Subject: Important new safety information for the use of PAXIL® (paroxetine hydrochloride) and PAXIL CR™ (paroxetine hydrochloride controlled release tablets) in patients taking pimozide.

Mississauga, Ontario (July 28, 2005) — GlaxoSmithKline Inc., following discussions with Health Canada, is informing patients of new safety information regarding Paxil and Paxil CR, both of which are medications used for treating the symptoms of depression and anxiety.

Based on the results of a recent clinical study, Paxil or Paxil CR must not be used together with pimozide (Orap®), an antipsychotic medication. Patients are advised NOT to take Paxil or Paxil CR with pimozide as their interaction increases the level of pimozide in the blood, which may result in arrhythmias (irregular heartbeats) that can sometimes be serious and even life-threatening. Patients should be aware that the symptoms of arrhythmia include dizziness, palpitations and fainting, and that they should seek immediate medical attention if these symptoms occur. If you are presently being treated with this drug combination, please consult your physician before changing your current therapy.

GlaxoSmithKline has sent a letter to healthcare professionals informing them of this 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). Following consultation with Health Canada, the Canadian prescribing information and consumer information for Paxil and Paxil CR has been revised. If patients have questions regarding their current Paxil or Paxil CR 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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Mississauga, Ontario
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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: 0701C
OTTAWA, Ontario, K1A OK9
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

For other inquiries, please refer to contact information:
Bureau of Cardiology, Allergy and Neurological Sciences
BCANS_Enquiries@hc-sc.gc.ca
Tel: (613) 941-1499
Fax: (613) 941-1668

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/hpfb-dgpsa/tpd-dpt/adverse_e.html
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html