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
- To continue after 6 cycles, BC Cancer Compassionate Access Program (CAP) approval must be obtained

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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BC Cancer Administration Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOCEtaxel</td>
<td>75 mg/m²</td>
<td>IV in 250 mL* NS or D5W over 1 hour (use non-DEHP equipment)</td>
</tr>
</tbody>
</table>

* If 75 to 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

<table>
<thead>
<tr>
<th>ANC (x 10^9/L)</th>
<th>Platelets (x 10^9/L)</th>
<th>Dose*</th>
</tr>
</thead>
<tbody>
<tr>
<td>greater than or equal to 1.5 and greater than or equal to 100</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>1.0 to less than 1.5 or 75 to less than 100</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>less than 1.0 or less than 75</td>
<td>Delay</td>
<td></td>
</tr>
</tbody>
</table>

*Consider decreasing DOCEtaxel to 75% if an episode of febrile neutropenia occurs with the prior cycle of treatment.

2. Hepatic dysfunction:

<table>
<thead>
<tr>
<th>Alkaline phosphatase</th>
<th>AST and/or ALT</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than 2.5 x ULN and less than 1.5 x ULN</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>2.5 to 5 x ULN and 1.5 to 5 x ULN</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>greater than 5 x ULN or greater than 5 x ULN</td>
<td>Delay*</td>
<td></td>
</tr>
</tbody>
</table>

*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 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: