**Public Communication -**
**Health Canada Endorsed Important Information on**
**TYKERB® (lapatinib ditosylate)**

March 25, 2013

**Subject:** **Updated Information – TYKERB® (lapatinib ditosylate)-based treatments are less effective than HERCEPTIN® (trastuzumab)-based treatments in certain settings**

GlaxoSmithKline Inc., in consultation with Health Canada, is providing Canadians with updated information on the use of the cancer treatment drug, TYKERB®. For breast cancer patients with metastatic breast cancer that is HER 2 positive, two recent studies have shown that use of TYKERB® in combination with chemotherapy is less effective than the use of HERCEPTIN® in combination with chemotherapy.

Based on the analyses of data from these two studies, GlaxoSmithKline would like to advise you of the following:

- In patients with metastatic breast cancer that is HER-2 positive, therapy with HERCEPTIN® should be considered a more effective initial treatment than therapy with TYKERB®.
- If you are taking TYKERB® and have any questions regarding how this new information may affect your treatment, contact your doctor.

GSK has sent a letter to healthcare professionals detailing the results of these two new studies. Furthermore, physicians have been informed that TYKERB®-based therapies should not be prescribed unless their patients' metastatic breast cancer has progressed during treatment with HERCEPTIN®-based therapies.

Further information may be obtained on the Canadian website of GlaxoSmithKline (www.gsk.ca) or on the Health Canada website.

For media inquiries, please contact GlaxoSmithKline Communications at (905) 819-3363.

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 serious or unexpected side effects in patients receiving TYKERB® should be reported to GlaxoSmithKline Inc. or Health Canada.

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

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, please contact Health Canada at:

Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

***Original signed by***

Dr. Glenn Crater,
Vice-President, Medical and Chief Medical Officer
GlaxoSmithKline Inc.

***References:***

Gelmon KA, Boyle F, Kaufman B, et al. Open-label phase III randomized controlled trial comparing taxane-based chemotherapy (Tax) with lapatinib (L) or trastuzumab (T) as first-line therapy for women with HER2+ metastatic breast cancer: Interim analysis (IA) of NCIC CTG MA.31/GSK EGF 108919. J Clin Oncol. 2012;30(suppl; abstr LBA671).

X Pivot, V Semiglazov, B Zurawsky, R Allerton, A Fabi, E Ciruelos, R Parikh, M DeSilvio, S Santillana and R Swaby : [CEREBEL (EGF111438): An open label randomized phase III study comparing the incidence of CNS metastases in patients(pts) with HER2+ Metastatic Breast Cancer (MBC), treated with Lapatinib plus Capecitabine (LC) versus Trastuzumab plus Capecitabine (TC). Ann Oncol (2012) 23(suppl 9): ixe5 abstract LBA11 doi:10.1093/annonc/mds499