

BCCA Protocol Summary for Maintenance Therapy of Advanced Non-Small Cell Lung Cancer (NSCLC) with Erlotinib After First-Line Chemotherapy

Protocol Code: ULUAVMTNE

Tumour Group: Lung

Contact Physician: Dr. Barbara Melosky

ELIGIBILITY:

- Stage IV non-small-cell lung cancer
- Stable disease as best response after 4 cycles of first-line platinum-based doublet
- Maintenance therapy to be started 21 to 42 days after fourth cycle of first-line platinum-based doublet
- ECOG performance status 0-1 at start of maintenance
- *BC Cancer Agency Compassionate Access Program (CAP) approval must be obtained*

EXCLUSIONS:

- Progressive disease after first-line platinum-based doublet
- Complete or partial response after 4 cycles of first-line platinum-based doublet
- Prior treatment with first-line EGFR tyrosine kinase inhibitor (ULUAVGEFF)
- ECOG 2-4
- Patients with moderate or severe hepatic impairment

TESTS:

- Baseline: liver enzymes, chest X-ray.
- During treatment: liver enzymes should be checked two weeks after starting erlotinib and at each subsequent visit.
- For patients with pre-existing liver disease or concomitant hepatotoxic medications, hepatic function should be closely monitored throughout treatment.
- As required: chest X-ray and scans to monitor index lesions.
- Chest radiographs should be performed for monitoring of dyspnea to rule out development of interstitial pneumonitis.

PREMEDICATIONS:

- no premedications needed

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Erlotinib	150 mg daily	PO

- continue until disease progression or undue toxicity

DOSE MODIFICATIONS:

1. **Rash:** generally improves with time but if severe, may require treatment interruption and/or dose reduction.
2. **Diarrhea:** if severe, may require treatment interruption and/or dose reduction.
3. **Elevated liver enzymes:** no guidelines for dose modification, but if very high may need to interrupt or stop therapy.

PRECAUTIONS:

1. **Skin toxicity:** rash, acne, dry skin and pruritus are common. They appear on the face, neck and trunk, and commonly fade or improve despite continuing erlotinib therapy. Interrupt or discontinue treatment if severe bullous, blistering or exfoliating conditions develop as fatal cases suggestive of Stevens-Johnson syndrome/toxic epidermal necrolysis have been reported.
2. **Diarrhea:** this is usually mild and self-limiting. No routine prophylactic antidiarrheal medication is needed.
3. **Gastrointestinal Perforation:** patients receiving concomitant corticosteroids and/or NSAID's, or who have prior history of peptic ulceration or diverticular disease are at increased risk for developing gastrointestinal perforation. Permanently discontinue erlotinib in patients who develop gastrointestinal perforation as fatalities have been reported.
4. **Ocular Disorders:** corneal perforation or ulceration have been reported. Interrupt or discontinue therapy if patients present with acute/worsening of ocular disorders such as eye pain.

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

Date activated: 01 July 2011

Date revised:

Reference:

Cappuzzo F et al. Erlotinib as maintenance treatment in advanced non-small cell lung cancer: a multicenter, randomized, placebo-controlled phase 3 trial. *Lancet Oncol* 2010;11(6): 521-9.