BCCA Protocol Summary for Adjuvant CARBOplatin and PACLitaxel Following Resection of Stage I, II and IIIA Non-small Cell Lung Cancer

Protocol Code: LUAJPC

Tumour Group: Lung

Contact Physician: Dr. Christopher Lee

ELIGIBILITY:
• Not eligible for LUAJNP
• Fully resected stage II or IIIA non-small cell lung cancer; fully resected stage IB non-small cell lung cancer if considered at high-risk for relapse, but uncertainty of benefit must be discussed with individual patient
• Lobectomy or pneumonectomy preferred; segmentectomy or wedge resection permitted
• Treatment to start within 60 days of definitive surgery
• ECOG performance status 0 or 1
• Prior to treatment, should consider Pneumococcal vaccine, and influenza vaccine, if appropriate for season

EXCLUSIONS:
• ECOG performance status 2 or higher

TESTS:
• Baseline: CBC & differential, platelets, creatinine, liver function tests, bilirubin
• Before each cycle: CBC & differential, platelets, creatinine
• If clinically indicated: bilirubin prior to each cycle

PREMEDICATIONS:
• PACLitaxel must not be started unless the following drugs have been given:
  45 minutes prior to PACLitaxel:
  - dexamethasone 20 mg IV in 50 mL NS over 15 minutes
  30 minutes prior to PACLitaxel:
  - diphenhydrAMINE 50 mg IV and ranitidine 50 mg IV in 50 mL NS over 20 minutes (compatible up to 3 hours when mixed in bag)
• Antiemetic protocol for High emetogenic chemotherapy (see protocol SCNAUSEA)
TREATMENT:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BCCA Administration Guideline</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>(give PACLitaxel first)</td>
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<tr>
<td>CARBOplatin</td>
<td>AUC 6</td>
<td>IV in 250 mL NS over 30 minutes</td>
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<tr>
<td>Dose = AUC x (GFR* + 25)</td>
<td></td>
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<tr>
<td>PACLitaxel</td>
<td>200 mg/m²</td>
<td>IV in 500 mL NS over 3 hours</td>
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<td>(use non-DEHP bag and non-DEHP tubing with 0.22 micron or smaller in-line filter)</td>
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- Repeat every 21 days x 4 cycles

Cockcroft formula:

\[
GFR = \frac{N \times (140 - \text{age in years}) \times \text{wt (kg)}}{\text{serum creatinine (micromol/L)}}
\]

N = 1.23 male, 1.04 female

The estimated GFR calculated using the Cockcroft-Gault equation should be capped at 125 mL/min when it is used to calculate the initial carboplatin dose. When a nuclear renogram is available, this clearance would take precedence.

DOSE MODIFICATIONS:

1. **Hematology**

<table>
<thead>
<tr>
<th>ANC (x 10⁹/L)</th>
<th>Platelets (x 10⁹/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>75-99</td>
<td>100%</td>
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<tr>
<td>1-1.49</td>
<td>or</td>
<td>75%</td>
</tr>
<tr>
<td>less than 1</td>
<td>or</td>
<td>less than 100</td>
</tr>
</tbody>
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2. **Arthralgia and/or myalgia:** If arthralgia and/or myalgia of grade 2 (moderate) or higher is not relieved by adequate doses of NSAIDs or acetaminophen with codeine (e.g., TYLENOL #3®), a limited number of studies report a possible therapeutic benefit using:
   - predniSONE 10 mg po bid x 5 days starting 24 hours post-PACLitaxel
   - gabapentin 300 mg po on day before chemotherapy, 300 mg bid on treatment day, then 300 mg tid x 7-10 days

3. **Neuropathy:** Dose modification or discontinuation may be required (see BCCA Cancer Drug Manual).

4. **Renal dysfunction:** If significant increase (greater than 20%) in creatinine, repeat nuclear renogram (if available) and recalculate CARBOplatin dose using new GFR.

5. **Hepatic dysfunction:** Dose reduction may be required for PACLitaxel (see BCCA Cancer Drug Manual)
PRECAUTIONS

1. **Hypersensitivity**: Reactions are common. See BCCA Hypersensitivity Guidelines.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Treatment</th>
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</table>
| **Mild** symptoms (e.g. mild flushing, rash, pruritus) | - complete PACLitaxel infusion. Supervise at bedside  
- no treatment required |
| **Moderate** symptoms (e.g. moderate rash, flushing, mild dyspnea, chest discomfort, mild hypotension) | - stop PACLitaxel infusion  
- give IV diphenhydrAMINE 25-50 mg and IV hydrocortisone IV 100 mg  
- after recovery of symptoms resume PACLitaxel infusion at 20 mL/hr for 5 minutes, 30 mL/hr for 5 minutes, 40 mL/hr for 5 minutes, then 60 mL/hr for 5 minutes. If no reaction, increase to full rate.  
- if reaction recurs, discontinue PACLitaxel therapy |
| **Severe** symptoms (i.e. one or more of respiratory distress requiring treatment, generalized urticaria, angioedema, hypotension requiring therapy) | - stop PACLitaxel infusion  
- give IV antihistamine and steroid as above. Add epinephhrine or bronchodilators if indicated  
- discontinue PACLitaxel therapy |

2. **Extravasation**: PACLitaxel causes pain and may, rarely, cause tissue necrosis if extravasated. Refer to BCCA Extravasation Guidelines.

3. **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated aggressively.

Contact Dr. Christopher Lee or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: 1 Mar 2009 (replacing LUAJCAT)

Date revised: 1 Aug 2016 (Size of filter specified, TALLman lettering formatted)

REFERENCES:
