PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
EVISTA® (raloxifene hydrochloride)

May 18, 2006

Subject: **Association of Evista® (raloxifene hydrochloride) with Death due to Stroke in Postmenopausal Women at Increased Risk for Heart Disease: Preliminary Results from the RUTH Trial.**

The RUTH (Raloxifene Use for The Heart) trial explored whether a 60 mg daily dose of Evista would reduce the risk of coronary events (e.g., heart attack) and the risk of invasive breast cancer in postmenopausal women with known heart disease or at high risk for heart attack. The study included more than 10,000 women (average age = 67 years) who had heart disease or were at high risk for coronary events.

- The RUTH study found an increase in death due to stroke for Evista compared to placebo (no drug). The incidence of stroke mortality was 1.5 per 1,000 women per year for placebo versus 2.2 per 1,000 women per year for Evista.

- The risk of stroke, heart attack, hospitalized acute coronary syndrome, death due to diseases involving the heart and/or blood vessels, or death from any cause was comparable for Evista and placebo.

Evista is currently prescribed for the treatment and prevention of osteoporosis in postmenopausal women. Evista is not prescribed for the prevention or reduction of the risk of cardiovascular disease.

If patients have concerns about risks associated with use of Evista, they should discuss this with their physician.

This advisory is not intended as medical advice. In order to understand the implications of this information to a patient's health and before a patient modifies the way they use this health product, it is important that the patients consult with their doctor or healthcare professional.

This advisory is in addition to a letter sent to health care professionals discussing the above-mentioned safety information. This letter is posted on both the Eli Lilly Canada website at www.lilly.ca and the Health Canada website at www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html.

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 case of death, stroke or other serious or unexpected adverse reactions in patients receiving Evista should be reported to Eli Lilly Canada or Health Canada at the following addresses:

Customer Response Centre
Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario M1N 2E8
Toll Free Number: 1-888-545-5972 or Fax: 1-888-898-2961

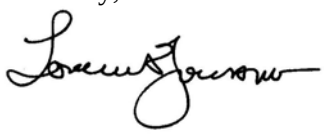
Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals 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.*

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:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

Sincerely,



Loren D. Grossman, MD, FRCPC, FACP
Vice President, Research and Development
Eli Lilly Canada Inc.