



PRESS RELEASE

**INTERIM ANALYSIS OF PHASE III STUDY
SHOWS TAXOTERE® (docetaxel)- BASED CHEMOTHERAPY REGIMENS
COMBINED WITH HERCEPTIN® (trastuzumab)
SIGNIFICANTLY IMPROVED DISEASE FREE SURVIVAL
IN EARLY-STAGE HER2-POSITIVE BREAST CANCER**

*Interim analysis of more than 3,000 patients in BCIRG006 study also shows
TAXOTERE® non-anthracycline-based chemotherapy combined with HERCEPTIN®
improved disease-free survival with no increase of cardiotoxicity
in patients with early stage HER2-positive breast cancer*

Edmonton, Canada and Paris, France – September 15th, 2005 – The Breast Cancer International Research Group (BCIRG) and sanofi-aventis announced results today from an interim efficacy analysis of a Phase III trial which shows two TAXOTERE®-based chemotherapy regimens in combination with HERCEPTIN®, monoclonal antibody therapy, significantly improved disease-free survival in women with early-stage human epidermal growth factor receptor 2 (HER2) positive breast cancer.

The BCIRG 006 trial compared a standard treatment arm of 4 cycles of doxorubicin and cyclophosphamide followed by TAXOTERE® for 6 cycles, (AC-T) to two Herceptin-containing regimens following initial surgery. One arm included the above regimen with one year of HERCEPTIN® (AC-TH) and the other was a non-anthracycline regimen of TAXOTERE® plus carboplatin plus one year of HERCEPTIN® (TCH). In the latter arm, the HERCEPTIN® was started concomitantly (TCH) with chemotherapy. Anthracyclines have been considered a key agent in early breast cancer therapy for over 25 years. HER2-positive breast cancer first described in 1987 in women whose tumors contain this alteration have a much more aggressive form of the disease. With the introduction of HERCEPTIN®, a targeted therapy against HER2 positive breast cancer, it was found

that there was a significant increase in cardiotoxicity when anthracycline was used in conjunction with HERCEPTIN®. The purpose of the BCIRG trial was twofold; first to determine if the introduction of Herceptin in early stage HER2 positive breast cancer significantly improves clinical outcomes and second, to determine if the increased cardiotoxicity seen with HERCEPTIN® when used with anthracyclines could be avoided using a novel regimen of TAXOTERE® without anthracyclines.

The BCIRG 006 study entered its first patient in March 2001 and has enrolled a total of 3,222 women. The study is now closed to accrual and the BCIRG continues to monitor patients for longer-term analysis. The results of the first interim efficacy analysis are presented today. The study was sponsored by sanofi-aventis, partially supported financially by Genentech, and conducted by the BCIRG.

This study has an Independent Data Monitoring Committee (IDMC) that reviewed findings from the trial, including cardiac safety data and the first interim efficacy analysis based on 322 events. The IDMC has agreed to release the data, as efficacy boundaries have been crossed for the two investigational arms. The relative reduction in the risk of relapse was 51% [95% CI: 35%-63%] and 39% [95% CI: 21%-53%] for the AC-TH and TCH arms, respectively, compared to the AC-T control arm. The IDMC had previously reviewed and released the cardiac safety (cut-off December 31, 2004) that showed the following proportion of protocol-defined cardiac events: 1.2%, 2.3% and 1.2% for the AC-T, AC-TH, and TCH arms respectively. Insufficient information is available at this time to evaluate the secondary endpoint of overall survival.

"In this poor prognosis population of women with HER2 positive breast cancer, the interim efficacy analysis of BCIRG 006 study conducted after 23 months of median follow up, demonstrates that the addition of HERCEPTIN® to two TAXOTERE®- containing chemotherapy regimens, with or without anthracycline, significantly improved disease-free survival in the adjuvant setting," said Dennis Slamon, PhD, MD, Co-Chair of the BCIRG 006 study and Director of Clinical and Translational Research at UCLA's Jonsson Comprehensive Cancer Center. *"In the first interim analysis, this novel regimen of TAXOTERE® without anthracyclines appears to avoid the problem of increased cardiotoxicity that has been reported when HERCEPTIN® is used together with anthracyclines."*

The BCIRG plans to present full interim efficacy and safety results, as well as updated cardiac analyses, during the San Antonio Breast Cancer Symposium in December 2005.

About 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 cause of cancer mortality in women of 40 to 59 years old. According to the American Cancer Society, an estimated 211,240 women will be diagnosed with breast cancer and approximately 40,000 women will die of the disease in the United States in 2005. A woman is diagnosed with breast cancer in the United States every three minutes. 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. Of women with breast cancer, twenty to 25% of these women will have HER2 positive breast cancers. With earlier screening and diagnosis, early management of patients may offer better chances of survival.

About BCIRG:

BCIRG is the scientific division of a non-for-profit CIRG (Cancer International Research Group) an Academic Research Organization led by internationally recognized cancer researchers. A strong clinical operation division provides a complete range of services to conduct and manage its clinical trials, ranging from small proof of concept studies up to international phase III trials. CIRG is located in Paris (France) and Edmonton AB (Canada).

For information about CIRG/BCIRG, please visit their website: WWW.CIRG.ORG

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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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