SANOFI SYNTHELABO SA
Form 6-K
January 07, 2004

**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 6-K

## REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULES 13a-16 OR 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

For the Month of January 2004
SANOFI-SYNTHELABO
(Exact name of registrant as specified in its charter)

174, avenue de France, 75013 Paris, FRANCE
(Address of principal executive offices)

(Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.)

Form 20-F __X__ Form 40-F____

(Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ____ No __X__

(If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____.

Paris, January 7, 2004

# ELOXATIN® is becoming a cornerstone therapy for the treatment of metastatic colorectal cancer in Europe

## After a successful Mutual Recognition Procedure, ELOXATIN® will be granted the full indication : Treatment of Metastatic Colorectal Cancer

Sanofi-Synthélabo announced today that ELOXATIN®, already indicated as a 1st line treatment of metastatic colorectal cancer in major European Countries, has successfully completed a Mutual Recognition Procedure in Europe, which will allow the product to be indicated for the full indication : ***Treatment of Metastatic Colorectal Cancer in combination with 5-fluorouracil and folinic acid*** (i.e. 1st line and 2nd line treatment).

***Eloxatin® Status***
ELOXATIN® received marketing approval in France for the 2nd line treatment of metastatic colorectal cancer in April 1996, and as a 1st line treatment in April 1998. In July 1999, ELOXATIN® was approved for the 1st line treatment indication in major European countries, through a mutual recognition procedure, France being the Reference Member State.

In the United States, ELOXATIN® received marketing approval in August 2002, for the 2nd line treatment of patients with metastatic carcinoma of the colon or rectum. In July 2003 the company filed an sNDA for the 1st line treatment of metastatic colorectal and ELOXATIN® was granted a 6-month priority review by the Food and Drug Administration in September 2003.

ELOXATIN® is currently marketed by Sanofi-Synthelabo in more than 60 countries for the 1st and/or 2nd line metastatic colorectal cancer.

Global sales of ELOXATIN® reached EUR 600 million for the first nine month of 2003, and should exceed EUR 800 million for the full year 2003.

Oxaliplatin is developed in association with Debiopharm S.A.

***Further development in adjuvant treatment following surgery***
New data results of MOSAIC study were presented during the 39th annual meeting of the American Society of

Clinical Oncology (ASCO), in June 2003, in adjuvant treatment of colorectal cancer following surgery, the early stage of the disease. In patients receiving oxaliplatin in addition to the current post surgery standard chemotherapy, 5-Fluorouracil/Leucovorin (5-FU/LV), for colon cancer the risk of recurrence at 3 years was reduced by 23% vs. current standard treatment alone. Adjuvant therapy is a treatment following surgery, with the goal of eradicating any remaining cancer cells, and increasing cure rate. Adjuvant therapy offers promise for not just extending the lives of patients, but helping to assure full recovery.

***Colorectal Cancer Leading Cause of Death***

About one million new cases of colorectal cancer are diagnosed worldwide every year, and about 150,000 new cases in the U.S. According to the American Cancer Society, colorectal cancer is the second leading cause of malignancy-related death in the U.S., accounting for 10 to 15% of all cancer death. Over a lifetime, about one in 18 people develop colorectal cancer, and, each year, about 56,000 people die from it in the U.S.

***Further development in other types of cancer***

Moreover an extensive worldwide clinical development program is ongoing to explore the benefit of ELOXATIN® in other types of cancers, primarily pancreatic and gastric cancer.

***Clinical Considerations about Eloxatin® in the United States***

In the US, ELOXATIN® (oxaliplatin for injection) is approved for use in combination with infusional 5-fluorouracil (5-FU) and leucovorin (LV), and is currently indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed during or within six months of completion of first-line therapy with the combination of bolus 5-FU/LV and irinotecan. The approval of ELOXATIN® was based on the response rate and time to tumor progression observed in an ongoing trial.

ELOXATIN® is an antineoplastic agent and as such should be administered under the supervision of a qualified physician experienced in the use of 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.

ELOXATIN® should not be administered to patients with a history of known allergy to ELOXATIN® or other platinum compounds. Women of childbearing potential should be advised not to become pregnant while receiving treatment with ELOXATIN®. As with other platinum compounds, hypersensitivity and anaphylactic/anaphylactoid reactions have been reported. ELOXATIN® is associated with pulmonary toxicity, which may be fatal and two distinct types of primarily peripheral sensory neuropathies: an acute, reversible type of early onset and a persistent type (>14 days). An acute syndrome of pharyngolaryngeal dysesthesia seen in 1-2% of patients characterized by subjective sensations of dysphagia or dyspnea, without any laryngospasm or bronchospasm (no stridor or wheezing) may also occur.

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Both 5-FU and ELOXATIN® are associated with gastrointestinal and hematologic adverse events. When ELOXATIN® is administered in combination with 5-FU, the incidence of these events is increased. The most frequently reported adverse events with ELOXATIN® in combination with infusional 5-FU/LV are acute neuropathy (56%), persistent neuropathy (48%), fatigue (68%), diarrhea (67%), nausea (65%) and vomiting (40%). Changes in hematology parameters were also seen: anemia (81%), leukopenia (76%), neutropenia (73%), and thrombocytopenia (64%).

Full prescribing information including boxed warning is available through www.eloxatin.com.

***This release contains statements that constitute forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based on management s current expectations or beliefs and are subject to a number of factors and***

***uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others that are described in our Form 20-F as filed with the US Securities and Exchange Commission on June 25, 2003 and in the Reference Document filed with the French Commission des Opérations de Bourse on April 23, 2003, could cause actual results to differ materially from those described in the forward-looking statements: the ability of Sanofi-Synthélabo to expand its presence profitably in the United States; the success of Sanofi-Synthélabo s research and development programs; the ability of Sanofi-Synthélabo to protect its intellectual property rights; and the risks associated with reimbursement of health care costs and pricing reforms, particularly in the United States and France. Sanofi-Synthélabo does not undertake any obligation to provide updates or to revise any forward-looking statements.***

***Investors and security holders may obtain a free copy of the Form 20-F and any other documents filed by Sanofi-Synthélabo with the US Securities and Exchange Commission at www.sec.gov, as well as of the Reference Document filed with the French Commission des Opérations de Bourse at www.cob.fr or directly from Sanofi-Synthélabo on the web site www.sanofi-synthelabo.com.***

***Investor Relations Department***

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: January 7, 2004

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay
Name: Marie-Helene Laimay
Title: Senior Vice President and
Chief Financial Officer