

BC Cancer Protocol Summary for Second-Line Chemotherapy of Advanced Non-Small Cell Lung Cancer (NSCLC) With Pemetrexed

Protocol Code:

LUAVPEM

Tumour Group:

Lung

Contact Physician:

Dr. Christopher Lee

ELIGIBILITY:

- Advanced non-small cell lung cancer
 - Restricted to disease of *non-squamous cell* histology
 - Disease of *squamous cell* histology may be treated only if a contraindication to Docetaxel exists
- 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

EXCLUSIONS:

- ECOG 3 or 4
- Prior treatment with LUAVPP or LUAVPMTN; BC Cancer Compassionate Access Program (CAP) approval must be obtained.

TESTS:

- Baseline: CBC & Diff, creatinine, 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 & Diff, alkaline phosphatase, ALT, total bilirubin, LDH
- If clinically indicated: creatinine

PREMEDICATIONS:

- Vitamin supplementation mandatory** starting at least 7 days prior to the first cycle, and to continue while on treatment until 21 days after last pemetrexed dose:
 - folic Acid 0.4 mg PO daily
 - vitamin B12 1000 mcg IM every 9 weeks
- Prophylaxis for skin rash: dexamethasone 4 mg PO BID for 3 days, beginning the day before chemotherapy. (May proceed with chemotherapy even if patient has not taken the pre-treatment dexamethasone doses. Instruct patient to begin immediately.)

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
pemetrexed	500 mg/m ²	IV in 100 mL NS over 10 minutes

- Repeat every 21 days until progression

DOSE MODIFICATIONS:**1. HEMATOLOGY**

Based on day 1 counts

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%
Less than 1.5	or	less than 100	Delay

2. RENAL DYSFUNCTION

Creatinine Clearance (mL/min)	Dose
Greater than or equal to 45	100%
Less than 45	Delay

3. MUCOSITIS

For next cycle

Mucositis Grade	Dose
0-2	100%
3-4	50% previous dose*
*Discontinue treatment after two dose reductions	

4. OTHER TOXICITIES

For any other grade 3 or higher toxicity, delay treatment until toxicity resolves, then resume with 25% dose decrease if considered appropriate to resume by attending oncologist

PRECAUTIONS:

1. **Vitamin supplements:** Appropriate prescription of folic Acid and vitamin B12 is essential. The incidence of adverse events such as febrile neutropenia related to pemetrexed is higher without vitamin supplementation.
2. **NSAIDS:** Concurrent nonsteroidal anti-inflammatory agents should be avoided as they may decrease the renal clearance of pemetrexed.
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) 930-2098 or 1-800-523-2885 with any problems or questions regarding this treatment program.

REFERENCES:

Hanna N, Shepherd FA, Fossella FV, et al. Randomized phase III study of pemetrexed versus docetaxel in patients with non-small-cell lung cancer previously treated with chemotherapy. J Clin Oncol 2004; 22: 1589-1597.