



Paris, february 3, 2005

SANOFI-AVENTIS RECEIVES FDA APPROVAL FOR NEW ELOXATIN[®] FORMULATION

Sanofi-aventis announced today that he has received marketing approval from the United States Food and Drug Administration for a new formulation of Eloxatin[®] (oxaliplatin for injection).

This new formulation, Eloxatin[®] INJECTION, is a clear, preservative-free, colorless solution which does not require reconstitution.

Eloxatin[®] INJECTION offers additional benefit and convenience to physicians and nurses since it involves fewer steps in the administration of Eloxatin[®].

About Eloxatin[®]

In Europe

Eloxatin[®] received approval in France for the second-line treatment of metastatic colorectal cancer in April 1996, and as a first-line treatment in April 1998. In July 1999, ELOXATIN was approved for the first-line treatment of advanced colorectal cancer in major European countries through the Mutual Recognition Procedure, France being the Reference Member State.

Eloxatin[®] successfully completed a Mutual Recognition Procedure in Europe in December 2003, which allowed the product to be marketed for the treatment of metastatic colorectal cancer in combination with 5-fluorouracil and folinic acid (i.e., in first- and second-line treatment).

In September 2004, the indication for Eloxatin[®] was extended in Europe, again through the Mutual Recognition Procedure, to include the “Adjuvant treatment of stage III (Dukes’ C) colon cancer after complete resection of primary tumor.”

In the United States

In the United States, Eloxatin[®], in combination with infusional 5-FU/LV, received approval on January 9, 2004, for the first-line treatment of advanced carcinoma of the colon or rectum (ie, first therapy for patients with metastatic colorectal cancer). This same ELOXATIN-based combination had initially (August 2002) received FDA approval for second-line treatment, (ie, therapy for previously treated patients with metastatic colorectal cancer).



On November 4, 2004, this ELOXATIN-based regimen was approved for the adjuvant treatment of stage III (Dukes' C) colon cancer after complete resection of the primary tumor.

Eloxatin[®] was developed in association with Debiopharm SA and is currently marketed by sanofi-aventis in more than 60 countries.

Colorectal Cancer as a Leading Cause of Death

Every year, about one million new cases of colorectal cancer are diagnosed worldwide.ⁱ About 194,000 new cases are detected in Europe and 150,000 in the United States. According to the American Cancer Society, colorectal cancer is the second leading cause of cancer-related death in the United States, accounting for 10% to 15% of all cancer deaths. Over a lifetime, about 1 in 18 people develop colorectal cancer and more than 56,000 people die from it in the United States each year.ⁱⁱ In Europe, 94,000 people die from colorectal cancer each year.ⁱⁱⁱ

Colorectal cancer is cancer that begins in the cells that line the colon or rectum. When these cancer cells spread away from the colon to distant locations in the body, the cancer is referred to as metastatic. Cancer cells may spread, or metastasize, through the blood or lymphatic system, or directly grow into tissues adjacent to the original cancer.

A diagnosis of colorectal cancer is associated with a stage, which reflects the extent of the cancer and whether it has spread. Patients with colorectal cancer that has spread to distant organs or tissues are said to have advanced, or metastatic, colorectal cancer, also known as stage IV colorectal cancer. Patients with advanced colorectal cancer can now more confidently expect to live twice as long as they could only a few years ago.

Further Development in Other Types of Cancer

An extensive worldwide clinical development program is ongoing to explore the potential benefits of Eloxatin[®] (oxaliplatin for injection) in other types of cancer.

Clinical Considerations for ELOXATIN

ELOXATIN, used in combination with infusional 5-FU/LV, is indicated for adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor. The indication is based on an improvement in disease-free survival, with no demonstrated benefit in overall survival after a median follow-up of 4 years.

ELOXATIN, used in combination with infusional 5-FU/LV, is indicated for the treatment of advanced carcinoma of the colon or rectum.

Eloxatin® (oxaliplatin for injection) should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.

Anaphylactic-like reactions to ELOXATIN have been reported and may occur within minutes of ELOXATIN administration. Epinephrine, corticosteroids, and antihistamines have been employed to alleviate symptoms, and discontinuation of ELOXATIN therapy may be required.

Adjuvant Colon Cancer Setting

The incidence of grade 3 or grade 4 events was 70% and 31% on the ELOXATIN combination arm and infusional 5-FU/LV arm, respectively. Granulocytopenia, paresthesia, diarrhea, vomiting, and nausea were the most common grade 3 or 4 adverse events. Paresthesia was seen in 92% of patients on the ELOXATIN combination; 21% had residual paresthesia at 18-month follow-up. Three percent and 0.5% had grade 2 and 3 paresthesias, respectively, at 18-month follow-up. Grade 3 or 4 hypersensitivity was noted in 3% and may require discontinuation of therapy. Hepatotoxicity, evidenced by increase in transaminases (57% vs 34%) and alkaline phosphatases (42% vs 20%), was observed more commonly in the ELOXATIN arm. The incidence of increased bilirubin was similar on both arms. Hepatic vascular disorders should be considered and investigated if abnormal liver function tests or portal hypertension are present and cannot be explained by liver metastases or other known etiologies.

Advanced Colorectal Cancer Setting

Fatigue, neuropathy, nausea, vomiting, diarrhea, stomatitis, neutropenia, and thrombocytopenia were the more common adverse events. Neither febrile neutropenia nor requirement for platelet transfusion was increased as compared to treatment with irinotecan plus bolus 5-FU/LV. Eloxatin® (oxaliplatin for injection) has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal. There have been reports while on study from clinical trials and from postmarketing surveillance of prolonged prothrombin time and INR occasionally associated with hemorrhage in patients who received ELOXATIN plus 5-FU/LV while on anticoagulants. Patients requiring oral anticoagulants may require closer monitoring. Hypersensitivity has been observed (<2% grade 3/4) in clinical studies and trials. It was usually managed with standard epinephrine, corticosteroid, and antihistamine therapy, and may require discontinuation of ELOXATIN therapy.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications, is available at:

www.fda.gov/cder/foi/label/2004/021492s0041b1.pdf.



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, diabetes, 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" 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 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, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

Press release

ⁱ Boyle P, Leon ME. Epidemiology of colorectal cancer. *Br Med Bull.* 2002;64:1-25.

ⁱⁱ American Cancer Society. *Cancer Facts & Figures 2004*. Available at: http://www.cancer.org/downloads/STT/CAFF_finalPWSecured.pdf. Accessed September 7, 2004.

ⁱⁱⁱ GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC Press. September 30, 2004.