



**GlaxoSmithKline Research
& Development Limited**
Stockley Park West
Uxbridge
Middlesex
UB11 1BU
United Kingdom

2012-02-15

Dear Dr Abadie,

Re: Withdrawal of TYVERB (lapatinib) Type II variation EMEA/H/C/II/17

I would like to inform you that at this point of time, Glaxo Group Limited (a wholly-owned subsidiary of the GlaxoSmithKline group of companies), has taken the decision to withdraw the application for a new indication for Tyverb Film-coated Tablets 250 mg in combination with paclitaxel for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2 (ErbB2).

The withdrawal is based on the following reason:

The CHMP's assessment that the lack of an active-controlled trial hampers the proper assessment of the benefit-risk benefit in European patients in the applied indication.

This decision will not have consequences for any patients enrolled in any ongoing GSK-sponsored Tyverb study at this time.

Following withdrawal, the Company intends to further evaluate the available data and we reserved the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,

