



European Union Approval for Taxotere[®] (docetaxel) in Prostate Cancer

Strasbourg, France – November 4, 2004 - Aventis, part of the sanofi-aventis Group announced today that the European Commission has approved Taxotere[®] (docetaxel) Injection Concentrate for use in combination with prednisone as a treatment for men with androgen-independent (hormone-refractory) metastatic prostate cancer.

The Commission approval is based on the results of a large landmark phase III clinical trial, TAX 327, which demonstrated that a Taxotere-based regimen significantly reduced the risk of death by 24 percent in men with androgen-independent (hormone-refractory) metastatic prostate cancer. Investigators in the TAX 327 trial also reported that Taxotere significantly improved patients' Prostate Specific Antigen (PSA) response by 43 percent and improved pain response by 59 percent, relative to mitoxantrone.

In the TAX 327 trial, investigators reported that Taxotere was well tolerated. The most commonly observed adverse events in TAX 327 were alopecia, fatigue and nausea. Grade 3-4 neutropenia was reported more frequently in the Taxotere group than the mitoxantrone group (32 percent vs 21.7 percent, $p=0.004$).

The results of this pivotal study were presented in June 2004 at the American Society of Clinical Oncology meeting (ASCO). On May 19, 2004, the U.S. Food and Drug Administration granted Taxotere approval for use in combination with prednisone as a treatment for men with hormone-refractory metastatic prostate cancer.

"Finally, we can offer our patients an effective chemotherapy for prostate cancer. The pivotal results of the TAX 327 study not only demonstrated a significant survival improvement, but also a significant improvement in the quality of life and improved pain response of patients, even during their chemotherapy." said Ronald de Wit, MD, PhD, lead European Investigator for TAX 327, Associate Professor, Senior Staff Medical Oncologist, Erasmus University Medical Center, Rotterdam, the Netherlands, and service Chief of Medical Oncology, Rotterdam Cancer Institute.

This European approval marks yet another important milestone for Taxotere and underscores sanofi-aventis commitment to positively impact the life of men with this disease. In addition, this action makes Taxotere the only drug approved for breast, lung and prostate cancer, three of the most prevalent cancers in the world today.



About Prostate Cancer

Prostate cancer ranks third worldwide in cancer incidence and sixth in cancer mortality among men. In the United States, more than 230,000 American men will be diagnosed with prostate cancer this year, and 30,000 will die of the disease. In the European Union, 138,000 new cases will be diagnosed, and 45,000 patients will die of the disease.

Current therapy for advanced prostate cancer is hormonal manipulation (i.e., blockage of androgen hormones like testosterone that would otherwise stimulate the growth of prostate cancer cells). However, the effects of this treatment typically last between 24 and 36 months, at which time patients may become refractory to hormonal therapy and be considered candidates for chemotherapy, such as Taxotere.

About Taxotere

Taxotere, 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 cancer cell death.

Taxotere is indicated for treatment of metastatic breast cancer and non-small cell lung cancer, and is being studied extensively in clinical trials for safety and efficacy in early-stage breast and gastric cancers. On August 18, 2004, the FDA approved Taxotere® for use in combination with doxorubicin and cyclophosphamide (TAC regimen) for the adjuvant (post surgery) treatment of patients with operable, node-positive breast cancer.

In 2003, Taxotere generated worldwide sales of over € 1.3 billion.

About sanofi-aventis

The sanofi-aventis Group 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, diabetes, central nervous system, internal medicine, vaccines. The sanofi-aventis Group is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).



Forward Looking Statement

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” and similar expressions. Although the management of Aventis and sanofi-aventis believe 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 Aventis and 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 and Aventis, including those listed under “Forward-Looking Statements” and “Risk Factors” in sanofi-aventis’s annual report on Form 20-F for the year ended December 31, 2003 and those listed under “Cautionary Statement Regarding Forward-Looking Statements” and “Risk Factors” in Aventis’s annual report on Form 20-F for the year ended December 31, 2003. Other than as required by applicable law, Aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Press release