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

22 April 2014

Dear Healthcare Professional,

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

GlaxoSmithKline, in consultation with Health Canada, would like to inform you of important new safety information relating to the use of BENLYSTA™ (belimumab). BENLYSTA™ is indicated, in addition to standard therapy, for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE).

- Two cases of Progressive Multifocal Leukoencephalopathy (PML) have been reported "post-market" in patients receiving BENLYSTA™, and other immune-modulating therapies for the treatment of SLE. One case was fatal.
- Healthcare providers should consider a diagnosis of PML in any patient on BENLYSTA™, presenting with new onset deficits or deterioration in cognition, speech or ocular functions, and/or motor and gait disturbances. Seizures may also occur.
- If PML is suspected it should be urgently investigated by a neurologist or other appropriate specialist. Where appropriate, immunosuppressant medications including BENLYSTA™ should be withheld until PML is excluded.

PML is a serious opportunistic brain infection that results in progressive deterioration of neurological function. PML is caused by infection or activation of the John Cunningham virus (JC virus) and can cause severe disability or death.

Two cases of PML have been reported spontaneously in adult female patients receiving BENLYSTA™ out of an estimated post-marketing exposure of over 15,000 SLE patient exposures. Both patients were also receiving mycophenolate mofetil (MMF) and prednisone. One of the patients died.

If PML is suspected, the patient should be urgently referred to a neurologist, or other appropriate specialist. Where appropriate, treatment with BENLYSTA™ and other immunosuppressant therapy should be withheld until PML is excluded.

The Product Monograph for BENLYSTA™ is being updated to include the risk of PML. This Healthcare Professional Communication, an accompanying Public Communication, and the Product Monograph can be accessed on Health Canada's website (http://www.hc-sc.gc.ca); or on the Canadian website of GlaxoSmithKline (www.gsk.ca).

Managing marketed health product-related adverse reactions depends on health care professionals and patients 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 PML 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

To correct your mailing address or fax number, contact GlaxoSmithKline Inc.

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, contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 1-613-954-6522
Fax: 1-613-952-7738

If you have any questions or require additional information, please contact the GlaxoSmithKline Inc. Medical Information Department at 1-800-387-7374.

Sincerely,

Original Signed by

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