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

May 8, 2009

Subject: Information on the association of TARCEVA® (erlotinib) with perforation of the bowel/gut, serious skin toxicities and eye disorders.

Hoffmann-La Roche Limited, in consultation with Health Canada, has informed Canadian health care professionals of new important safety information regarding the association of TARCEVA® (erlotinib) with perforation of the bowel/gut, serious skin toxicities and eye disorders.

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.

- **Rare cases have been reported in which patients have developed perforation of the bowel/gut.**
- **Very rare cases have been reported in which patients have developed serious skin toxicities and/or eye disorders.**
- **It is important that you tell your physician of any changes with regards to your skin or eyes as well as any stomach/intestinal pains you might be experiencing while you are on TARCEVA.**

It is important to carefully read the Consumer Information (package insert) as this gives details about what information you should tell your physician.

You should consult your physician immediately if you experience any of the following signs or symptoms:

- nausea
- vomiting
- stomach pain
- swollen or enlarged abdomen
- eye pain or vision difficulties
- skin rash, discolouration, blistering, or pain

The TARCEVA Product Monograph is currently being reviewed by Health Canada in conjunction with the manufacturer regarding the above mentioned safety concerns and will be updated accordingly.

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