

BC Cancer Protocol Summary for Second- or Later-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Erlotinib

Protocol Code: LUAVERL

Tumour Group: Lung

Contact Physician: Dr. Barbara Melosky

ELIGIBILITY:

- Advanced non-small-cell lung cancer.
- Ambulatory performance status.
- Second- or later-line monotherapy for disease progression after prior chemotherapy
- Note. Patients must have progressive disease on or after first- or second-line therapy. Patients should not switch over between gefitinib (LUAVGEFF) or AFAtinib (LUAVAFAT) and erlotinib.
- *For first-line therapy, or indications other than the above, BC Cancer Compassionate Access Program (CAP) approval must be obtained*

EXCLUSIONS:

- Prior treatment with maintenance erlotinib (LUAVMTNE)
- Patients with moderate or severe hepatic impairment should not be treated with Erlotinib

TESTS:

- Baseline: [alkaline phosphatase](#), [ALT](#), [total bilirubin](#), [LDH](#), chest X-ray.
 - C-reactive protein and albumin (optional, and results do not have to be available to proceed with first treatment)
- During treatment: [alkaline phosphatase](#), [ALT](#), [total bilirubin](#) and [LDH](#) 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:

- At physician's discretion, prophylaxis for rash: minocycline 100 mg PO BID.

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
erlotinib	150 mg daily	PO

- Discontinue if no clinical benefit after four weeks.
- Careful re-evaluation after initiation of therapy is essential as erlotinib should be continued only if tumour regression continues or the disease is stable and cancer-related symptoms have improved. Continued erlotinib for “psychological” palliation in the face of progressive disease is inappropriate.

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 anti-diarrheal 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.

Reference:

Shepherd FA, Pereira JR, Ciuleanu T, et al. Erlotinib in previously treated non-small-cell lung cancer. N Engl J Med 2005;353:123-32.