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

August 6, 2014

Dear Health Care Professional

Subject: ARZERRA™ (ofatumumab) – Fatal infusion reaction reported in a patient with Chronic Lymphocytic Leukemia (CLL) who received intravenous ofatumumab

GlaxoSmithKline Inc. (GSK), in consultation with Health Canada, would like to inform you of important new safety information regarding a fatal infusion-related reaction following the use of 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.

- A post-marketing case of fatal infusion reaction has been reported in a patient with CLL with no known history of cardiac disease.
- The current ARZERRA™ Product Monograph is being updated to include the appropriate warnings and precautions to reflect the potential for fatal infusion reactions.
- Health Care Professionals are reminded that serious infusion reactions may still occur with administration of ofatumumab despite premedication. If a severe infusion reaction is suspected, stop the infusion immediately and provide symptomatic treatment.
  - Ofatumumab should be administered under the supervision of a physician experienced in the use of cancer therapy and in an environment where facilities to adequately monitor and treat infusion reactions are available.
  - Appropriate premedications should always be administered as prescribed in the product label.

Health care professionals should inform their patients regarding the risk of fatal infusion reactions associated with the use of ARZERRA™ (ofatumumab).
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 or infusion reactions 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,

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