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Press release

Taxotere® Significantly Improves Survival Compared with paclitaxel In Women With Advanced Breast Cancer

-- Results of a Head-to-Head Study Comparing Two of the Most Widely Used Chemotherapy Agents in Breast Cancer Published in the Journal of Clinical Oncology --

Paris – August 18, 2005 – The sanofi-aventis Group announced today that the *Journal of Clinical Oncology* has published the results of a phase III trial which demonstrate that treatment with TAXOTERE® (docetaxel) Injection Concentrate significantly improved overall survival and median time to disease progression compared with paclitaxel in women with advanced breast cancer whose disease had progressed after previous treatment with an anthracycline-based therapy. The study shows a statistically significant median overall survival of 15.4 months for TAXOTERE® versus 12.7 months for paclitaxel (HR, 1.41; 95% CI, 1.15 to 1.73; p=0.03).[1] TAXOTERE® and paclitaxel are agents in a class known as taxanes, which are commonly used to treat women with advanced breast cancer.[2]

This study randomized 449 patients with locally advanced or metastatic breast cancer after prior failure with an anthracycline-containing chemotherapy regimen from 53 U.S. and Canadian centers. The patients received either TAXOTERE® (100 mg/m^2, 1-hour intravenous infusion every 21 days) or paclitaxel (175 mg/m^2, 3-hour intravenous infusion every 21 days) – each drug given at the dosage and schedule as approved by the EMEA and Food and Drug Administration.[1] This trial demonstrates that, among all patients who were assigned to receive either TAXOTERE® or paclitaxel (intent to treat analysis), TAXOTERE® conferred significantly longer median time to progression than paclitaxel (5.7 months vs. 3.6 months, p<0.0001)**.** Among patients evaluable for response (tumor shrinkage), those who received TAXOTERE® had significantly higher response rates (37.4% vs. 26.4%, p=0.02) and significantly longer median duration of response (7.5 months vs. 4.6 months, p=0.01), than those who received paclitaxel. When response was evaluated on an intent-to-treat basis (primary end point), the overall response rate was higher for TAXOTERE® (32.0% vs. 25.0%, p=0.10, ns) compared with paclitaxel. However, this difference was not significant.

"This is the first clinical trial to directly compare these extensively used taxanes. Preclinical and laboratory evidence suggested that TAXOTERE® and paclitaxel are different," said Stephen E. Jones, MD, Medical Director of U.S. Oncology Research, Director of Breast Cancer Research, Baylor-Sammons Cancer Center, Dallas, Texas. "The results from this head-to-head study provide oncologists with the clinical evidence of these differences. Rarely have we seen trials for the treatment of women with advanced breast cancer that demonstrate significant differences in survival."

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Patients in the study continued to receive study drug as long as they were responding to treatment. Patients received a median of six cycles of TAXOTERE® compared to a median of four cycles of paclitaxel. The use of G-CSF, a bone marrow growth factor that may be administered to reduce febrile neutropenia in patients receiving myelosuppressive chemotherapy, was only permitted following an initial episode of grade 4 leukopenia or neutropenia (low white blood cell counts) persisting longer than seven days, or when associated with fever. The adverse events reported in the study were consistent with those previously observed in TAXOTERE® studies and are not different from those observed in routine clinical practice.[1] The incidence of treatment-related hematologic and nonhematologic adverse events was greater for TAXOTERE® than for paclitaxel; however, quality of life scores were not statistically different between treatment groups over time.[1]

Other Study Results and Protocol

The randomized, controlled, multi-center, phase III trial enrolled 449 women from 53 institutions in the United States and Canada. Two hundred twenty-five women with a median age of 56 years received TAXOTERE® while 224 patients, average age 54, were administered paclitaxel. Primary endpoints of the study were objective response and tolerance. Secondary endpoints included overall survival, duration of response, time to progression (time without the cancer growing) and quality of life. Quality of life scores were similar between treatment arms over time despite an increased incidence of grade 3/4 toxicities, including neutropenia (decrease in white blood cells which help fight infection)(93.3% vs 54.5% p<0.001), infections (9.9% vs 1.8% p<0.001), diarrhea (5.4% vs 0.5% p<0.001) and edema (fluid retention)(6.8% vs 0.5% p<0.001) in women who received TAXOTERE®. Quality of life was assessed using the Functional Assessment of Cancer Therapy (FACT) measurement system for breast cancer, FACT-B. The questionnaire is designed to assess quality of life including the emotional, functional, physical and social well being of patients. The women completed the questionnaire prior to treatment, after cycle 4 and at the end of the treatment.

"The study reinforced that TAXOTERE® is an effective agent in the treatment of advanced breast cancer," said Dr. Stephen E. Jones. "The data from this study suggest that we have a treatment that may be able to benefit more women with advanced breast cancer."

Breast Cancer

Breast cancer is the most frequently diagnosed cancer in women. It is the second-leading cause of cancer death in women after lung cancer, and since 1990 is increasing predominantly in women 50 and over. It is the first cancer mortality reason in women of 40 to 59 years old.

More than one million new cases of breast cancer are reported worldwide annually and more than 400,000 women die each year from the disease. The risk of a woman developing breast cancer during her lifetime is approximately 13 percent. In the European Union, more than 191,000 new cases are diagnosed each year and more than 60,000 women will die. In the United States, breast cancer will represents this year more than 215,000 new cases and 40,000 will die. With earlier screening and diagnosis, early management of patients may offer better chances of survival.

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About TAXOTERE®

TAXOTERE® is currently approved in the United States to treat patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy, and it is also approved in combination with doxorubicin and cyclophosphamide (TAC regimen) for the adjuvant (post surgery) treatment of patients with operable, node-positive breast cancer.

TAXOTERE® is approved for the treatment of patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) in combination with cisplatin, who had not received prior chemotherapy, and it also is approved for patients with unresectable locally advanced or metastatic NSCLC after failure of prior platinum-based chemotherapy. In addition, the U.S. Food and Drug Administration has approved TAXOTERE® for use in combination with prednisone as a treatment for men with androgen-independent (hormone-refractory) metastatic prostate cancer.

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 disease, thrombosis, oncology, metabolic diesases, central nervous system, internal medicine, 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 operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expect," "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, 2004. 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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