |

ULN = upper limit of normal

3. Severe Fatigue:

For patients who experience severe fatigue, consider:

- dose reduction to 75% (27 mg/m²) and/or
- schedule adjustment to weekly DOCEtaxel for 3 weeks followed by 1 week rest (1 cycle = 4 weeks) to complete 32 weeks total treatment *including previous DOCEtaxel treatments* given on 8-week cycle schedule)

PRECAUTIONS:

1. **Fluid retention:** Although fluid retention is less likely to occur with weekly DOCEtaxel, dexamethasone premedication must be given to reduce incidence of 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 2 cycles (ie, at cycle 3). Note: this information is intended to provide guidance but physicians must use their clinical judgment when making decisions regarding monitoring and dose adjustments.
6. **Lacrimation:** DOCEtaxel is secreted into lacrimal fluid and excessive lacrimation leading to tear duct stenosis may occur, especially with weekly DOCEtaxel. Early intubation should be considered.⁴

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: 01 Nov 2002

Date revised: 1 Aug 2014 (non-PVC changed to non-DEHP)

References:

1. Hainsworth JD, Burris HA III, Yardley DA, Bradof JE, et al. Weekly docetaxel in the treatment of elderly patients with advanced breast cancer: a Minnie Pearl cancer research network phase II trial. *J Clin Oncol* 2001;19:3500-05.
2. Burstein HJ, Manola J, Younger J, Parker LM, et al. Docetaxel administered on a weekly basis for metastatic breast cancer. *J Clin Oncol* 2000;18:1212-9.
3. Stemmler J, Mair W , Stauch M et al. Weekly docetaxel with or without corticosteroid premedication as first or second-line treatment in patients (pts) with metastatic breast cancer (MBC). [Abstract 231] *Proc Am Soc Clin Oncol* 2002;21:58a.
4. Esmaeli B, Hortobagyi G, Esteva F et al. Canalicular stenosis secondary to weekly docetaxel: a potentially preventable side effect. *Ann Oncol* 2002;13:218-21.