FDA approves Tykerb (lapatinib) in combination with Xeloda (capecitabine) for the treatment of advanced or metastatic breast cancer in women who have progressed on prior therapy

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This press release is intended for business journalists and analysts/investors. Please note that this release may not have been issued in every market in which GSK operates.

GlaxoSmithKline's bew breast cancer drug may give women more options

PHILADELPHIA, PA, March 13, 2007 — GlaxoSmithKline plc [NYSE: GSK, LSE: GSK] announced today that the United States Food and Drug Administration (FDA) approved *TYKERB*® (lapatinib), in combination with Xeloda® (capecitabine), for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. It is the first targeted, once-daily oral treatment option for this patient population. *TYKERB* was granted Priority Review by the FDA in November 2006.

"*Tykerb* is a significant breakthrough for women with advanced HER2 (ErbB2) positive breast cancer. The data clearly show that this small molecule, oral, targeted agent, in combination with capecitabine, is effective for women whose disease has progressed on previous therapies, including anthracyclines, taxanes and trastuzumab," said Paolo Paoletti, MD, Senior Vice President of the Oncology Medicine Development Center at GSK. "The approval of *TYKERB* demonstrates our R&D organization's strong commitment to the discovery and development of novel cancer treatments. We are dedicated to the further study and development of Tykerb in a variety of settings including adjuvant breast cancer as well as in other solid tumor

types."

This approval reflects more than 16 years of research, including more than 60 clinical trials and investigator-initiated collaborative research studies. *TYKERB* inhibits two validated targets in oncology, the kinase components of the EGFR (ErbB1) and HER2 (ErbB2) receptors, commonly associated with cancer cell proliferation and tumor growth. As a targeted therapy, *TYKERB* is designed to interfere with discrete cellular processes or disease mechanisms prevalent in cancer. *TYKERB* will be available in the United States within two weeks and, as an oral therapy, offers added convenience for patients.

"The approval of *TYKERB* is an important milestone in our commitment to become a major oncology company that focuses on scientific innovation and genuine patient needs," said Chris Viehbacher, President, US Pharmaceuticals at GSK. "Our rich pipeline of oncology medicines underscores our commitment to cancer patients. This commitment extends to programs to help ensure that women who may benefit from *TYKERB* will have access to it."

TYKERB Patient Support

To support patient access, GSK has established a single source for information and support called *Tykerb® CARES*. Through this comprehensive program, knowledgeable consultants are available to answer product-related questions from patients and physicians, and can assist them with obtaining *TYKERB.* Additionally, *Tykerb® CARES* reimbursement counselors will help patients understand their insurance coverage and, if appropriate, assist in identifying alternative financial support. More information regarding *Tykerb® CARES* can be found by calling 1-866-4-TYKERB (89-5372). Program hours are Monday — Friday, 8:30 am — 8:00 pm ET.

TYKERB Clinical Results

This approval was based on the pivotal Phase III trial of 399 patients which showed that the median time to disease progression as assessed by independent reviewers was 27.1 weeks on the combination of *TYKERB* and capecitabine versus 18.6 weeks on capecitabine alone in women with advanced or metastatic HER2 (ErbB2) positive breast cancer whose disease had progressed following treatment with trastuzumab and other cancer therapies. The hazard ratio of 0.57 (95% CI: 0.43, 0.77, p =

0.00013) represents a 43 percent reduction in the risk of progression for the patients on the combination arm.[1] Differences between treatment groups based on unblinded investigator assessments were smaller but continued to be clinically and statistically significant.

Adverse events (AEs) leading to discontinuation were similar in the *TYKERB*-capecitabine combination arm (14 percent) versus capecitabine alone (14 percent). Most commonly reported AEs in the *TYKERB*-capecitabine combination arm included diarrhea, hand-foot syndrome, nausea, rash, vomiting and fatigue. Left ventricular ejection fraction (LVEF), a measure of the strength of the heart's pumping capacity, was monitored during the study. Among 198 patients who received the *TYKERB*-capecitabine combination treatment, three experienced an asymptomatic (grade 2) decrease in LVEF and one experienced a symptomatic (grade 3) decrease in LVEF.

Ongoing Trials

GSK has a comprehensive clinical program that is actively studying *TYKERB* in other breast cancer settings and other cancers to better identify patient populations that may respond to *TYKERB*.

Marketing applications for lapatinib *(TYKERB/TYVERB)* have been filed around the world, including the European Union, Switzerland, Canada, Brazil, Australia, and South Korea.

About *Tykerb*

TYKERB, a small molecule that is administered orally, inhibits the tyrosine kinase components of the EGFR (ErbB1) and HER2 (ErbB2) receptors. Stimulation of EGFR (ErbB1) and HER2 (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.

About GlaxoSmithKline

GlaxoSmithKline — one of the world's leading research-based pharmaceutical and healthcare companies — is committed to improving the quality of human life by

GlaxoSmithKline at http://www.gsk.com.

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under "Risk Factors" in the Operating and Financial Review and Prospects in the company's Annual Report on Form 20-F for 2005.

Notes to editors:

TYKERB® is a registered trademark of the GlaxoSmithKline group of companies in the United States.

TYVERB® is a registered trademark of the GlaxoSmithKline group of companies in Europe and is the proposed trade name in certain markets, pending regulatory approval.

Herceptin® is a registered trademark of Genentech, Inc. in the U.S.and Roche Pharmaceuticals in Europe.

Xeloda® is a registered trademark of Roche Pharmaceuticals.

To access the latest GSK Oncology media materials, visit http://www.gsk.com/media or http://www.gskcancermedia.com

Enquiries:

US Media enquiries:	Sarah Alspach	+1 919 483 2839
	Mary Anne Rhyne	+1 919 483 2839

UK Media enquiries:	Philip Thomson	+44 20 8047 5502
	Alice Hunt	+44 20 8047 5502
	Gwenan White	+44 20 8047 5502
European Analyst/Investor enquiries:	Anita Kidgell	+44 20 8047 5542
	Sally Ferguson	+44 20 8047 5543
	David Mawdsley	+44 20 8047 5564
US Analyst/ Investor enquiries:	Frank Murdolo	+1 215 751 7002
	Tom Curry	+1 215 751 5419

References

1. Data on file, GlaxoSmithKline, King of Prussia.

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