Public Communication -
Health Canada Endorsed Important Safety Information on
ZELBORAF® (vemurafenib)

April 7, 2014

Subject: Association of ZELBORAF® (vemurafenib) Use with Liver Problems

Hoffmann-La Roche Limited (Roche Canada), in collaboration with Health Canada, would like to inform you of important new safety information regarding the risk of liver problems reported with ZELBORAF (vemurafenib) treatment.

ZELBORAF is used in adult patients to treat a type of skin cancer that has a change in a gene called BRAF and that cannot be removed by surgery or has spread to other parts of the body.

- Liver problems, including severe cases, have been reported with ZELBORAF.
- If you are using ZELBORAF, your doctor should be monitoring you for any signs of liver problems with appropriate blood tests before starting to use ZELBORAF and monthly while on ZELBORAF, or as appropriate for your condition.
- Talk to your doctor right away if your skin or the whites of your eyes turn yellow, you feel tired, your urine turns dark or brown, you have severe itching, you have nausea or vomiting or you do not want to eat. Your doctor will evaluate if you need to reduce your dose, interrupt it temporarily or stop treatment to prevent or manage any liver problems.

Roche Canada will be working with Health Canada to update the safety information for ZELBORAF.

Roche Canada has sent a letter to health care professionals informing them of this important safety information. This information may also be obtained on the Web sites of Health Canada (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2013/index-eng.php) and Roche Canada (http://rochecanada.com). If you have questions regarding your ZELBORAF prescription, please contact your doctor.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Any case of liver problems or other serious or unexpected adverse reactions in patients receiving ZELBORAF should be reported to Roche Canada or Health Canada.

Hoffmann-La Roche Limited
Drug Safety Department
7070 Mississauga Road
Mississauga, Ontario, L5N 5M8
Toll free : 1-888-762-4388
Fax: 905-542-5864
E-mail: mississauga.drug_safety@roche.com

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 (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 ZELBORAF, 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.

Original signed by

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