PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on PrBENLYSTA™

May 8, 2012

Subject: Association of BENLYSTA™ (belimumab) with hypersensitivity and infusion reactions

GlaxoSmithKline Inc., in consultation with Health Canada, would like to inform you of important new safety information regarding hypersensitivity and infusion reactions, in association with BENLYSTA™ (belimumab) treatment.

BENLYSTA™ is a prescription drug used to treat adults with lupus (systemic lupus erythematosus, also called SLE), who are also receiving other medicines for lupus. At the time of authorization of BENLYSTA™, information and warnings about allergic (hypersensitivity) reactions occurring more often in patients treated with BENLYSTA™ (compared to patients not treated with BENLYSTA™) were included in the Product Monograph.

The Product Monograph for BENLYSTA™ has been updated with important information for patients, as described below:

- BENLYSTA™ can cause a reaction to the infusion or an allergic (hypersensitivity) reaction. These can affect 1 to 10 users in 100, and can occasionally be severe, and can cause death. They are more likely to happen on the day of treatment, but can happen later.
- BEFORE you receive BENLYSTA™, tell your healthcare provider if you have had an allergic reaction to other drugs or shots/injections. You may be given medicines to help prevent reactions before you are given BENLYSTA™.
- Contact your doctor immediately if you develop any of the following symptoms after being treated with BENLYSTA™:
    - ❍ swelling of face, mouth, lips or tongue, causing difficulty in breathing
    - ❍ rash, possibly with itchy raised bumps or hives
    - ❍ light-headedness when you stand up (possibly due to low blood pressure)
    - ❍ slow heart beat
    - ❍ shortness of breath

The updated Product Monograph for BENLYSTA™ is available at www.gsk.ca.

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 Health Canada Web site. If you have questions regarding your BENLYSTA™ prescription, please contact your doctor.

For media inquiries please contact GSK Communications at (905) 819-3363.

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 serious hypersensitivity and infusion reactions, or other serious or unexpected adverse reactions in patients receiving BENLYSTA™ should be reported to GlaxoSmithKline Inc. or Health Canada:

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4
Tel.: 1-800-387-7374

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at: 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678 6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator: 0701E
    Ottawa, Ontario, K1A 0K9

The Reporting Form, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Heath Products Directorate
E-mail: mhpd dpsc@hc-sc.gc.ca
Tel: 613-954-6522
Fax: 613-952-7738

Sincerely,

original signed by

Dr. Glenn Crater,
Vice-President, Medical and Chief Medical Officer