

## **FOR IMMEDIATE RELEASE**

### **New therapy option for advanced HER2 breast cancer approved in Canada**

***TYKERB™ is the first oral, once-a-day HER2 targeted therapy approved by Health Canada***

**MISSISSAUGA, ON (May 26, 2009)** – Women living with HER2 positive breast cancer now have a new treatment option for the first time in almost ten years. Health Canada has approved Tykerb™ (lapatinib ditosylate) tablets for use in combination with an oral chemotherapy, capecitabine (Xeloda®), for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress HER2 (ErbB2) and who have progressed following prior therapies including taxanes, anthracyclines and trastuzumab (Herceptin®). HER2 positive breast cancer is an aggressive form of the disease that affects approximately 20 per cent of breast cancer patients.<sup>i</sup>

“Today marks an important milestone,” said Dr. Kathleen Pritchard, Senior Scientist at Sunnybrook Odette Cancer Centre, and Professor of Medicine at the University of Toronto. “Tykerb is a new way to treat HER2 positive breast cancer that gives women with advanced HER2 positive breast cancer another weapon in the fight to control their disease, where before they had no other options.”

Tykerb™ slows the progression of advanced breast cancer in patients whose disease has progressed following treatment with other cancer therapies. Women with HER2 (ErbB2) positive breast cancer are at a greater risk of disease progression and death compared to women with tumours that do not overexpress this protein.<sup>ii</sup>

Tykerb™ has a novel mechanism of action that is different from current licensed targeted therapies for HER2 positive disease. It is a small molecule that is administered orally and works by getting inside the cancer cell and inhibiting the EGFR (ErbB1) and HER2 (ErbB2) receptors, which are involved in the growth and proliferation of some cancers.

“In 2004, when my breast cancer came back, my doctor said I was out of treatment options,” says Cecile Comeau, a Canadian HER2 positive breast cancer patient. “He then suggested I join a clinical trial for a new oral therapy, I had nothing to lose. That decision has meant everything to me, and to my family.”

“Tykerb’s approval means a new option in our arsenal in the fight against HER2 positive breast cancer and we look forward to the day when it is made available to Canadian women in every province,” says Diana Ermel, President, Canadian Breast Cancer Network. “Dedication to research and new therapies like this one provides women with more tools they need to fight their disease.”

"The approval of Tykerb is very important for women with HER2 positive breast cancer – both now and in the future," says Virginia Yule, Executive Director, Willow Breast Cancer Support Canada. "When new treatments become available, they provide more options for physicians and women to deal with their breast cancer."

### **About Breast Cancer**

- In 2009, an estimated 22,700 Canadian women will be diagnosed with breast cancer.<sup>iii</sup>
- For Canadian women, breast cancer is the second leading cause of cancer mortality.<sup>iv</sup>
- Breast cancer is the most common cancer and cause of cancer death in women aged 20 – 59, accounting for 37 per cent of new cases and 22 per cent of deaths.<sup>v</sup>
- One in nine women is expected to develop breast cancer during her lifetime. One in 28 will die of it.<sup>vi</sup>
- HER2 (otherwise known as ErbB2) positive breast cancer is an aggressive form of cancer that hits women in their prime. Approximately 20 per cent of women with breast cancer overexpress the HER2 (ErbB2) protein.<sup>vii</sup> Since it is a particularly aggressive form of cancer, women with HER2 (ErbB2) positive breast cancer are at a greater risk of disease progression and death compared to women with breast cancer tumors that do not overexpress HER2 (ErbB2).<sup>viii</sup> The five-year relative survival rate is significantly lower among women with a more advanced stage (stage III or IV) of cancer at diagnosis at 59% and 26% respectively.<sup>ix</sup>
- GSK has a comprehensive clinical trial program that is actively studying Tykerb™ tablets in other breast cancer settings and other cancers to better identify patient populations that may respond to therapy. These include the earlier stages of HER2 (ErbB2) positive breast cancer,<sup>x,xi,xii</sup> inflammatory breast cancer,<sup>xiii</sup> brain metastases,<sup>xiv</sup> as well as head and neck, and gastric cancers.<sup>xv,xvi</sup>

### **Clinical Trials**

The approval was based on a pivotal phase III trial (EGF100151) in which women with locally advanced or metastatic HER2 positive breast cancer whose disease had progressed following prior treatment with anthracyclines, taxanes and trastuzumab were given either the combination of Tykerb™ and capecitabine, or capecitabine alone. Tykerb™ in combination with capecitabine was shown to increase the median time to progression compared to capecitabine alone. There was a consistent benefit in time to progression (TTP) by both unblinded investigator and blinded independent assessment, although the magnitude of TTP by independent assessment was likely overestimated.

- By investigator assessment, median TTP was increased from 18.3 weeks to 23.9 weeks when taken in combination with capecitabine versus capecitabine alone.
- By independent assessment, median TTP was increased from 18.6 weeks to 27.1 weeks in the Tykerb™ with capecitabine compared to the capecitabine alone.

In Canada more than 50 investigators have been involved in Tykerb™ breast cancer clinical trials to date involving over 290 patients in nine provinces.

The most common adverse events during therapy with Tykerb™ plus capecitabine were gastrointestinal (diarrhea, nausea and vomiting), skin toxicities (hand foot syndrome and rash) and fatigue. The majority of adverse events and laboratory abnormalities were

mild to moderate in severity. The most common grade 3 and 4 adverse reactions were diarrhea and hand foot syndrome. Tykerb™ has also been associated with cardiac toxicity, pulmonary toxicity and hepatotoxicity.<sup>xvii</sup>

**Attention Broadcast Outlets: B-roll footage is available on Tuesday, May 26<sup>th</sup>**

**Time of feed:** 11:00 –11:30 and 14:00 – 14:30 EST continuous loop

**Coordinates:** Anik F2, C-Band, Transponder 3B @111.1 West Vertical Polarization, D/L Freq 3820MHz; Audio subcarriers 6.8 left, 6.2 right

For assistance with the feed please call: 1-800-565-1471

**About GlaxoSmithKline Inc.**

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<sup>ii</sup> Slamon DJ, Clark GM, Wong SG, Levin WJ, Ullrich A, McGuire WL. Human breast cancer: correlation of relapse and survival with amplification of the HER-2/neu oncogene. *Science* 1987;235:177-87.

<sup>iii</sup> Canadian Cancer Society’s Steering Committee: *Canadian Cancer Statistics 2009*. Toronto: Canadian Cancer Society, 2009.

<sup>iv</sup> Ibid.

<sup>v</sup> Ibid.

<sup>vi</sup> Ibid.

<sup>vii</sup> Ross JS, Slodkowska EA, Symmans WF, et al. The HER-2 receptor and breast cancer : ten years of targeted anti-HER-2 therapy and personalized medicine. *The Oncologist* 2009;14:320-368.

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<sup>ix</sup> Canadian Cancer Statistics 2007. Canadian Cancer Society. Page 84.

<sup>x</sup> Moy B, et al. Phase III study of lapatinib after completion of adjuvant chemotherapy in trastuzumab-naïve women with ErbB2-overexpressing breast cancer: TEACH Study. Poster presentation, 10<sup>th</sup> International Conference on Primary Therapy of Early Breast Cancer in St Gallen, Switzerland. Thursday 17<sup>th</sup> March 2007.

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<sup>xiii</sup> Kaufman B, Trudeau M, Awada A, et al. Lapatinib monotherapy in patients with Her2-overexpressing relapsed or

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<sup>xiv</sup> Lin NU, Dieras V, Paul D, et al. Multicenter phase II study of lapatinib in patients with brain metastases from HER2-positive breast cancer. *Clin Cancer Res* 2009;15(4):1452-1459.

<sup>xv</sup> El-Hariry, I., Harrington K. et al. A phase I, open label study (EGF100262) of lapatinib plus chemoradiation in patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN). Oral presentation, 1st International Meeting on Innovative Approaches in Head & Neck Oncology, Barcelona, Spain. 22nd - 24th February 2007.

<sup>xvi</sup> Ravaud A, Gardner, R. Hawkins H et al. Efficacy of lapatinib in patients with high tumor EGFR expression: Results of a phase III trial in advanced renal cell carcinoma (RCC). *Journal of Clinical Oncology*, 2006 ASCO Annual Meeting Proceedings Part I. Vol 24, No. 18S (June 20 Supplement) 2006: 4502

<sup>xvii</sup> Product Monograph of Tykerb™ (lapatinib ditosylate) tablets, GlaxoSmithKline Inc., May 2009.