

**LANDMARK TYKERB™ (LAPATINIB DITOSYLATE) DATA PUBLISHED IN THE *NEW ENGLAND JOURNAL OF MEDICINE***

*Study Authors Conclude that Further Investigation Into Earlier Use In The Treatment of HER2 Positive Breast Cancer is Warranted*

**MISSISSAUGA, ON – December 28, 2006** – Data from a Phase III study reporting that Tykerb™ (lapatinib ditosylate) tablets plus Xeloda® (capecitabine) is superior to capecitabine alone in women with HER2 (ErbB2) positive advanced breast cancer who had progressed following prior therapy, including Herceptin® (trastuzumab), was published today in the *New England Journal of Medicine* (NEJM).<sup>i</sup> Based on the findings, the study authors concluded that given its distinct mechanism of action and activity, as a small molecule dual receptor tyrosine kinase inhibitor, Tykerb™ tablets should be investigated for use in the earlier treatment of HER2 (ErbB2) positive breast cancer.<sup>i</sup> Tykerb™ is an investigational drug and has not been approved for marketing by any regulatory body.

“Patients with advanced or metastatic HER2 (ErbB2) positive breast cancer have limited options once their cancer has progressed on trastuzumab and standard initial chemotherapy regimens. There has been a clear need for alternative treatments to help women with metastatic breast cancer in this advanced setting. Tykerb™ tablets combined with capecitabine has demonstrated superior efficacy over capecitabine alone in this group of patients and we look forward to it being made available to women suffering from this devastating disease,” said lead investigator Charles Geyer, M.D., Director of Breast Medical Oncology at Allegheny General Hospital, Pittsburgh, Pennsylvania, U.S.A.

Study results demonstrate combination treatment with Tykerb™ tablets were not associated with an increase in either serious toxicity or rates of discontinuation related to adverse events (AEs), compared to capecitabine treatment alone. The most common AEs were diarrhea, hand-foot syndrome and rash distinct from hand-foot syndrome.<sup>i</sup>

According to The Canadian Cancer Society, breast cancer is the most common cancer in Canadian women. In 2006, an estimated 22,200 women will be diagnosed with breast cancer and 5,300 will die of it.<sup>ii</sup> Women with HER2 positive breast cancer are at a greater risk of disease

progression and death compared to those women with tumors that do not over-express HER2.<sup>iii</sup> Metastatic breast cancer eventually develops resistance to trastuzumab.<sup>iv,v</sup>

“We are extremely enthusiastic that *NEJM* has chosen to publish this important data which we believe will truly change the treatment paradigm for thousands of women suffering from late stage breast cancer,” said Paolo Paoletti, M.D., Senior Vice President of the Oncology Medicine Development Centre at GlaxoSmithKline (GSK). “It is also exciting news that these results suggest there may be a role for Tykerb<sup>™</sup> tablets in the earlier treatment of breast cancer,” he added.

To access the full manuscript, beginning December 28<sup>th</sup>, please visit: [www.NEJM.org](http://www.NEJM.org) and click on “Current Issue.”

### **About Tykerb<sup>™</sup> (Lapatinib Ditosylate) Tablets**

Tykerb<sup>™</sup> is a small molecule dual receptor tyrosine kinase inhibitor discovered and developed by GSK as an oral once daily therapy, and is currently being investigated in breast cancer and other solid tumors. Tykerb<sup>™</sup> tablets inhibit both the tyrosine kinase components of EGFR (ErbB1) and HER2 (ErbB2) receptors. Stimulation of these receptors is associated with cell proliferation and multiple processes involved in tumor progression, invasion, and metastases. Over-expression of these receptors has been reported in a variety of human tumors and is associated with poor prognosis and reduced overall survival.

GSK is using advanced technologies, including pharmacogenomics, to better define patient populations that may respond to Tykerb<sup>™</sup> tablets.

### **Regulatory Status of Tykerb<sup>™</sup> Tablets**

Tykerb<sup>™</sup> has been submitted for marketing approval in Canada, the United States, European Union, Switzerland, Australia and New Zealand for the treatment of advanced or metastatic HER2 (ErbB2) positive breast cancer in women who have progressed despite prior therapy, including trastuzumab. By the end of 2006, GSK aims to have also filed Tykerb<sup>™</sup> tablets in a number of countries in Asia, Latin America and Middle East.

## **About GlaxoSmithKline**

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and health-care companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. In Canada, GSK is among the top 15 investors in research and development, contributing more than \$135 million in 2005 alone. GSK is an Imagine Caring Company, and is consistently recognized as one of the 50 best companies to work for in Canada.

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### **For more information, please contact:**

Vesna Krklinski

Six Degrees Medical Consulting

Telephone: 416-388-4893

Email: VKrklinski@sixdegreesmed.com

### **Notes to editors:**

Tykerb™ is also designated at GW572016.

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Xeloda® is a registered trademark of Roche Pharmaceuticals.

To access the latest GSK Oncology media materials, visit [www.gskcancermedia.com](http://www.gskcancermedia.com)

### **References:**

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