Studies Showing Significant Survival Improvement with Taxotere®-based Regimens in the Induction Treatment of Patients with Locally Advanced Head and Neck Cancer are Published in the Same Issue of the *New England Journal of Medicine*

Results of Two Major Clinical Studies TAX 323 and TAX 324 Published

Bridgewater, New Jersey – October 24, 2007 – Sanofi-aventis announced today that results of two clinical studies demonstrating that Taxotere® (docetaxel) Injection Concentrate, when added to cisplatin and 5-fluorouracil for induction therapy, significantly improved overall survival (OS) in patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN) are published in the October 25 issue of the *New England Journal of Medicine (NEJM).*

In the TAX 324 trial, which included primarily North American centers, patients who received Taxotere added to cisplatin and 5-fluorouracil (TPF, n=255) experienced a longer median overall survival (OS) of 71 months vs. 30 months (p=0.006) for patients receiving cisplatin and 5-fluorouracil alone (PF, n=246), representing a more than three-year improvement in median OS for patients treated with TPF and a 30% decrease in the relative risk of death.

In the European TAX 323 (EORTC 24971) trial, conducted on inoperable patients only, the patients treated with TPF (n=177) experienced a significantly longer progression free survival of 11.0 months, compared with 8.2 months for patients treated with PF alone (n=181). At a median follow-up period of 51.1 months, patients receiving the Taxotere-based regimen demonstrated a median OS improvement of 4.3 months compared to those receiving the standard chemotherapy (without Taxotere): 18.8 months vs. 14.5 months (HR: 0.73; p=0.02). Treatment with TPF in the TAX 323 study resulted in a 27% reduction in the risk of death.

"*TAX 324 study results show that sequential therapy starting with a Taxotere-based chemotherapy regimen significantly increases survival in patients who are suffering from this particularly deadly form of cancer,"* said the lead clinical investigator of the TAX 324 study, Marshall Posner, MD, Medical Director of the Head and Neck Oncology Program at Dana-Farber Cancer Institute in Boston.

"Survival rates among patients with unresectable locoregionally advanced squamous cell carcinoma have always been low. These data give these patients new reason for hope," said Jan B. Vermorken, MD, PhD, Head of Oncology Department, University Hospital Antwerp and Head of the EORTC section on Head and Neck Cancer and Principal Investigator of the EORTC 24971/TAX 323 study.

The approval by the U.S. Food and Drug Administration (FDA) and the positive opinion by the European Agency for the Evaluation of Medicinal products (EMEA) of the indications for Taxotere in combination with cisplatin and 5-fluorouracil for the induction treatment of patients with locally advanced SCCHN were based on the TAX 323 and TAX 324 study results.

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About the Studies
Both studies are phase III, randomized, open-label trials that included patients with stage III or IV SCCHN with no distant metastases.

The **TAX 323 study (EORTC 24971)** enrolled 358 European patients with inoperable tumors. Patients were randomized to receive an infusion of Taxotere 75 mg/m^2 plus cisplatin 75 mg/m^2 on day one, and a five-day continuous infusion of fluorouracil 750 mg/m^2 daily or intravenous cisplatin 100 mg/m^2 on day one followed by five-day continuous infusion of fluorouracil 1000 mg/m^2 per day. In both groups, treatment was given every three weeks for up to four cycles. Within four to seven weeks from the initiation of the last cycle of chemotherapy, both groups of patients were then given radiation therapy for seven weeks.

The Taxotere-based regimen demonstrated a significantly longer progression-free survival (the primary endpoint of the study). The updated survival analysis performed in 2005 at a median follow-up period of 51.1 months confirmed the survival benefit, demonstrating a 4.3 month higher median overall survival for patients receiving the Taxotere-based regimen than for those receiving the standard chemotherapy (without Taxotere): 18.8 months vs. 14.5 months (HR: 0.73; p=0.02). Treatment with TPF resulted in a 27% reduction in the risk of death. In addition, the best overall response to chemotherapy was significantly higher in the Taxotere®-based regimen arm compared to the standard arm: 68% (n=120) versus 54% (n=98) (p=0.006).

Patients in the TPF arm compared to the cisplatin and fluorouracil arm (PF) had grade 3/4 neutropenia (76.9% vs. 52.5%), alopecia (11.6% vs. 0%), anemia (9.2% vs. 12.8%) and infection (6.9% vs. 6.1%). Patients receiving the PF regimen had greater grade 3/4 nausea (6.7% vs. 0.6%), vomiting (4.5% vs. 0.6%) and stomatitis (11.2% vs. 4.6%). Commonly seen adverse events in the Taxotere-based regimen included febrile neutropenia (5.2%) and neutropenic infection (13.9%).

The **Tax 324 study** included not only inoperable patients, but also patients whose tumors were considered potentially operable with low surgical cure or whose tumors were not removed in order to preserve organ function. Patients were randomly assigned to be treated every three weeks for three cycles either with an intravenous infusion of Taxotere 75 mg/m² plus cisplatin 100 mg/m² on day one and fluorouracil 1000 mg/m² per day on days one through four, or the standard therapy, which was intravenous cisplatin 100 mg/m² followed by fluorouracil 1000 mg/m² per day for five days. Both groups of patients were then given concomitant weekly chemotherapy and radiation therapy for seven weeks. Surgery was performed for those patients considered candidates at the end of the above treatment sequence.

Median overall survival (the primary end point of the study) was significantly improved for patients treated with the Taxotere-based therapy: 71 months vs. 30 months for patients receiving the standard treatment, with a relative risk of death that was 30% lower (HR 0.70; p=0.006). This represents a more than three year absolute improvement in median overall survival. The probability to survive three years was 62% in the Taxotere arm compared to 48% in the standard arm (p=0.0058).

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 febrile neutropenia (12% vs 7%), neutropenic infection (12% vs 8%), and grade 3/4 neutropenia (83% vs. 56%), dizziness (4% vs. 2%), 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 thrombocytopenia (11% vs. 4%), stomatitis (27% vs. 21%), lethargy (10% vs. 5%) and vomiting (10% vs. 8%). The incidence of other grade 3/4 events was similar between the two groups, such as nausea, anorexia and constipation.

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

About Taxotere®
Indications and Usage

Breast Cancer
Taxotere® is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.

Taxotere® in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.

Non-Small Cell Lung Cancer (NSCLC)
Taxotere®, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy.

Taxotere® in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic NSCLC who have not previously received chemotherapy for this condition.

Prostate Cancer
Taxotere® in combination with prednisone is indicated for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer.

Gastric Cancer
Taxotere® in combination with cisplatin and flourouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.

Head and Neck Cancer
Taxotere® in combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

About TAXOTERE®

Important safety information

WARNING: Taxotere® treatment can cause serious, physically limiting, and potentially life-threatening side effects, such as infection, low blood-cell counts, allergic reaction and retention of excess fluid (edema).

Taxotere® should not be given to patients with low white–blood-cell counts, abnormal liver function, or a history of allergic reactions to Taxotere® or any of the ingredients in Taxotere®.

Before each Taxotere® treatment, all patients treated with Taxotere® must receive another medicine called dexamethasone. This drug can help reduce the risk of fluid retention (edema) and allergic reactions.

Taxotere® should be administered only under the supervision of a qualified physician experienced in the use of anticancer treatments. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

Treatment-related acute myeloid leukemia (AML) has occurred in patients given anthracyclines and/or cyclophosphamide, including use with Taxotere® in adjuvant therapy for breast cancer. The most common severe side effects are low white–blood-cell count, anemia, fatigue, diarrhea, and mouth and throat irritation. Low white–blood-cell count can lead to life-threatening infections. The earliest sign of infection may be fever, so tell your doctor right away if you have a fever. Other common side effects from Taxotere® include nausea, vomiting, hair loss, rash, infusion-site reactions, odd sensations (such as numbness, tingling, or burning) or weakness in the hands and feet, nail changes, muscle and/or bone pain, or excessive tearing.

Because of the potential risk of fetal harm, pregnant women should not receive Taxotere®. Women of childbearing potential should avoid becoming pregnant during treatment with Taxotere®.

Before receiving Taxotere®, tell your doctor if

- You have any allergies
- You are taking any other medicines — including nonprescription (over-the-counter) drugs, vitamins, and dietary or herbal supplements

When taking Taxotere®, contact your doctor if

- You have symptoms of an allergic reaction (warm sensation, tightness in your chest, itching/hives, or shortness of breath)
- You experience any other side effects

For full prescribing information, including boxed WARNING, call 800-633-1610 or visit www.fda.gov/cder/foi/label/2006/020449s039lbl.pdf.

About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).

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