PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on TARCEVA® (erlotinib)

December 17, 2008

Subject: The use of TARCEVA® (erlotinib) in patients with moderate liver impairment and advanced cancer

Hoffmann-La Roche Limited, in consultation with Health Canada, has informed Canadian health care professionals of new important safety information regarding the use of TARCEVA® (erlotinib) in patients with moderate liver impairment and advanced cancer.

TARCEVA is used to treat patients with non-small cell lung cancer at an advanced stage in which chemotherapy has not helped to stop the disease.

- **In a study of patients with advanced cancer and moderate liver impairment, a number of patients with liver impairment died during treatment or within 30 days of the last dose compared to patients with normal liver function.**
- **Your liver function should be closely monitored by your doctor if you are currently or have recently taken TARCEVA.**

It is important to carefully read the Consumer Information (package insert) section of the Product Monograph or the information listed below, as this gives details about what information you should tell your doctor.

You should consult your doctor immediately if you experience any of the following signs or symptoms suggesting possible serious liver side effects:

- dark urine
- yellowing of the skin
- abdominal pain, especially on the right side
- general itchiness
- decreased appetite
- nausea or vomiting
- fatigue or tiredness

If you have had any liver problems BEFORE beginning treatment with TARCEVA, or you are experiencing liver problems during treatment with TARCEVA, including "abnormal tests for liver function", you should tell your doctor or pharmacist.

Managing marketed health product related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any occurrence of serious and/or unexpected adverse reactions in patients receiving TARCEVA should be reported to Hoffmann-La Roche Limited, or Health Canada at the following addresses:

Hoffmann-La Roche Limited
Drug Safety Department
2455 Meadowpine Boulevard
Mississauga, Ontario, L5N 6L7
or call toll free at: 1-888-762-4388
or Fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)
E-mail: bmors_enquiries@hc-sc.gc.ca
Tel: (613) 941-3171
Fax: (613) 941-1365

Sincerely,

Lorenzo Biondi,
Vice President, Medical and Regulatory Affairs
Hoffmann-La Roche Limited