

**Pivotal Phase III trial shows that Tykerb™ (lapatinib ditosylate) tablets
nearly doubles time to progression for patients with
ErB2 (HER2) positive advanced breast cancer**

*Other data presented at ASCO show Tykerb™ also demonstrates preliminary
activity in breast cancer-associated brain metastases and activity in
relapsed inflammatory breast cancer*

MISSISSAUGA, ON – June 3, 2006 – GlaxoSmithKline plc [NYSE:GSK, LSE: GSK] today announced late-breaking results from a large, randomized, pivotal Phase III study of its small molecule dual kinase inhibitor, Tykerb™ (lapatinib ditosylate). In this study, the combination of Tykerb™ and Xeloda® (capecitabine) versus capecitabine alone nearly doubled time to progression (36.9 weeks [8.5 months] in the combination arm versus 19.7 weeks [4.5 months] with capecitabine alone, p=0.00032) in women with refractory advanced or metastatic ErbB2 positive breast cancer whose disease had progressed following treatment with Herceptin® (trastuzumab) and other cancer therapies.¹ In April 2006, GSK stopped enrollment of the study based on the unanimous recommendation of an Independent Data Monitoring Committee (IDMC) because it had met its primary endpoint of time to disease progression, and exceeded the predetermined stopping criteria outlined in the committee charter.

Results of this, and several other important Tykerb™ studies, are being presented today at the 2006 American Society of Clinical Oncology (ASCO) annual meeting in Atlanta, Georgia.

Tykerb™ is an investigational drug and is not yet approved for marketing by any regulatory body.

“Because ErbB2 positive breast cancer may eventually progress during or following treatment with trastuzumab, there has been a need for an effective alternative treatment that can successfully block the function of ErbB2 in another way,” said Charles Geyer, M.D., Director of Breast Medical Oncology at Allegheny General Hospital (Pittsburgh, Pennsylvania) and principal investigator for this trial. “These results indicate that lapatinib [Tykerb™] can provide a needed alternative when trastuzumab no longer appears to be helping to control the disease.”

Tykerb™, a small molecule that is administered orally, inhibits the tyrosine kinase components of ErbB1 and ErbB2 receptors. Stimulation of ErbB1 and ErbB2 is associated with cell proliferation and with multiple processes involved in tumor progression, invasion, and metastases. Overexpression of these receptors has been reported in a variety of human tumors and is associated with poor prognosis and reduced overall survival.

The international, multicenter, open-label study (EGF100151), enrolled 392 patients who had advanced or metastatic breast cancer with documented ErbB2 overexpression and whose disease progressed following treatment with trastuzumab and other cancer therapies. The interim analysis included 321 patients (160 in the Tykerb™-capecitabine arm and 161 in the capecitabine monotherapy arm).¹ Canadian sites were involved in this study.

Adverse events (AEs) leading to discontinuation were similar in the Tykerb™-capecitabine combination arm (14 percent) versus capecitabine alone (11 percent), as were overall AEs. AEs in the Tykerb™-capecitabine arm included diarrhea, hand-foot syndrome and rash. An asymptomatic relative decrease of ≥ 20 percent in left ventricular ejection fraction (LVEF), a measure of the strength of the heart observed through electrocardiogram, occurred in 2.5 percent of patients on the combination arm and less than 1 percent of patients on capecitabine; all patients recovered normal LVEF.

Tykerb™ Activity in Brain Metastases Associated with Breast Cancer

Treatment for brain metastases is an area of unmet medical need as one-third of women with ErbB2 overexpression and metastatic breast cancer develop central nervous system (CNS) or brain metastases. Once the disease advances to this stage, overall disease prognosis is poor with the average one-year survival from diagnosis estimated at about 20 percent.⁴ Additional analysis from the EGF100151 study (Late-Breaking Abstract) suggests that Tykerb™ may play a role in decreasing the occurrence of brain metastases. In the interim analysis, only 4 patients experienced CNS relapse in the Tykerb™-capecitabine arm versus 11 in the capecitabine alone arm.¹

Another study (abstract #503) being presented today at ASCO provides preliminary evidence suggesting that Tykerb™ may be effective in treating brain metastases associated with breast cancer. The Phase II trial was conducted by investigators at the Dana-Farber/Harvard Cancer Center, the University of North Carolina, and Georgetown University and was sponsored by the National Cancer Institute's Cancer Therapeutic Evaluation Program (CTEP). The trial evaluated Tykerb™ in 39 patients with ErbB2 positive breast cancer who had developed CNS metastases while on trastuzumab. As reported in the abstract, two patients achieved partial response as measured by RECIST, a linear measure of solid tumors. An additional five patients achieved

stable disease for ≥ 16 weeks. Volumetric analysis, which is a more precise three dimensional measure of tumor volume, was performed in 20 patients. Eight of the patients (40 percent) showed volumetric decline in CNS lesions – five patients showed ≥ 30 percent volumetric decline and an additional three patients showed 15-30 percent volumetric decline. Although the trial did not demonstrate the hypothesized level of activity as assessed by RECIST, the study concludes that there is sufficient evidence of preliminary clinical effect to suggest that Tykerb™ can penetrate the CNS.² The most common adverse events with Tykerb™ were diarrhea (grade 3, 21 percent), fatigue (grade 3, 16 percent), and rash (grade 3, 5 percent).

Inflammatory Breast Cancer

Inflammatory Breast Cancer (IBC) is an especially aggressive and devastating form of breast cancer that is associated with severe side effects and extremely poor prognosis. IBC occurs when breast cancer cells block the lymph vessels in the breast skin and it generally spreads quickly to other parts of the body. Women with IBC live an average of about three years after diagnosis.⁵

Another trial presented today (Abstract #502) at ASCO evaluated Tykerb™, as a single agent in patients with relapsed or refractory IBC. In this study, 57 patients were assigned to one of two groups. The first group were ErbB2 overexpressors and the second were ErbB2 non-overexpressors. Both groups received daily Tykerb™ treatment. The analysis presented showed that 62 percent of patients who were ErbB2 overexpressors, had a clinical response to Tykerb™ (15 out of 24).³

In this trial, Tykerb™ was generally well tolerated. The majority of side effects associated with Tykerb™ were grade 1/2 skin and gastrointestinal.

“Breast cancer is the most common cancer in Canadian women. In 2006 an estimated 22,300 women will be diagnosed with breast cancer and 5,300 will die of it,” said Dr. Karen Gelmon, Canadian Medical Oncologist and Head Breast Tumour Group and Clinical Head Advanced Therapeutics for the BC Cancer Agency in Vancouver, British Columbia. “New advances in breast cancer research play a pivotal role in shaping the successful control of this major cancer killer amongst Canadian women.”

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 \$140 million in 2004 alone. GSK is an Imagine Caring Company, and is consistently recognized as one of the 50 best companies to work for in Canada.

-30-

For more information, please contact:

Hill & Knowlton

- Peter Gay: 416-413-4732 (office) / 416-523-1420 (on-site ASCO) / peter.gay@hillandknowlton.ca
- Farah Meghji: 416-413-4737 (office) / 416-894-3174 (cell) / farah.meghji@hillandknowlton.ca
- Julie Holroyde: 416-413-4625 (office) / 416-805-7942 (cell) / julie.holroyde@hillandknowlton.ca

GlaxoSmithKline

- Corporate Communications: 905 819 3363

Notes to editors:

Tykerb™ is also designated as GW572016.

Tykerb™ is used under license by GlaxoSmithKline Inc.

Xeloda® and Herceptin® are registered trademarks of Roche Pharmaceuticals.

To access the latest GSK Oncology media materials, visit <http://www.cancermedia.com>

References:

1. Late breaking clinical trial presented at The 2006 ASCO Annual Meeting, 3 June 2006.
2. Abstract #503 - Phase II trial of lapatinib for brain metastases in patients with HER2+ breast cancer.
3. Abstract #502 - EGF103009, a Phase II trial of lapatinib monotherapy in patients with relapsed/refractory inflammatory breast cancer (IBC): Clinical activity and biologic predictors of response.
4. R. Weil et al. Breast Cancer Metastasis to the Central Nervous System. American Journal of Pathology. 2005;167:913-920.
5. National Cancer Institute.