

BCCA Protocol Summary For Second-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Docetaxel

Protocol Code: LUAVDOC

Tumour Group: Lung

Contact Physician: Dr. Nevin Murray

ELIGIBILITY:

- Advanced non-small cell lung cancer
- Prior treatment with first-line chemotherapy
 - May be used as third-line systemic therapy if prior treatment with an EGFR tyrosine kinase inhibitor as first- or second-line treatment
- ECOG performance status 0, 1 or 2
- In any one patient either LUAVPEM or LUAVDOC (i.e. - one or the other, **but not both**) will be reimbursed.
- Class II form must be submitted at the time of initiation of treatment. To continue after 6 cycles, BC Cancer Agency Compassionate Access Program (CAP) approval must be obtained.

TESTS:

- Baseline: CBC & differential, platelets, liver enzymes
 - Before each treatment: CBC & differential, 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 administration of docetaxel
- A minimum of 3 doses of dexamethasone pre-treatment are required
- Additional antiemetics are 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 mL* NS or D5W over 1 hour (use non-PVC equipment)

* If 75-185 mg, use 250 mL bag. If greater than 185 mg, use 500 mL bag.

- Repeat every 21 days x 6 cycles
- Discontinue if no clinical benefit after 2 cycles

DOSE MODIFICATIONS:

1. Hematology

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose*
greater than or equal to 1.5	and	greater than 100	100%
1-1.49	or	75-100	75%
less than 1	or	less than 75	Delay
*Consider decreasing docetaxel to 75% if an episode of febrile neutropenia occurs with the prior cycle of treatment			

2. Hepatic dysfunction:

Alkaline phosphatase		AST and/or ALT	Dose
less than 2.5 x ULN	and	less than 1.5 x ULN	100%
2.5 - 5 x ULN	and	1.5 - 5 x ULN	75%
greater than 5 x ULN	or	greater than 5 x ULN	Delay*
*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 to docetaxel 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.
- Extravasation:** Docetaxel causes pain and tissue necrosis if extravasated. Refer to BCCA Extravasation Guidelines.
- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
- 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. Nevin Murray 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 2000

Date revised: 1 Feb 2011 (eligibility updated)

REFERENCES:

Shepherd FA, Dancey J, Ramlau R, et al. Prospective randomized trial of docetaxel versus best supportive care in patients with non-small-cell lung cancer previously treated with platinum-based chemotherapy. *J Clin Oncol* 2000;18:2095-2103.