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Dear Healthcare Professional:

Re: TYKERB® (lapatinib) and hepatotoxicity

This communication from GlaxoSmithKline is to notify you of important safety information for TYKERB.

GSK has observed that hepatotoxicity (predominantly transaminase elevations) may occur during treatment with TYKERB. Rarely, hepatotoxicity has been severe. Elevated liver enzymes generally returned to normal when patients stopped taking TYKERB.

There have been a small number of liver-related deaths in the TYKERB clinical trial program. GSK has looked closely at each one of these cases. Because of the patients' medical condition and underlying cancer, including in some cases liver metastases, it is difficult to ascertain what role TYKERB may have played in these cases.

Healthcare Professionals please take the following actions:

1. Monitor liver function before initiation of treatment, every 4 to 6 weeks, and as clinically indicated.
2. TYKERB dosing should be discontinued for patients with severe changes in liver function and treatment with TYKERB should not be restarted.
3. Share this information with your patient's other Healthcare Professional(s) if applicable, e.g. family doctor.

As of 05 December 2007, approximately 8702 subjects were estimated to have received TYKERB in clinical trials. Since marketing approval, TYKERB exposure is estimated as 1318 subject years as of September 2007. A crude incidence of 0.4% was reported for hepatotoxicity (predominantly transaminase elevations) in the entire TYKERB clinical trial program. Seven events of hepatotoxicity (predominantly transaminase elevations) have been reported from spontaneous sources.

GSK will continue to carefully evaluate all liver events from clinical trials and post marketing reports to improve its understanding of TYKERB's role in these events.

GSK will keep you informed of relevant developments in a timely manner.

If you have any questions, please contact the GSK Response Center at 1-888-825-5249.

Sincerely,



Steven Stein, MD
Medicine Development Leader
Oncology Medicine Development Center
GlaxoSmithKline

TYKERB is indicated in combination with 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.