ABSTRACT #4007
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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

Chicago, IL -- June 3, 2007 -- FOLFOX4, an Eloxatin® (oxaliplatin injection)-based chemotherapy regimen, significantly improved the overall survival (OS) of patients with surgically resected (removed) 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 or 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 significant 20% reduction in the risk of dying after a median of six years compared to 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 Medicine," 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 (cancer of the colon and/or rectum).

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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. Other common side effects include thrombocytopenia, anemia, nausea, increase in transaminases and alkaline phosphatase, diarrhea, emesis, fatigue and stomatitis.

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®

Indications and Usage

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.

Clinical Safety Considerations

Eloxatin® 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.

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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.

- Eloxatin® should not be administered to patients with a history of known allergy to Eloxatin® or other platinum compounds. Hypersensitivity and anaphylactic/anaphylactoid reactions to Eloxatin® have been reported and were similar in nature and severity to those reported with other platinum compounds (ie, rash, urticaria, erythema, pruritus, and, rarely, bronchospasm and hypotension). These reactions occur within minutes of administration and should be managed with appropriate supportive therapy. Drug-related deaths from this reaction have been reported

- Eloxatin® may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant while receiving Eloxatin®. It is not known whether Eloxatin® or its derivatives are excreted in human milk

- Eloxatin® has been associated with pulmonary fibrosis (<1% of study patients), which may be fatal. The combined incidence of cough and dyspnea was 7.4% (<1% grade 3, no grade 4) in the Eloxatin® plus 5-FU/LV arm compared to 4.5% (no grade 3, 0.1% grade 4) in the 5-FU/LV alone arm in the adjuvant colon cancer study. In this study,
one patient died from eosinophilic pneumonia in the Eloxatin® combination arm. The combined incidence of cough, dyspnea, and hypoxia was 43% (7% grade 3 and 4) in the Eloxatin® plus 5-FU/LV arm compared to 32% (5% grade 3 and 4) in the irinotecan plus 5-FU/LV arm in patients with previously untreated colorectal cancer. In case of unexplained respiratory symptoms, Eloxatin® should be discontinued until pulmonary investigation excludes interstitial lung disease or pulmonary fibrosis

- Eloxatin® is associated with two types of primarily peripheral sensory neuropathy: an acute, reversible type of early onset and a persistent type (>14 days). In patients with advanced colorectal cancer paresthesias occurred in 77% (all grades) and 18% (grade 3/4) of previously untreated patients. In previously treated patients, acute neuropathy occurred in 56% (all grades) and 2% (grade 3/4) of patients; persistent neuropathy occurred in 48% (all grades) and 6% (grade 3/4) of patients. In patients with stage II and III colon cancer, paresthesia was seen in 92% (all grades) and 13% (grade 3/4) of patients; 21% (all grades), 0.5% (grade 3/4) had residual paresthesia at 18-month follow-up

- Hepatotoxicity, as evidenced in the adjuvant study by increase in transaminases and alkaline phosphatase was observed more commonly in the Eloxatin® combination arm. The incidence of increased bilirubin was similar on both arms. Changes noted on liver biopsies include: peliosis, nodular regenerative hyperplasia or sinusoidal alterations, perisinusoidal fibrosis and veno-occlusive lesions. Hepatic vascular disorders should be considered and, if appropriate, investigated in case of abnormal liver function test results or portal hypertension not explained by liver metastases

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- Monitoring of white blood cell count with differential, hemoglobin, platelet count and blood chemistries (including ALT, AST, bilirubin and creatinine) is recommended before each Eloxatin® cycle

- The safety and effectiveness of Eloxatin® plus 5-FU/LV in patients with renal impairment have not been evaluated. Since the primary route of platinum elimination is renal, this combination should be used with caution in patients with preexisting renal impairment. Clearance of these products may be decreased by coadministration of potentially nephrotoxic compounds, although this has not been specifically studied

- The incidence of diarrhea, dehydration, hypokalemia, leukopenia, fatigue and syncope were higher in patients ≥65 years old

- Extravasation may result in local pain and inflammation that may be severe and lead to complications, including necrosis. Injection site reaction, including redness, swelling and pain, has been reported

- There have been reports of prolonged prothrombin time and INR occasionally associated with hemorrhage in patients receiving Eloxatin® plus 5-FU/LV while on anticoagulants. Patients receiving Eloxatin® plus 5-FU/LV and requiring oral anticoagulants may require closer monitoring

- The most common adverse reactions in patients with stage II or III colon cancer receiving adjuvant therapy were peripheral sensory neuropathy, neutropenia, thrombocytopenia, anemia, nausea, increase in transaminases and alkaline phosphatase, diarrhea, emesis, fatigue, and stomatitis. The most common adverse reactions in patients with advanced colorectal cancer were peripheral sensory neuropathy, fatigue, neutropenia, nausea, emesis, and diarrhea

For more information about Eloxatin® or for full prescribing information, including BOXED WARNING, visit www.eloxatin.com.

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).

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