



**ABSTRACT #4067**

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**ELOXATIN<sup>®</sup> (oxaliplatin injection)-BASED CHEMOTHERAPY  
SETS NEW TREATMENT BENCHMARK IN  
PATIENTS WITH METASTATIC COLORECTAL CANCER**

**FOLFOX4 Chemotherapy Results in Improved Long-term [Five-years] Overall Survival  
for these Seriously Ill Patients**

**Chicago, IL – June 4, 2007** – FOLFOX4, an Eloxatin<sup>®</sup>-based chemotherapy regimen, provided significant improvements in long-term [five-years] overall survival (OS) and time to disease progression (TTP) - a longer period of stable disease - in patients with metastatic (advanced) colorectal cancer. Importantly, the FOLFOX4 results were significantly better than those achieved with irinotecan-based chemotherapy, known as IFL, and IROX, a combination of irinotecan and Eloxatin<sup>®</sup>. These data were presented today at the 43<sup>rd</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago in an updated analysis of the N9741 study.

FOLFOX4 (Eloxatin<sup>®</sup> combined with infusional 5-FU/LV) was established in the United States as first line treatment for advanced colorectal cancer after the initial presentation of the N9741 study results in 2003 and subsequent Food and Drug Administration (FDA) approval in January 2004. The updated analysis confirms the earlier results and identifies FOLFOX4 chemotherapy as the strongest predictor of improvement in both overall survival and time to disease progression.

**N9741 Five-Year Analysis**

This study evaluated several chemotherapy regimens using various combinations of Eloxatin<sup>®</sup>, 5-FU/LV and irinotecan in 1,691 previously untreated patients with metastatic colorectal cancer who were randomized to seven arms.

Metastatic colorectal cancer patients given the Eloxatin<sup>®</sup>-based regimen FOLFOX4 were almost twice as likely to survive at least five years as those on irinotecan-based therapy (IFL). Five-year survival and time-to-progression rates were calculated using Kaplan-Meier methods for each treatment arm. Patients treated with FOLFOX4 had a 9.2% overall chance of surviving for five years after treatment, the best of all the results reported. In comparison, the chance of living five years was 5.4% among patients treated with Eloxatin<sup>®</sup> plus irinotecan (IROX) (p=.016) and 3.8% (p<.001) among patients treated with the combination of 5-FU/LV and irinotecan (IFL).

FOLFOX4 slowed the progression of the disease compared to IROX and IFL. The median TTP was significantly longer among FOLFOX4-treated patients at 9.2 months compared to 6.5 months with IROX (p<.001) and 6 months with IFL (p<.001). FOLFOX4 patients were significantly more likely to experience any grade 3 or greater side effects (odds ratio of 1.65, p<.001) and were lower in men than in women (OR 0.63, p<0.001). The most common



side effects were peripheral sensory neuropathy, fatigue, neutropenia, nausea, vomiting, and diarrhea.

“Our five-year overall survival results with first-line FOLFOX4 set a new benchmark for treating metastatic colorectal cancer,” said lead investigator Richard Goldberg, MD, University of North Carolina School of Medicine, Chapel Hill, NC. “Adding Eloxatin® to standard chemotherapy significantly prolonged survival for these patients and also delayed disease progression.”

### **Treatment with FOLFOX4 Predicts Important Benefits**

Receiving FOLFOX4 was found to be the most powerful prognostic factor for predicting overall survival as well as time to progression. Those factors that were predictive of a worse outcome were: higher baseline performance status, neutrophil count, and alkaline phosphatase, as well as a greater number of disease sites. While being 70 years or older was associated with poorer survival, it was not predictive of time to progression, response rate or grade 3 or greater toxicity.

For more information about Eloxatin® or for full prescribing information, including BOXED WARNING, visit [www.eloxatin.com](http://www.eloxatin.com).

### **About Colorectal Cancer**

Strides have been made in the management of colorectal cancer but it is still the second leading cause of cancer-related deaths in the United States. At Stage II, the cancer has grown through the wall of the colon or rectum but has not yet spread to nearby lymph nodes. In Stage III, the cancer has invaded one or more of the local lymph nodes but has not spread to distant sites. Metastatic colorectal cancer means that the cancer has spread to other nodes and/or organs in the body. The American Cancer Society estimates that in 2007 there will be about 112,340 new cases of colon cancer and 41,420 new cases of rectal cancer in the United States.

### **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 organization, 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*



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