sanofi aventis

recherche & développement

To: Dr. Eric ABADIE (CHMP Chairman)
EMEA
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Chilly-Mazarin, November 14th, 2008

Subject: Withdrawal of Docetaxel Winthrop, 20 mg/0.5 ml and 80 mg/2 ml, concentrate and solvent for solution for infusion (EU/1/07/384/001-002), EMEA/H/C/000808/II/05

Dear Dr. Abadie,

Sanofi-aventis has made the decision to withdraw the aforementioned application for the new indications for Docetaxel Winthrop:

"Doxorubicin and cyclophosphamide followed by Docetaxel Winthrop in combination with trastuzumab (AC→TH) is indicated for the adjuvant treatment of patients with operable breast cancer whose tumours overexpress HER2."

"Docetaxel Winthrop in combination with trastuzumab and carboplatin (TCH) is indicated for the adjuvant treatment of patients with operable breast cancer whose tumours overexpress HER2."

The withdrawal is based on the following reason:
The CHMP's opinion that the study design did not adequately define the contribution of Docetaxel Winthrop.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

We agree for this letter to be published on the EMEA website.

Yours sincerely,

Sanofi-aventis
Corporate Regulatory Affairs
Regulatory Development