Health Canada Endorsed Important Safety Information on ARZERRA™ (ofatumumab)

January 27, 2014

Dear Health Care Professional

Subject: ARZERRA™ (ofatumumab) – Recommendations to screen, monitor and to manage hepatitis B virus reactivation

GSK, in consultation with Health Canada, would like to inform you of important new updates to the recommendations for screening, monitoring and management of Hepatitis B reactivation in patients treated with ARZERRA™ (ofatumumab).

ARZERRA™ is an anti-CD20 antibody that is authorized in Canada under a Notice of Compliance with conditions, for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.

- Use of anti-CD20 antibody therapies such as ARZERRA™ has been shown to be associated with Hepatitis B virus reactivation in seropositive patients.
- Patients who have active Hepatitis B virus (HBV) infection should not be treated with ARZERRA™.
- All patients should be screened for HBV infection before starting treatment with ARZERRA™. In seropositive patients, consultation with a physician having expertise in liver disease is recommended. Patients should be monitored for clinical and laboratory signs of hepatitis or HBV reactivation during therapy and for several months after completion of treatment.
- Immediately discontinue ARZERRA™ in patients who develop reactivation of HBV. Resumption of ARZERRA™ in patients whose HBV reactivation has resolved should be discussed with physicians with expertise in managing Hepatitis B virus infection.

The use of anti-CD20 antibody therapies such as ARZERRA™ has been associated with HBV reactivation in patients with positive HBV surface antigen (HBsAg+ve) and in those with negative HBV surface antigen plus positive anti-HB core antibody (HBsAg-ve/HBcAb+ve), particularly when administered in combination with chemotherapy.

The existing information in the ARZERRA™ Product Monograph has been updated to include the new recommendations for screening, monitoring and management of Hepatitis B reactivation.

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 HBV reactivation or other serious or unexpected adverse reactions in patients receiving ARZERRA™ should be reported to GlaxoSmithKline Inc. or Health Canada.

The revised Product Monograph may be accessed on the Health Canada Website at http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp, or on the Canadian Website of GlaxoSmithKline (www.gsk.ca).

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 about this new information, please contact GlaxoSmithKline Medical Information Department at 1-800-387-7374.

Sincerely,

Original Signed By

Vito S. Racanelli, MD
Dir Medical Affairs,
GlaxoSmithKline Inc.