ABSTRACT# LBA5
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THE ELOXATIN®-BASED REGIMEN (FOLFOX4) SIGNIFICANTLY IMPROVED PROGRESSION FREE SURVIVAL WHEN GIVEN BEFORE AND AFTER SURGERY IN PATIENTS WITH RESECTABLE LIVER METASTASES FROM COLORECTAL CANCER

Presentation at ASCO Plenary Session Reports
EORTC 40983 (EPOC) Intergroup Study Results

Chicago, IL -- June 4, 2007 – Results of the randomized phase III EORTC 40983 Intergroup study, or EPOC study, demonstrate for the first time that peri-operative (pre and post surgery) FOLFOX4 (Eloxatin® (oxaliplatin injection) in combination with a standard chemotherapy regimen for colon cancer, 5-fluorouracil/leucovorin (5-FU/LV)) given to patients with resectable liver metastases from colorectal cancer significantly improved Progression-Free Survival (PFS) compared to surgery alone. (PFS is the time from the start of therapy until disease progression or death). The EPOC study results were presented today at the Plenary Session of the 43rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL.

At a median follow-up of three years, FOLFOX4 treatment given before and after surgery significantly improved PFS by 9.2% and reduced the risk of relapse by 27% (HR=0.73, p=0.025) among patients for whom resection was successful. When evaluating results among all randomized patients, including the 61 patients who were not able to undergo liver metastases resection or were ineligible, FOLFOX4 did not significantly improve PFS compared to surgery alone (7.2% absolute difference, p=0.058). However, when taking into account all eligible patients (171 in each arm), even those not resected, FOLFOX4 treatment significantly improved PFS by 8.1% and reduced the risk of relapse by 23% (H=0.77, CI:0.60-1.00 ; p=0.041).Results showed that FOLFOX4 given before resection did not prevent patients' ability to undergo surgery.

The most common adverse events were with preoperative chemotherapy: diarrhea (Grade3: 8.2%), sensory neuropathy (Grade3: 2.3%), neutropenia (Grade3/4:18.1%); and with post-operative chemotherapy: sensory neuropathy (Grade3: 9.6%), neutropenia (Grade3/4: 34.8%). There were 25.2% surgical complications in the peri-operative chemotherapy arm and 15.9% in the surgery alone arm (P=0.04); the operative mortality remains very low (<1%), whatever the treatment arm: two deaths after surgery in the standard arm and one in the experimental arm.

"The EPOC study is an ambitious trial and the largest clinical trial of its kind conducted in this patient group. Its success is due largely to the international cooperation and the multidisciplinary team effort of healthcare professionals," said principal investigator

Professor Bernard Nordlinger, past chairman of the EORTC GI group, chair of the Department of Surgery and Oncology, Hospital Ambroise Pare, Assistance Publique-Hôpitaux de Paris, Boulogne, France. “These results suggest that the treatment paradigm for colorectal cancer liver metastases may change to include peri-operative oxaliplatin-based chemotherapy.”

About the EPOC Study

The EPOC (Eloxatin® for Peri-Operative Use) Study is a randomized multicenter phase III intergroup study sponsored and conducted by the EORTC (European Organization for Research and Treatment of Cancer), in collaboration with AGITG (Australasian Gastro-Intestinal Trials Group), EORTC GITCG (EORTC Gastrointestinal Tract Cancer Group), ALM-CAO (Arbeitsgruppe Lebermetastasen und –tumoren in der Chirurgischen Arbeitsgemeinschaft Onkologie), CRUK (Cancer Research UK) and FFCD (Fondation Francophone de Cancérologie Digestive). It was supported by sanofi-aventis.

This trial evaluated the benefit of combining peri-operative chemotherapy and surgery for patients with resectable liver metastases from colorectal cancer. Progression-Free Survival (PFS) was the primary endpoint. The objective of the trial was to demonstrate a 40% increase in median PFS, with 80% power and two-sided significance level of 5%, resulting in HR=0.71. Safety data, a secondary end-point, were previously reported at ASCO in 2005.

A total of 364 patients with up to four liver metastasis initially considered resectable, were randomly assigned to be treated by either surgery alone (standard regimen) or with the experimental treatment: peri-operative FOLFOX4 – six cycles for three months before and six cycles for three months after surgery. In the experimental arm, 151 patients’ liver metastases were resected; of these, 115 patients (63%) received post-operative chemotherapy. In the standard arm, 152 patients’ liver metastases were resected. Eloxatin is not approved for peri-operative use in the United States.

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. 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 one 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.

Colorectal cancer 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. It is estimated that about half of all colon cancer patients will develop liver metastases, found either at first diagnosis or recurrence after treatment. Resectable liver metastases (the type of liver metastases seen in patients in this trial) occur in approximately 10-20% of patients.

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.

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

- 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 the EORTC
Created in 1962, the European Organisation for Research and Treatment of Cancer (EORTC) is a not-for-profit international cancer research organisation under the Belgian Law.

The EORTC has the mission to develop, conduct, coordinate and stimulate laboratory and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patients' quality of life. The ultimate goal of the EORTC is to improve the standard of cancer treatment in Europe, through the development of new drugs and other innovative approaches, and to test more effective therapeutic strategies, using drugs which are already commercially available, or surgery or radiotherapy.

The EORTC has the aim to facilitate the passage of experimental discoveries into state-of-the-art treatment by keeping to a minimum the time lapse between the discovery of new anti-cancer agents and the implementation of their therapeutic benefit for patients with cancer. The EORTC promotes multidisciplinary cancer research in Europe and is linked to other leading biomedical research organisations around the world. EORTC's research takes place in over 300 university hospitals in 32 countries and the unique network of investigators of the EORTC comprises more than 2000 clinicians collaborating on a voluntary basis in 19 multidisciplinary groups. The EORTC Headquarters based in Brussels consist of more than 150 researchers of 15 nationalities including medical doctors, statisticians, data managers, quality of life specialists, healthcare professionals and computer specialists as well as research fellows and administrative staff.

For more information visit the EORTC website: www.eortc.be

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 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.

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