Health Canada Endorsed Important Safety Information on RITUXAN® (rituximab)

June 7, 2011

Subject: RITUXAN® (rituximab) and Severe and/or Fatal Infusion Related Reactions in Patients with Rheumatoid Arthritis (RA)

Hoffmann-La Roche Limited, in consultation with Health Canada, has informed health care professionals of important safety information regarding RITUXAN® (rituximab) in Rheumatoid arthritis patients and severe infusion reactions.

RITUXAN is a medication that is given by intravenous infusion to treat lymphoid tissue and bone marrow cancer as well as treat adults with moderate to severe rheumatoid arthritis.

Roche would like to inform you of the following:

- Severe infusion related reactions resulting in death have been reported in four persons with rheumatoid arthritis who were given RITUXAN. None were in Canada.
- An infusion reaction can include the following: fever, chills, difficulty breathing, tightness of chest and/or throat, upset stomach, and rash. Notify your healthcare professional if you experience any of these symptoms.
- If a severe infusion reaction occurs, RITUXAN administration needs to be stopped.
- As severe reactions can occur during the infusion of RITUXAN, it is important that you are closely monitored during and after the infusion by a healthcare professional, especially if you have a heart condition.
- It is important that you receive a medication to reduce fever, such as TYLENOL®, an antihistamine, such as BENADRYL®, and a steroid such as Prednisone, before your infusion of RITUXAN.

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 occurrence of serious and/or unexpected adverse reactions in patients receiving RITUXAN should be reported to Hoffmann-La Roche Limited, or Health Canada at the following addresses:

Hoffmann-La Roche Limited
Drug Safety Department
2455 Meadowpine Boulevard
Mississauga, Ontario, L5N 6L7
or call toll free at: 1-888-762-4388
or Fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

Should you have any questions or require additional information regarding the use of RITUXAN, please contact the Drug Information Department at Hoffmann-La Roche Limited at 1-888-762-4388 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time.

Sincerely,

Lorenzo Biondi,
Vice President, Medical and Regulatory Affairs
Hoffmann-La Roche Limited