FOLFOX4 (ELOXATIN®-based chemotherapy) AFTER SURGERY IMPROVES OVERALL SURVIVAL IN PATIENTS WITH EARLY (STAGE III) COLON CANCER

- Survival analysis (6-year median follow-up) of the MOSAIC study presented at this year’s ASCO -

Paris, France, June 3, 2007 - FOLFOX4, an Eloxatin® (oxaliplatin injection)-based chemotherapy regimen, significantly improved the overall survival (OS) of patients with surgically resected stage III colon cancer when compared to standard chemotherapy (5-FU/LV) according to the six-year survival analysis of the MOSAIC study presented today at the 43rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL.

The updated analysis of the study’s primary endpoint (3-year disease free survival - DFS, including stage II and stage III patients), confirms the benefit of FOLFOX4 versus 5-FU/LV alone at 5 years.

Six-Year Survival Data from the MOSAIC Trial
The MOSAIC data demonstrate that stage III colon cancer patients, treated after complete surgical resection of the tumor with Eloxatin® in combination with infusional 5-FU/LV, had a significantly 20% reduction in the risk of dying after a median of six years than those treated with 5-FU/LV alone (HR= 0.80, CI [0.66-0.98]).

"For decades, the standard of care for colon cancer patients has been 5-FU/LV. This is the first time that the addition of another agent, Eloxatin®, to standard 5FU/LV-based chemotherapy has shown a significant survival advantage in the adjuvant treatment of stage III colon cancer patients. We have looked forward to these results since we presented the primary analysis from this study at ASCO in 2003 and subsequently published it in the New England Journal of Medecine," said the principal investigator Professor Aimery de Gramont, Oncology department, Hospital Saint Antoine, Paris, France. “This is important news since it supports the disease free and overall survival” He added

Eloxatin®, used in combination with infusional 5-FU/LV, is indicated in the US and in Europe for the adjuvant (post-surgical) treatment of stage III colon cancer patients who have their primary tumors surgically removed. The indication is based on the improvement in disease-free survival seen in the MOSAIC trial. At the time of the original analysis, there was no demonstrated benefit in overall survival after a median follow-up of 4 years. Eloxatin® in combination with infusional 5-FU/LV is also indicated for the treatment of advanced colorectal cancer.

About MOSAIC
The MOSAIC Study was conducted in 148 centers in 20 countries and supported by sanofi-aventis. In this multi-center trial, 2,246 patients with stage II or stage III colon cancer whose tumor had been completely surgically removed randomly received 5-FU/LV or FOLFOX4 every two weeks for 12 cycles. The primary endpoint evaluated how the addition of Eloxatin® affected DFS. Final DFS, at 5 year Follow Up, are consistent with earlier results (HR:0.80, P=0.003).
Results for patients with stage II disease did not show a significant advantage with FOLFOX4 in terms of disease-free or overall survival.

The most frequently reported side effect was neutropenia (decrease in the number of white blood cells) in 79% of patients, but this was severe (grade 3/4) in 41% of patients and complicated by fever or infection in only 1.8% of cases. Among patients (92%) experiencing peripheral sensory neuropathy ("tingling or numbness" in the fingers or toes), it was severe in 12% of patients, and partial or total recovery was observed in almost all cases within 18 months following treatment.

About Colorectal Cancer
Colorectal cancer is a leading cause of death. Every year, about one million new cases of colorectal cancer are diagnosed worldwide. About 381,000 new cases are detected in Europe and 150,000 in the United States. According to the American Cancer Society, colorectal cancer is the third leading cause of cancer-related death in the U.S., accounting for about 10% of all cancer deaths. Over a lifetime, about 1 in 18 people develop colorectal cancer, and more than 52,000 people are expected to die from it in the U.S. this year. In Europe, 204,000 people die from colorectal cancer each year.

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 5FU/LV, received approval on January 9, 2004, for the first-line treatment of advanced carcinoma of the colon or rectum (i.e., first therapy for patients with metastatic colorectal cancer). This same Eloxatin®-based combination had initially (August 2002) received FDA approval for second-line treatment, (i.e., 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® is currently not approved in pancreatic cancer or in stomach (gastric) cancer. Eloxatin® was developed in association with Debiopharm SA and is currently marketed by sanofi-aventis in more than 60 countries.

About sanofi-aventis
Sanofi-aventis is one of the world leaders in the pharmaceutical industry, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and 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, as amended. 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, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “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, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.

References:


2. de Gramont A, et al. Oxaliplatin/5FU/LV in adjuvant colon cancer: updated efficacy results of the MOSAIC trial, including survival, with a median follow-up of 6 years. Abstract #4007 accepted for presentation at the 43rd Annual Meeting of the American Society of Clinical Oncology.


