Taxotere® (docetaxel) significantly improves the survival of patients with advanced prostate cancer

- Long term results confirm the survival benefit of Taxotere®-based treatment in patients with metastatic hormone refractory prostate cancer -

Paris, France, February 23, 2007 - Sanofi-aventis today announced, at the ASCO Prostate Cancer Symposium, long term survival results of the large TAX 327 Phase III clinical trial.

The overall survival benefit for the patients with metastatic hormone refractory prostate cancer (mHRPC), receiving 3-weekly 75mg/m² Taxotere® (docetaxel)-prednisone regimen compared to mitoxantrone-prednisone gives a median survival 19.3 months vs. 16.3 months, p=0.005; resulting in a reduction of the risk of death by 21% for patients receiving the 3-weekly 75mg/m² Taxotere®-prednisone regimen.

These results are consistent with the data from the original analysis.

The survival benefit is observed regardless of age, presence or absence of pain and baseline PSA (Prostate Specific Antigen) level, performance status and quality of life measured with FACT-P at baseline level.

These results were highly significant in patients with high PSA at baseline level (≥115ng/ml: 17.5 months vs 12.8 months, p=0.008), absence of pain (23.0 months vs 19.8 months, p= 0.009), with good performance status (≥90%: 22.8 months vs 19.8 months, p= 0.011) and patients with impaired quality of life (FACT-P < 109: 18.3 months vs 12.4 months, p= 0.002). Statistical significance of median survival was not reach regarding age, PSA < 115ng/ml, presence of pain, performance status ≤80% and quality of life with FACT-P ≥109.

The results of the weekly Taxotere® regimen remain comparable as when reported in 2004¹, with the same trend for survival.

From the initial 2004 results, the most commonly observed adverse events in patients receiving Taxotere®3-weekly were anemia, alopecia, fatigue and nausea and the incidence of grade 3 and 4 neutropenia was 32% vs. 22% (p≤ 0.05) and febrile neutropenia occurring in 3% of the patients treated with the 3-weekly 75mg/m² Taxotere®-prednisone regimen, compared to 2% with the mitoxantrone-prednisone regimen.

“This update of the TAX327 study has demonstrated statistically significant improved survival for all patients and for those without pain or with high PSA level and confirms that 3-weekly 75mg/m² Taxotere® plus prednisone is the first-line standard of care in patients with metastatic hormone refractory prostate cancer”, said Dr Ian Tannock, MD, PhD, Department of Medical Oncology and Hematology, Princess Margaret Hospital and University of Toronto and co-chair of the TAX 327 study.
About TAX 327 Study
From March 2000 through June 2002, 1006 men with metastatic hormone refractory prostate cancer were enrolled in the TAX 327 international multicenter phase III randomised non-blinded study.

Patients randomly assigned to Taxotere® groups received either 75 mg/m² of Taxotere® as intravenous infusion every three weeks, or 30 mg/m² of Taxotere® weekly for five of every six weeks. Patients randomly assigned to the standard treatment received 12 mg/m² of mitoxantrone every three weeks. All patients received 5 mg of prednisone given orally twice daily. On average, patient tended to receive the greater number of cycles in the docetaxel arm (every 3 weeks: 9.5 cycles) than in the mitoxantrone arm (every 3 weeks: 5 cycles).

The primary end point was overall survival. Secondary end points were pain, Prostate Specific Antigen (PSA) levels, and the quality of life. All statistical comparisons were against mitoxantrone.

A primary analysis performed in August 2003 and published in the New England Journal of Medicine in 2004 already demonstrated that the study end-points have been reached, showing that Taxotere® every three weeks given with prednisone, led to a superior survival and improved clinical benefit in terms of pain, serum PSA level, and quality of life, as compared with mitoxantrone plus prednisone.

The 3-weekly 75mg/m² Taxotere® (docetaxel)-prednisone regimen was approved for use as a treatment for androgen independent (hormone-refractory) metastatic prostate cancer in the USA in May 2004 and in October 2004 in Europe.


About Prostate Cancer
Prostate cancer ranks third worldwide in cancer incidence and sixth in cancer mortality among men. In Europe in 2004, according to the International Agency for Research on Cancer, 238,000 men were diagnosed with prostate cancer and 85,000 died from prostate cancer in the same year. Approximately 219,000 men in the U.S. are expected to be diagnosed with the disease in 2007 and over 27,000 men are expected to die from the disease. In the European Union, over 200,000 new cases are expected to be diagnosed, and over 60,000 patients are expected to die each year. Since the incidence of prostate cancer increases with age, the aging of the overall population is expected to further increase the number of prostate cancer patients.

About TAXOTERE®
Taxotere® is currently approved in 5 different cancer types:

• In Breast Cancer
In the United States and in Europe Taxotere®, is approved to treat patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. It 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 the adjuvant setting (post surgery) it is approved in the US and in Europe in combination with doxorubicin and cyclophosphamide (TAC regimen) for the treatment of patients with operable, node-positive breast cancer. Finally, in Europe, Taxotere® is approved in combination with trastuzumab for the treatment of patients with metastatic breast cancer overexpressing HER2 receptor.

• **In Lung Cancer**
  In the US 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, and it also is 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 US and in Europe.

• **In Gastric (Stomach) cancer**
  The FDA and the Committee for Medicinal Products for Human Use (CHMP) of the European Agency for the Evaluation of Medicinal Products (EMEA) approved in March 2006, the use of TAXOTERE® Injection Concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with advanced stomach (gastric) cancer, including cancer of the gastroesophageal (GE) junction, who have not received prior chemotherapy for advanced disease.

• **In Head and Neck Cancer**
  In October 2006, the European Medicines Agency (EMEA) and the FDA approved Taxotere® (docetaxel) Injection Concentrate in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN).

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**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 organisation, 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. 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 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, 2005. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.