

BC Cancer Protocol Summary for Palliative Treatment of Metastatic Esophagogastric Adenocarcinoma with DOCEtaxel

Protocol Code

GIAVDOC

Tumour Group

Gastrointestinal

Contact Physician

GI Systemic Therapy

ELIGIBILITY:

- Patients with metastatic esophagogastric adenocarcinoma unsuitable for, or who have progressed on, platinum-based chemotherapy
- Adequate marrow reserve, renal and hepatic function
- ECOG status 0 - 2

EXCLUSIONS:

- Previous treatment with a taxane
- Grade 2 – 4 peripheral neuropathy.

TESTS:

- Baseline: CBC and differential, platelets, LFTs (bilirubin, ALT, GGT, alkaline phosphatase) Optional CEA, CA 19-9
- Before each treatment: CBC and differential, platelets
- Before cycle 4 and anytime if clinically indicated*: bilirubin, ALT, GGT, alkaline phosphatase
*See Precaution #5 for guidelines regarding hepatic dysfunction.
- If clinically indicated: CEA, CA 19-9

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:

| Drug | Dose | BCCA Administration Guideline |
|-----------|----------------------|------------------------------------------------------------------------------------|
| DOCEtaxel | 75 mg/m ² | IV in 250 to 500 mL NS over 1 hour (see Precaution #2 (Use non-DEHP equipment)) |

Repeat every 21 days, for 6 cycles. Discontinue if a delay of more than 21 days, disease progression or unacceptable toxicity.

DOSE MODIFICATIONS:

1. Hematological

| ANC (x10 ⁹ /L) | | Platelets (x10 ⁹ /L) | Dose | Dose after Neutropenic Sepsis on DOCEtaxel |
|------------------------------|-----|---------------------------------|---------------------|--------------------------------------------|
| Greater than or equal to 1.5 | and | Greater than or equal to 100 | 100% | 75% |
| 1.0 to less than 1.5 | or | 75 to less than 100 | 75 % | 75% |
| Less than 1.0 | or | Less than 75 | Delay* ¹ | Delay* ¹ |

* if ANC recovers within 14 days, then treatment re-started at 100%

¹ if lengthy grade 4 neutropenia (ANC less than 0.5 x10⁹/L) for more than 7 days, then dose reduce to 55 mg/m².

2. Hepatic dysfunction:

| Alkaline Phosphatase | | AST 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 6 x ULN | 75% |
| greater than 5 x ULN | or | greater than 5 ULN | discuss with contact physician |

ULN = upper limit of normal

PRECAUTIONS:

- Fluid retention:** Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
- 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 BC Cancer Hypersensitivity Guidelines.
- Extravasation:** DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.
- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively. Refer to BC Cancer Febrile Neutropenia Guidelines.
- 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 the GI Systemic Therapy physician at your regional cancer centre or the GI Systemic Therapy Chair Dr. Janine Davies at (604) 877-6000 or 1-800-670-3322 with any problems or questions regarding this treatment program.

References:

1. Ford HER, Marshall A, Bridgewater JA et al. Docetaxel versus active symptom control for refractory oesophagogastric adenocarcinoma (COUGAR-02): an open-label, phase 3 randomised controlled trial. *Lancet Oncol* 2014;15:78-86.