BC Cancer Protocol Summary For Second or Later-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with DOCEtaxel

Protocol Code: *LUAVDOC*

Tumour Group: *Lung*

Contact Physician: *Dr. Christopher Lee*

ELIGIBILITY:

- Advanced non-small cell lung cancer
- Treatment of disease progression in patients who have received prior platinum-based chemotherapy
- 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

TESTS:

- Baseline: CBC & differential, platelets, alkaline phosphatase, ALT, total bilirubin, LDH
    - C-reactive protein and albumin (optional, and results do not have to be available to proceed with first treatment)
- Before each treatment: CBC & differential, platelets
- Before Cycle 4 and anytime if clinically indicated*: alkaline phosphatase, ALT, total bilirubin, LDH

*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	BC Cancer Administration Guideline
DOCEtaxel	75 mg/m^2	IV in 250 to 500 mL NS or D5W over 1 hour (use non-DEHP equipment)

- Repeat every 21 days until disease progression or unacceptable toxicity
- 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 or equal to 100	100%
1.0 to less than 1.5	or	75 to less than 100	75%
less than 1.0	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 to 5 x ULN	and	1.5 to 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:

1. **Fluid retention**: Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
2. **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 BC Cancer Hypersensitivity Guidelines.
3. **Extravasation**: DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer 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 ALT) 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. Christopher Lee or tumour group delegate at (604) 930-4064 or 1-800-663-3333 with any problems or questions regarding this treatment program.

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.