European Medicines Agency
Press office

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PRESS RELEASE
Sanofi-Aventis Pharma S.A. withdraws its application for an extension of indication for Taxotere and Docetaxel Winthrop (docetaxel)

The European Medicines Agency (EMEA) has been formally notified by Sanofi-Aventis Pharma S.A. of its decision to withdraw its application for an extension of indication for the centrally authorised medicines Taxotere (docetaxel) 20 mg/0.5 ml and 80 mg/2 ml, concentrate and solvent for solution for infusion and Docetaxel Winthrop (docetaxel) 20 mg/0.5 ml and 80 mg/2 ml, concentrate and solvent for solution for infusion.

Taxotere and Docetaxel Winthrop were expected to be used for the adjuvant treatment of patients with operable breast cancer whose tumours overexpress HER2 in the following combinations:

- in combination (given simultaneously) with trastuzumab following a chemotherapy regimen based on doxorubicin and cyclophosphamide;
- in combination with trastuzumab and carboplatin.

Taxotere was first authorised in the European Union on 27 November 1995. Docetaxel Winthrop was authorised on 20 April 2007 following an informed consent application to the application for Taxotere. Taxotere and Docetaxel Winthrop are currently indicated for the treatment of breast cancer, non-small cell lung cancer and prostate cancer, gastric adenocarcinoma and head and neck cancer.

The applications for the extension of indication for Taxotere and Docetaxel Winthrop were submitted to the EMEA on 20 December 2007. On 24 July 2008, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the extension of indication for the medicines. Following this, the company requested a re-examination of the opinion, which was under review by the CHMP at the time of the withdrawal.

In its official letters, the company stated that the withdrawal is based on the CHMP's opinion that the study design did not adequately define the contribution of Taxotere and Docetaxel Winthrop.

More information about Taxotere and Docetaxel Winthrop and the state of the scientific assessment at the time of the withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letters from the company, will be published on the EMEA website in due course.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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