FOR IMMEDIATE RELEASE

# Taxotere® (docetaxel) Granted FDA Priority Review for Treatment of Locally Advanced Squamous Cell Carcinoma of the Head and Neck Prior to Chemoradiotherapy and Surgery

*-- Review Based on a Clinical Trial Demonstrating Improved Overall Survival and 30% Lower Death Rate Compared to Standard Regimen Alone --* [1]

Bridgewater, NJ – June 27, 2007 – Sanofi-aventis announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and assigned priority review status to the supplemental new drug application (sNDA) for Taxotere® (docetaxel) Injection Concentrate in combination with cisplatin and fluorouracil for the induction (neo-adjuvant) therapy of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN) prior to chemoradiotherapy and surgery.

The FDA grants Priority Review to products that, if approved, would be a significant improvement compared to marketed products, including non-drug products in the treatment, diagnosis or prevention of a disease.[2] The Prescription Drug User Fee Act (PDUFA) date for completion of review by the FDA of the Taxotere sNDA is slated for Fall 2007. Currently, Taxotere in combination with cisplatin and fluorouracil is approved for the induction therapy of inoperable advanced SCCHN.[3] To date, Taxotere has received a total of seven indications in the U.S. If granted, this will be the eighth FDA approval for Taxotere in five different tumor types.

"We are very pleased that FDA has granted priority review to Taxotere as part of a sequential treatment program that also includes chemoradiotherapy and surgery for advanced head and neck cancer," said Dr. Nassir Habboubi, Vice President of U.S. Medical Affairs, Oncology, for sanofi-aventis. "We are hopeful that Taxotere may soon be available for many patients suffering from advanced head and neck cancer. Sanofi-aventis is committed to continuing the development of effective chemotherapeutics and seeking FDA review and approvals of treatments for patients with many types of cancer."

**Submission Based on Clinical Trial TAX 324**

The FDA submission is based on results of TAX 324, a randomized, open-label, international phase III trial presented at the American Society of Clinical Oncology (ASCO) annual meeting in 2006 showing a Taxotere-based regimen, versus standard chemotherapy, improved overall survival as part of a sequential treatment plan for locally advanced SCCHN. All patients entering the study had stage III or IV cancer with no distant metastases. Patients in both treatment groups had tumors of the oral cavity, oropharynx, larynx or hypopharynx that could not be removed, tumors considered operable but unlikely to be cured with surgery, or tumors that could not be removed in order to preserve crucial organs.

Patients were treated every three weeks for three cycles with either Taxotere 75 mg/m$^2$ plus cisplatin 100 mg/m$^2$ and fluorouracil 1000 mg/m$^2$ a day for four days (TPF) or intravenous cisplatin 100 mg/m$^2$ followed by fluorouracil 1000 mg/m$^2$ a day for five days (PF), the standard therapy. Both groups of patients were then given weekly chemotherapy (carboplatin) together with radiation therapy for seven weeks, followed by surgery for those patients

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identified as candidates. The primary endpoint of the study was to evaluate overall survival (OS); secondary endpoints included progression-free survival (PFS), response rates (RR), and toxicity.

Overall survival was significantly improved for patients treated with Taxotere based therapy compared to patients receiving just cisplatin and fluorouracil; the relative risk of death was 30% lower (HR 0.70; p=0.0058). Patients treated with the Taxotere based therapy had a longer median overall survival of 70.6 months vs. 30.1 months for patients receiving cisplatin and fluorouracil, which represents a 40 month absolute improvement in median OS for patients treated with TPF. At three years, 62% of patients who received TPF were alive compared with 48% of those receiving PF[1].

"This randomized trial demonstrated that Taxotere-based induction chemotherapy followed by chemoradiotherapy and surgery improved overall survival and progression-free survival for patients with locally advanced squamous cell carcinoma of the head and neck," said TAX 324 clinical investigator Marshall Posner, MD, Medical Director of the Head and Neck Oncology Program at Dana-Farber Cancer Institute in Boston. "These results provide potential hope for these patients, in whom survival rates have been historically low. If approved, the addition of Taxotere to standard therapy would represent a clinically important treatment option."

In addition to improvements in overall survival and mortality, the TAX 324 trial showed that progression free survival (PFS) defined as either tumor progression, the length of time before the cancer progressed, or death, was significantly improved with Taxotere. The intent-to-treat population included 255 patients in the TPF arm and 246 patients in the PF arm. The risk reduction for disease progression or death was significantly reduced by 29% (HR 0.71; p=0.004) for patients treated with Taxotere plus cisplatin and fluorouracil compared to patients receiving just cisplatin and fluorouracil. Fifty-three percent of patients treated with the Taxotere regimen were alive without cancer progression at two years versus 42% of standard therapy patients. At three years, 49% of patients in the Taxotere group were alive without disease progression versus 37% of patients in the group without Taxotere treatment. Although not statistically significant, the overall response rate was also increased among patients treated with Taxotere: 72% of patients versus 64% of patients not treated with Taxotere (p=.07).[1]

Overall, the incidence of grade 3/4 toxicity was 65% in the Taxotere arm (TPF) compared to 62% in the group receiving cisplatin and fluorouracil (PF). Patients treated with TPF had more grade 3/4 neutropenia (84% vs. 56%), febrile neutropenia (12% vs 7%), neutropenic infection (12% vs 8%), alopecia (4% vs 1%) and diarrhea (7% vs. 3%) than those in the PF group. Patients in the PF group had more grade 3/4 stomatitis (27% vs. 21%), lethargy (10% vs. 5%), vomiting (10% vs. 8%) and altered hearing (3% vs. 1%). The incidence of other grade 3/4 events was similar between the two groups: nausea 14%, anorexia 12% and constipation 1%.

**Head and Neck Cancer, a Deadly Disease**

More than 640,000 people worldwide are diagnosed with head and neck cancer each year, and more than 350,000 die from the disease annually.[4] Head and neck cancer is a group of many related diseases that mostly begin in the cells that line the mucosal surfaces in the head and



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neck area such as the mouth, nose and throat.[5] The term encompasses cancers of the oral cavity, salivary glands, paranasal sinuses and nasal cavity, pharynx, larynx, and lymph nodes in the upper part of the neck.[5]

See accompanying full prescribing information, including boxed WARNING, or call 800-633-1610 or visit www.taxotere.com.

**About sanofi-aventis**

Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one 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 diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

***Forward Looking Statements***

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

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5. National Cancer Institute. "Head and Neck Cancer: Questions and Answers." Available at: www.cancer.gov/cancertopics/factsheet/Sites-Types/head-and-neck



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