Safety Information for Patients Taking Serevent® (salmeterol xinafoate) for Asthma

MISSISSAUGA, Ontario (September 4, 2003) – GlaxoSmithKline Inc., following discussions with Health Canada, would like to inform consumers about safety information regarding Serevent® (salmeterol xinafoate) and the results of a large asthma safety study conducted in the United States.

The purpose of this U.S. study, known as the SMART (Salmeterol Multi-center Asthma Research Trial), was to compare the rates of adverse events between two groups of asthma patients. In addition to their regular asthma therapy, one group of patients was taking Serevent whereas the other received placebo. The primary focus of the study was to compare respiratory-related deaths and life-threatening experiences between the two groups.

The SMART was started in 1996, after the FDA received post-marketing reports of several asthma deaths associated with the use of Serevent Inhalation Aerosol and following the publication of studies raising concern about the regular use of short-acting and long-acting beta$_2$-agonists, including Serevent.

In January 2003, the study was stopped prematurely following a planned interim analysis, due to concerns regarding a small increase in the occurrence of asthma-related deaths in patients treated with Serevent. A further subgroup analysis showed that there was no significant increase observed in respiratory or asthma-related events, including asthma-related deaths, in Caucasian patients. However, a higher number of these events in the African American patients treated with Serevent was observed. Due to the low rate of the adverse event that was the primary focus of the study, the findings from this analysis are not conclusive.

In Canada, Serevent is not approved to be used on its own for the management of asthma. Patients must already be taking optimal doses of corticosteroids, before they can take Serevent as an additional therapy. Conducted only in the U.S., the SMART was not designed to assess whether or not patients who were taking corticosteroids, in addition to Serevent, were at a reduced risk of adverse events when compared to those patients who did not take any corticosteroids.

Although the SMART results were specific to Serevent, it is possible that the events seen in the SMART could also be observed with other long-acting beta$_2$-agonist "controller" asthma medications.

People with asthma can sometimes suffer life-threatening attacks or episodes of bronchospasm (asthma attacks) as a result of their disease. **Medications should not be stopped without consulting a physician. Abruptly stopping medications may result in deteriorating asthma control, which may be life-threatening.** People with asthma who have any questions regarding their current prescription or treatment should contact their physician or pharmacist directly.

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Serevent is a long-acting beta$_2$–agonist and a “controller” medication for the treatment of asthma. Controllers should be taken regularly to prevent asthma symptoms like wheezing, shortness of breath and coughing**. Serevent should not be used alone for the maintenance treatment of asthma and is not a substitute for inhaled corticosteroids.** As outlined in the Product Monograph, Serevent is approved for add-on therapy in those patients already managed with appropriate maintenance doses of inhaled corticosteroids. The active drug in Serevent, salmeterol, is also contained in the products Serevent Diskus®, and Advair® (salmeterol xinafoate/fluticasone propionate), also manufactured by GlaxoSmithKline Inc.

GlaxoSmithKline has sent a letter to healthcare professionals in Canada 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).

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For media inquiries, please contact:
Alison Steeves
(905) 819 3363

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.*