Subject: Important safety information for patients taking Lamictal® (lamotrigine)

Mississauga, Ontario (September, 2004) — GlaxoSmithKline Inc., following discussions with Health Canada, is informing patients of new safety information regarding Lamictal® (lamotrigine), a medication for the treatment of epilepsy.

A recently completed study has demonstrated that when Lamictal is used in combination with birth control pills, the amount of the active ingredient (lamotrigine) in the blood was significantly reduced. As a result, the dose of Lamictal may need to be adjusted in patients who are also taking birth control pills, or other female hormonal treatments.

In addition to the study, there has also been a limited number of reports of seizures, unexpected pregnancies and of menstrual bleeding disorders (e.g. breakthrough bleeding) occurring in patients who were taking both Lamictal and birth control pills or other hormonal treatments.

Women taking Lamictal are advised to inform their doctor if they are also taking birth control pills, or other female hormonal treatments, like hormone replacement therapy. They should not start or stop these medications without consulting their doctor. They should also promptly notify their doctor if they experience changes in menstrual pattern (e.g., break-through bleeding) while receiving Lamictal in combination with these medications.

GlaxoSmithKline has sent a letter to healthcare professionals informing them of the new safety information. This information may be obtained on the Canadian website of GlaxoSmithKline (http://www.gsk.ca) or on the website of the Therapeutic Products Directorate of Health Canada (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_public_e.html). The company is working with Health Canada to revise the Canadian prescribing information for Lamictal. If patients have questions regarding their current Lamictal prescription, they are asked to contact their doctor or pharmacist.

For media inquiries, please contact Cathy Metson or Alison Steeves, (905) 819-3363.

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Any suspected adverse reactions can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll free for consumers and health professionals:
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 TPD web site or in The Canadian Compendium of Pharmaceuticals and Specialties.