The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB, which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **AstraZeneca Canada Inc**. Contact the company for a copy of any references, attachments or enclosures.

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

April 10, 2007

Subject: Use of IRESSA® in patients with Squamous Cell Carcinoma of the Head and Neck (SCCHN) failed to prolong survival and increased bleeding events.

AstraZeneca Canada Inc., in consultation with Health Canada, would like to inform all patients in the IRESSA Patient Registry (IPR) Program of new information from a clinical trial on the use of IRESSA in patients who have head and neck cancer. It should be noted that head and neck cancer is not an approved use for IRESSA, but patients with this diagnosis may be participating in the IPR Program if benefiting from therapy.

In a large clinical trial in patients with head and neck cancer, patients received IRESSA 250 mg, IRESSA 500 mg or methotrexate chemotherapy. The purpose of the study was to compare how long head and neck cancer patients lived if they were treated with IRESSA or methotrexate. Results from the study showed that neither dose of IRESSA prolonged life compared with patients receiving methotrexate.

Also in this study, it was found that more patients treated with IRESSA, when compared to methotrexate, suffered from bleeding from the cancer in their head and neck as a possible side effect. 9% (14/158) of patients taking IRESSA 250 mg and 11% (19/166) of patients taking IRESSA 500 mg suffered bleeding from their head and neck cancer, compared to 2% (3/159) of patients taking methotrexate. In most of these patients the bleeding was mild to moderate and got better. In some rare cases, patients died from the bleeding. There were 36 patients who had bleeding in the study, and 3 patients (all taking IRESSA) died from the bleeding.

As a patient in the IRESSA Patient Registry program, Health Canada, in collaboration with AstraZeneca, has requested that you be made aware of these new study results. **It is recommended that you review the use of IRESSA in your treatment plan with your own physician.**

IRESSA will continue to be available to patients currently benefiting from treatment who have been prescribed IRESSA as of October 31, 2006, and were registered into the IRESSA Patient Registry as of December 31, 2006. Please contact the IRESSA Patient Registry at 1-866-473-7720 for more details.

If you are participating in a clinical trial using IRESSA to treat head and neck cancer and receive IRESSA directly from your physician, your case should be reviewed with your physician, as therapy may need to be discontinued.

Any suspected adverse drug reaction can be reported to:

AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, ON L4Y 1M4 T
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: (866) 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.*

For other inquiries related to this communication, please contact Health Canada at:

Therapeutics Products Directorate
Telephone: (613) 941-3171
Fax: (613) 941-1365
E-mail: BMORS_Enquiries@hc-sc.gc.ca

Should you have any questions or require additional information about 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).

IRESSA® and the AstraZeneca logo are trade-marks of the AstraZeneca group of companies.