Public Communication -
Health Canada Endorsed Important Safety Information on
PrBENLYSTA™ (belimumab)

25 April 2014

Subject: Progressive Multifocal Leukoencephalopathy (PML) reported in patients receiving BENLYSTA™ (belimumab) for Systemic Lupus Erythematosus (SLE)

GlaxoSmithKline Inc, (GSK) in consultation with Health Canada, would like to inform you of important new safety information for patients currently receiving BENLYSTA™ (belimumab).

BENLYSTA™ is a drug used to treat adult patients with SLE (also known as lupus), who are also receiving other medicines for this condition.

Progressive multifocal leukoencephalopathy (PML) is a serious brain condition caused by the John Cunningham virus (JC virus) in individuals with suppressed immune system. It can cause severe disability or death.

- PML has been reported in two patients receiving BENLYSTA™ and other drugs that suppress the immune system, for the treatment of lupus. One of the cases resulted in death.
- The signs and symptoms of PML may include but are not limited to:
    - Memory loss and/or trouble thinking
    - Confusion
    - Problems with vision
    - Difficulty with swallowing, talking or walking
    - Seizures
- Contact your doctor immediately if you experience any of the above or any other unusual symptoms after being treated with BENLYSTA™. Immediately inform your doctor if you experience any new or worsening of such symptoms while taking BENLYSTA™.
- If PML is suspected, it should be urgently investigated by a neurologist or other appropriate specialist.

Two cases of PML have now been reported out of approximately 15,000 patients with SLE who have so far been treated with BENLYSTA™. While the exact role of BENLYSTA™ in the development of PML is not yet clear, its contribution to this risk cannot be excluded. Based on the information to date, physicians treating patients with SLE should consider that BENLYSTA™ may increase the risk of PML.

GlaxoSmithKline Inc. has sent a letter to healthcare professionals informing them of this new safety information. Further information can be found on the Canadian website of GlaxoSmithKline (www.gsk.ca) or on the Health Canada Web site (www.healthycanadians.gc.ca/index-eng.php).

If you have questions regarding your BENLYSTA™ prescription, please contact your doctor.

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

Managing marketed health product-related side effects depends on health care professionals and patients reporting them. Any case of PML or other serious or unexpected side effects in patients receiving BENLYSTA™ should be reported to GlaxoSmithKline Inc. or Health Canada.

GlaxoSmithKline Inc.
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Phone: 1-800-387-7374

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Original signed by

Dr. Sally Taylor
Country Medical Director, Canada
GlaxoSmithKline Inc.