



Landmark Taxotere[®] Study in Early Stage Breast Cancer Published in the *New England Journal of Medicine*

-- Earlier use of TAXOTERE[®]-based therapy shows improved long-term survival and reduced chance of recurrence --

Paris, France – June 1, 2005 – The sanofi-aventis Group announced today that the *New England Journal of Medicine* has published the results of a landmark phase III study that demonstrates that an adjuvant (after surgery) TAXOTERE[®] (docetaxel) Injection Concentrate-based regimen showed a significant 28 percent reduction in risk of relapse (p=0.001) and a significant 30 percent reduction in the risk of death (p=0.008) after 55 months of follow-up in women with operable, node-positive breast cancer. The results were observed regardless of the nodal, hormone-receptor, menopausal and HER-2/neu status.

Conducted by the Breast Cancer International Research Group (BCIRG), this large, multi-center trial (BCIRG 001/ TAX 316) involved nearly 1,500 patients from around the world. The study analysis included all the women (intent-to-treat group) who were treated with either TAC (TAXOTERE[®] with doxorubicin and cyclophosphamide) after surgery or with a standard adjuvant regimen known as FAC (5-fluorouracil, doxorubicin and cyclophosphamide).

“What is particularly important about the TAXOTERE[®] findings is that the risk of relapse is reduced in both hormone receptor positive and hormone receptor negative patients and is irrespective of the number of positive lymph nodes, which means that all women with operable, node-positive breast cancer may potentially benefit from the TAC therapy,” said Dr. Miguel Martin, Hospital Clínico San Carlos, Madrid- Spain, President of the GEICAM (Grupo Español de Investigación en Cáncer de Mama), and member of the BCIRG steering committee.

TAXOTERE[®] is the only FDA approved drug in the taxane class with an established disease-free survival benefit in both hormone receptor positive and negative disease.

This is the first time these results have been published; however, these findings were presented at the 26th San Antonio Breast Cancer Symposium (SABCS) in 2003.

“In this study, 87 percent of women treated in the TAXOTERE[®] arm were alive at five years versus 81 percent in the arm without TAXOTERE[®]. The data from the study suggest that by substituting TAXOTERE[®] for 5-fluorouracil after surgery, we now have a treatment that may be able to benefit more women with early stage breast cancer,” said John R. Mackey, MD, FRCP(C), Co-Chair of the study, Department of Oncology, University of Alberta, and Cross Cancer Institute, Edmonton, Canada.

“These results provide hope for women with node positive early breast cancer,” said Dr. Jean-Paul Guastala, anti cancer centre Léon Berard, Lyon-France, and co-chair of the study. “With

TAXOTERE[®], nearly nine out of ten women in this study are alive at five years compared to eight out of ten with the standard FAC regimen.”

TAXOTERE[®] in combination with doxorubicin and cyclophosphamide has received FDA and EMEA approval for the adjuvant treatment of patients with operable node-positive breast cancer.

About the BCIRG 001 / TAX 316 Study

The primary endpoint of this multi-center study was to compare the disease-free survival after treatment with TAXOTERE[®] in combination with doxorubicin (Adriamycin) and cyclophosphamide (Cytoxan), (TAC), to a standard regimen of 5-fluorouracil, doxorubicin and cyclophosphamide, (FAC).

The study enrolled 1,491 pre- and post-menopausal women with operable, node-positive breast cancer from 112 sites in 20 countries between June 1997 and June 1999. Women were randomized to receive either TAC or FAC in the adjuvant setting.

Follow-up data (55 months) of women on the study did not identify unexpected side effects and confirmed the results already presented at the time of the first interim analysis (33 months). Specifically, the TAC regimen was associated with a higher rate of febrile neutropenia (low white blood cell count that can lead to infections) compared with FAC (24.7 percent versus 2.5 percent). However, incidence of severe infection was similar (3.9 percent versus 2.2 percent) and there were no treatment-related deaths due to infection in the study. Patients in the study were not treated with primary prophylactic G-CSF (granulocyte colony-stimulating factor), but G-CSF was required for subsequent cycles following the first episode of febrile neutropenia and/or infection. An antibiotic prophylaxis was systematically administered to all women treated with TAC.

Other severe adverse events occurring in 5 percent or more of patients treated with TAC included neutropenia, nausea, stomatitis and asthenia, and with FAC included neutropenia, nausea, vomiting and asthenia.

More than 90 percent of patients in both treatment groups received all six cycles of treatment.

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 1,000,000 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 (about one in seven of all women in the United States). 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 represent 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.

About TAXOTERE®

TAXOTERE® (docetaxel), a drug in the taxoid class of chemotherapeutic agents, inhibits cancer cell division by essentially “freezing” the cell’s internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell cycle. TAXOTERE® promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing and resulting in death in some cancer cells.

TAXOTERE® is indicated for early stage and metastatic breast cancer, non-small cell lung cancer, and androgen-independent (hormone-refractory) metastatic prostate cancer.

TAXOTERE® is being studied extensively in clinical trials for safety and efficacy in head and neck and gastric cancers.

About sanofi-aventis

Sanofi-aventis is the world’s third largest pharmaceutical company, 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 disorders, central nervous system, internal medicine, and vaccines. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY)

The sanofi-aventis Group conducts business in the U.S. through its affiliates Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc.

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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