Health Canada Endorsed Important Safety Information on KADCYLA™ (trastuzumab emtansine)

Roche

October 9, 2013

Dear Health Care Professional:

Subject: Potential Risk for Medication Error Due to Name Confusion Between KADCYLA™ (trastuzumab emtansine) and HERCEPTIN® (trastuzumab)

Hoffmann-La Roche Limited (Roche), in consultation with Health Canada, would like to bring to your attention the potential risk for medication error due to the similarity in the non-proprietary names of KADCYLA and another breast cancer medication, HERCEPTIN, and the importance of ensuring that the correct product is administered to patients.

On September 11, 2013, Health Canada authorized KADCYLA for the following indication:

KADCYLA (trastuzumab emtansine), as a single agent, is indicated for the treatment of patients with HER2-positive, metastatic breast cancer who received both prior treatment with HERCEPTIN (trastuzumab) and a taxane, separately or in combination. Patients should have either received prior therapy for metastatic disease, or developed disease recurrence during or within 6 months of completing adjuvant therapy.

- **KADCYLA (trastuzumab emtansine) and HERCEPTIN (trastuzumab) are NOT the same product.**
- **There is a potential risk for medication error between KADCYLA and HERCEPTIN.**
- **Health care professionals should use both the brand name KADCYLA and its full non-proprietary name (trastuzumab emtansine) when prescribing the medication to patients.**
- **When preparing and administering KADCYLA, health care professionals should check:**
  - **The prescription, to ensure that KADCYLA is the intended medication to be administered;**
  - **The dosage, to ensure that the recommended dose of KADCYLA is administered (refer to Dosage and Administration section of the Product Monograph (1));**
  - **The vial labels, to ensure that the drug is KADCYLA and not HERCEPTIN.**

KADCYLA is an antibody-drug conjugate with the non-proprietary name trastuzumab emtansine and HERCEPTIN is an antibody with the non-proprietary name trastuzumab. The doses, treatment schedules and authorized indications for KADCYLA and HERCEPTIN are different. The dosage for KADCYLA and HERCEPTIN are as follows:

- KADCYLA is administered every 3 weeks (3.6 mg/kg)
- HERCEPTIN is administered every 3 weeks (8 mg/kg loading dose; 6 mg/kg maintenance dose), or weekly (4 mg/kg loading dose; 2 mg/kg maintenance dose)

The indication for KADCYLA is as described above; the indications for HERCEPTIN can be found in the Product Monograph for HERCEPTIN (2).

Health care professionals must be aware that confusion between these products may lead to dosing errors and potential harm to patients. In addition to the measures above, Roche has differentiated the packaging for KADCYLA and HERCEPTIN by the use of different colours. Such precautions should help to reduce the potential for medication errors. For additional information on KADCYLA, please refer to the Product Monograph (1).

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 medication error due to name confusion between KADCYLA and HERCEPTIN or other serious or unexpected adverse reactions in patients receiving KADCYLA should be reported to Hoffmann-La Roche Limited or Health Canada. Medication errors can also be reported to the Institute for Safe Medication Practices (ISMP) Canada through the Canadian Medication Incident Reporting and Prevention System.

Hoffmann-La Roche Limited
Drug Safety Department
7070 Mississauga Road
Mississauga, Ontario, L5N 5M8
or call toll free at: 1-888-762-4388
or fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

To correct your mailing address or fax number, contact Hoffmann-La Roche Limited.

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:
Biologics and Genetic Therapies Directorate (BGTD)
E-mail: BGTD_DGO_Enquiries@hc-sc.gc.ca
Telephone: 613-946-7264
Fax: 613-946-5214

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

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

References:

1. KADCYLA Canadian Product Monograph. Hoffmann-La Roche Limited, Mississauga, Ontario. September 11, 2013.
2. HERCEPTIN Canadian Product Monograph. Hoffmann-La Roche Limited, Mississauga, Ontario. September 24, 2013.