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Press release

TAXOTERE® RECEIVES POSITIVE OPINION FROM THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE RECOMMENDING APPROVAL IN THE EUROPEAN UNION FOR METASTATIC STOMACH CANCER

TAXOTERE® demonstrates a 23% reduction in the risk of mortality, offering new hope of long-term survival for patients with advanced stomach cancer

Paris, France – March 24, 2006 – Sanofi-aventis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has issued a positive opinion recommending approval in Europe of TAXOTERE® (docetaxel) Injection Concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with metastatic stomach cancer, including the cancer of the gastro esophageal (GE) junction, who have not received prior chemotherapy for their metastatic disease. This is the first CHMP positive opinion for the treatment of advanced stomach cancer demonstrating a survival advantage in more than a decade, thereby offering physicians and their patients an important new option for treating a disease that is the second leading cause of cancer death worldwide.
The U.S. Food and Drug Administration (FDA) has already approved this supplemental indication on March 23, 2006.

The CHMP based its decision on results from the Tax 325 study, the largest international phase III clinical trial in previously untreated advanced stomach cancer involving 445 patients. Patients treated with the TAXOTERE®-based chemotherapy regimen (TAXOTERE® plus cisplatin and 5-fluorouracil, TCF) experienced a significant 23 percent reduction in the risk of death compared to patients who received a current standard treatment of cisplatin and 5-fluorouracil (CF), (median follow-up: 23 months). The median overall survival was significantly longer with the TAXOTERE®-containing regimen (9.2 vs 8.6 months, p=<0.02) with a hazard ratio of 1.29 (95% CI: 1.04-1.61). Time to disease progression was nearly two months longer in the TAXOTERE®-containing arm (5.6 vs 3.7 months, p=0.0004), hazard ratio 1.47 (CF/TCF 95% CI/ 1.19 -1.83).

"This additional indication for a TAXOTERE®-based regimen, will represent a new reference treatment for metastatic gastric cancer patients in this very difficult disease," said Professor Eric Van Cutsen from the University Hospital of Gasthuisberg, Leuven, Belgium, principal European investigator of the TAX325 trial *"With an optimal treatment option and appropriate risk management of this TAXOTERE®-based regimen, physicians will now have a more effective therapeutic strategy for their patients"*

Approval from the European Commission for the use of a TAXOTERE®-based regimen in the treatment of patients with metastatic gastric cancer would mark the eighth indication in Europe for TAXOTERE®, which is already approved in combination with other agents for the treatment of some of the most common cancers, including locally advanced and adjuvant breast cancer, unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC), and androgen-independent (hormone-refractory) metastatic prostate cancer.

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About the TAX 325 Study

Locally advanced or metastatic stomach cancer has a poor prognosis with a low long-term survival of only 11.5 percent. This study was undertaken to evaluate the benefits of adding TAXOTERE® to a standard chemotherapy regimen. The primary study endpoint was time to tumour progression (TTP), which was significantly improved with TAXOTERE® based therapy (5.6 months) compared to standard treatment (3.7 months) with a 32 percent reduction in the risk of progression (log-rank test p=0.0004). The main secondary endpoint was to detect a statistically significant increase in overall survival. Other secondary objectives included response rate, time to treatment failure, duration of response, safety profiles, quality of life and disease related symptoms.

In total, 81.4 percent of the patients experienced at least one Grade 3-4 (severe) side effect with the TAXOTERE®- based regimen versus 75.4 percent in the control arm with neutropenia being the most common Grade 3-4 side effect in the TAXOTERE®- based regimen. The most common (all grade) side effects associated with the TAXOTERE®- based regimen were anemia, neutropenia, diarrhea, and nausea. The most common (all grade) side effects associated with the cisplatin and 5-fluorouracil arm were anemia, neutropenia, nausea and vomiting. Primary prophylactic use of growth factor support (granulocyte-colony stimulating factor, G-CSF) was not allowed per the study protocol. G-CSF is a bone marrow growth factor that may be administered to reduce febrile neutropenia in patients receiving myelosuppressive chemotherapy. In the TAXOTERE® arm, febrile neutropenia and/or neutropenic infection occurred in 12 percent of patients receiving secondary prophylactic G-CSF compared to 28 percent who did not, which represents a 57 percent reduction.

These results were last presented at the American Society of Clinical Oncology (ASCO) annual meeting in 2005.

With this new indication, TAXOTERE® is now approved for eight indications in the United States and Europe in four different tumour types:

<u>In Breast Cancer:</u>

- In the United States and in Europe TAXOTERE®, is approved for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy,
- TAXOTERE® is also approved in Europe in combination with doxorubicin for patients who have received prior cytotoxic therapy for this condition and in combination with capecitabine after failure of cytotoxic therapy which would have included anthracycline,
- In Europe, TAXOTERE® is approved in combination with trastuzumab for the treatment of patients with metastatic breast cancer- over expressing Her2 receptor.
- In the adjuvant setting (post surgery) TAXOTERE® is approved in the U.S. and in Europe in combination with doxorubicin and cyclophosphamide (TAC regimen) for the treatment of patients with operable, node-positive breast cancer.

<u>In Lung Cancer:</u>

- In the U.S. and in Europe, TAXOTERE®, in combination with cisplatin, is approved for the treatment of patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not received prior chemotherapy,

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- TAXOTERE® is also approved, as a single agent, for patients with unresectable locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy.

In Prostate cancer:

- TAXOTERE® is approved for use in combination with prednisone as a treatment for androgen-independent (hormone-refractory) metastatic prostate cancer in the U.S. and in Europe.

About Stomach Cancer

Stomach cancer is the 4th most common type of cancer worldwide with more than 934,000 new patients every year. It is also the second most common cause of cancer death worldwide; with more than 700,000 deaths annually. There were about 22,800 new cases of stomach cancer in the United States in 2005. In Europe, this number is over 143,000 patients. At diagnosis, most patients with stomach cancer have advanced disease with an expected two-year survival of only 11.5 percent.

About sanofi-aventis

Sanofi-aventis is the world's 3rd largest pharmaceutical company, ranking number 1 in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic disorders, central nervous system, internal medicine, and vaccines. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).

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