PUBLIC ADVISORY
Health Canada Endorsed Important Information on IRESSA® (gefitinib) 250 mg tablets

August 26, 2005

Health Canada Endorsed Important Information on IRESSA® (gefitinib) 250 mg tablets

Health Canada, in consultation with AstraZeneca Canada Inc., is recommending new restrictions on the use of the lung cancer drug IRESSA, the brand name for gefitinib. While IRESSA has not been shown to have a significant impact in extending patient survival, a recent study has found it to be effective in shrinking tumours in patients with a certain tumour characteristic.

IRESSA is generally used when a specific form of lung cancer fails to respond to two other types of treatments. The drug targets a protein called Epidermal Growth Factor Receptor (EGFR). Patients can be grouped into three categories based on the level of EGFR expressed in their tumour: positive, negative and unknown. The recent study suggests that patients whose tumours are EGFR expression status positive or unknown have significantly better rates of tumour shrinkage when treated with IRESSA versus a sugar pill. However, EGFR negative patients appear unlikely to benefit from IRESSA treatment.

The data from this pivotal post-marketing study will be reviewed by Health Canada in an expedited manner and the labeling will be updated.

Any suspected adverse drug reaction can be reported to:
AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, ON L4Y 1M4
Tel : 1-800 433-0733
Fax : 1-800-267-5743
www.astrazeneca.ca

Any suspected adverse drug reactions can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
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 (AR), consumers and Health professional may call toll free:
Tel: (613) 234-2345
Fax: (866) 678-6789
cadrmp@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.*

Should you have any questions or require additional information regarding IRESSA® , please contact your health care provider (physician, nurse or pharmacist) or AstraZeneca Medical Information at 1-800-668-6000 (English) and/or 1-800-461-3787 (French).