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

January 27, 2014

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

GSK, in consultation with Health Canada has informed health care professionals of important safety updates regarding the use of ARZERRA™.

ARZERRA™ is a medication that is administered into the veins to treat chronic lymphocytic leukemia (CLL), a type of blood cancer.

- Use of ARZERRA™ has been shown to be associated with recurrence of Hepatitis B virus infection in patients who show evidence of a previous infection with the Hepatitis B virus, in a blood test. It is advised that all patients be tested for hepatitis B virus infection before starting treatment with ARZERRA™.
- Infection with hepatitis B virus causes inflammation of the liver which may show as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue.
- Patients who experience any of these symptoms should immediately contact their healthcare provider. Patients who show evidence of hepatitis B virus infection may be referred to a liver disease expert for ongoing follow-up and management. Patients with a history of hepatitis should report this to their physician.
- ARZERRA™ is not to be used in patients with active hepatitis B viral disease. Tell your doctor if you think you have hepatitis B.

The prescribing information for ARZERRA™ has been revised to include new recommendations for the screening, follow-up and management of patients with Hepatitis B reactivation.

GSK has sent a letter to healthcare professionals informing them of this important safety information. This information may be obtained on the Canadian website of GlaxoSmithKline Inc. (www.gsk.ca) or on the Health Canada website.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious hepatitis B recurrence or other serious or unexpected side effects in patients

receiving ARZERRA™ should be reported to GlaxoSmithKline or Health Canada.

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

You can report any suspected side effect 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.

Original Signed By

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