

BCCA Protocol Summary for Third-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Gefitinib (IRESSA®)

Protocol Code: ULUAVGEF

Tumour Group: Lung

Contact Physician: Dr. Nevin Murray

ELIGIBILITY:

- Demonstrated clinical benefit from gefitinib therapy.
 - NOTE: New patients may not start gefitinib.
- Advanced non-small cell lung cancer
- EGFR expression positive or unknown
- Ambulatory performance status.
- Third-line monotherapy for disease progression after first- and second-line chemotherapy
- A BCCA “Compassionate Access Program” or “Undesignated Indication” request with appropriate clinical information for each patient must be approved prior to treatment
- Patient must be registered with the IRESSA® Patient Registry (1-866-473-7720). A maximum one-month supply will be sent at a time. Each refill must be requested from the registry.

TESTS:

- Baseline: liver enzymes, chest X-ray.
- During treatment: liver enzymes should be checked two weeks after starting gefitinib and at each subsequent visit.
- 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
Gefitinib	250 mg daily	PO

- Discontinue if no clinical benefit after four weeks.
- Careful re-evaluation after initiation of therapy is essential as gefitinib should be continued only if tumour regression continues or the disease is stable and cancer-related symptoms have improved. Continued gefitinib 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.
2. **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 gefitinib therapy.
2. **Diarrhea:** this is usually mild and self-limiting. No routine prophylactic antidiarrheal medication is needed.

Call Dr. Nevin Murray 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 Apr 2009 (replacing ULUGEF)

Date revised: 1 Feb 2011 (deleted)

REFERENCES:

1. Kris MG, Natale RB, Herbst RS, et al. Efficacy of gefitinib, an inhibitor of the epidermal growth factor receptor tyrosine kinase, in symptomatic patients with non-small cell lung cancer: a randomized trial. JAMA 2003;290(16):2149-58.
2. Fukuoka M, Yano S, Giaccone G, et al. Multi-institutional randomized phase II trial of gefitinib for previously treated patients with advanced non-small-cell lung cancer.[comment]. J Clin Oncol 2003;21(12):2237-46.