

# 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

## GlaxoSmithKline's New 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