

# BCCA Protocol Summary for Adjuvant **CARBO**platin and **PACLI**taxel 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:**

- **PACLI**taxel must not be started unless the following drugs have been given:
  - 45 minutes prior to **PACLI**taxel:
    - Dexamethasone 20 mg IV in 50 mL NS over 15 minutes
  - 30 minutes prior to **PACLI**taxel:
    - 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:

Drug	Dose	BCCA Administration Guideline
(give <b>PACLI</b> taxel first)		
<b>CARBO</b> platin	AUC 6 Dose = AUC x (GFR* + 25)	IV in 250 mL D5W over 30 minutes
<b>PACLI</b> taxel	200 mg/m <sup>2</sup>	IV in 500 mL NS over 3 hours (use non-PVC equipment, in-line filter)

- Repeat every 21 days x 4 cycles

Cockcroft formula:

$$\text{GFR} = \frac{N \times (140 - \text{age in years}) \times \text{wt (kg)}}{\text{serum creatinine (micromol/L)}} \quad N = 1.23 \text{ male, } 1.04 \text{ female}$$

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

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose
greater than or equal to 1.5	and	greater than or equal to 100	100%
1.0-1.49	or	75-99	75%
less than 1.0	or	less than 100	Delay*

- 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-**PACLI**taxel
  - Gabapentin 300 mg po on day before chemotherapy, 300 mg bid on treatment day, then 300 mg tid x 7-10 days
- Neuropathy:** Dose modification or discontinuation may be required (see BCCA Cancer Drug Manual).
- Renal dysfunction:** If significant increase (greater than 20%) in creatinine, repeat nuclear renogram (if available) and recalculate **CARBO**platin dose using new GFR.
- Hepatic dysfunction:** Dose reduction may be required for **PACLI**taxel (see BCCA Cancer Drug Manual)

## PRECAUTIONS

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

<i>mild</i> symptoms (e.g. mild flushing, rash, pruritus)	<ul style="list-style-type: none"><li>▪ complete <b>PACLI</b>taxel infusion. Supervise at bedside</li><li>▪ no treatment required</li></ul>
<i>moderate</i> symptoms (e.g. moderate rash, flushing, mild dyspnea, chest discomfort, mild hypotension)	<ul style="list-style-type: none"><li>▪ stop <b>PACLI</b>taxel infusion</li><li>▪ give IV Diphenhydr<b>AMINE</b> 25-50 mg and IV Hydrocortisone IV 100 mg</li><li>▪ after recovery of symptoms resume <b>PACLI</b>taxel 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.</li><li>▪ if reaction recurs, discontinue <b>PACLI</b>taxel therapy</li></ul>
<i>severe</i> symptoms (i.e. <i>one</i> or more of respiratory distress requiring treatment, generalized urticaria, angioedema, hypotension requiring therapy)	<ul style="list-style-type: none"><li>▪ stop <b>PACLI</b>taxel infusion</li><li>▪ give IV antihistamine and steroid as above. Add Epinephrine or bronchodilators if indicated</li><li>▪ discontinue <b>PACLI</b>taxel therapy</li></ul>

2. **Extravasation:** **PACLI**taxel 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: 01 Apr 2011 (estimated GFR capped, reformatted with TALLman lettering)

## REFERENCES:

1. Strauss GM, Herndon J, Maddaus A, et al. Randomized clinical trial of adjuvant chemotherapy with paclitaxel and carboplatin following resection in Stage IB non-small cell lung cancer (NSCLC): Report of Cancer and Leukemia Group B (CALGB) Protocol 9633. Proc Am Soc Clin Oncol 2004; abstr 7019.
2. Strauss GM, Herndon II JE, Maddaus, MA, et al. Adjuvant paclitaxel plus carboplatin compared with observation in stage IB non-small cell lung cancer: CALGB 9633 with the Cancer and Leukemia Group B, Radiation Therapy Oncology Group, and North Central Cancer Treatment Group Study Groups. J Clin Oncol 2008; 26: 5043-51.