SANOFI SYNTHELABO SA
Form 6-K
January 20, 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 19, 2004

ELOXATIN submitted in the United States and in Europe for the adjuvant treatment of patients with colon cancer

Adjuvant Regimen with Eloxatin shows a major Reduction in Disease Recurrence

Sanofi-Synthélabo announced today that it has submitted a supplemental New Drug Application (sNDA) in the United States and an extension of indication in Europe with France as Reference Member State for ELOXATIN (oxaliplatin for injection) in the ***adjuvant treatment of patients with colon cancer.***

Adjuvant therapy is a treatment following surgery with the goal of eradicating any remaining cancer cells and increasing the cure rate. In fact, adjuvant therapy offers promise for not just extending patients lives, but helping to assure full recovery without recurrence of cancer.

Few treatment options exist for colon cancer in adjuvant setting. The submission for ELOXATIN in this indication will allow to extend patients benefit to early stages and therefore curable stages of the disease, said Professor Aymery DE GRAMONT, Head of Oncology Division at Saint-Antoine Hospital, Paris. *The major reduction in disease recurrence obtained with ELOXATIN in the adjuvant setting will significantly impact the treatment of early stages of the disease, especially the ones with lymph nodes involvement* .

Efficacy results of the Multicenter International Study of Oxaliplatin/ 5-Fluorouracil/Leucovorin (5-FU/LV) in the Adjuvant Treatment of Colon Cancer (MOSAIC) were presented at the 39th annual meeting of the American Society of Clinical Oncology (ASCO) in June 2003. This pivotal trial showed that the addition of ELOXATIN to the current standard of post-operative (adjuvant) chemotherapy (5FU/LV) for colon cancer reduces the risk of recurrence by 23% ($p<0.01$) at three years in patients who have undergone surgery for their primary tumor.

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.

ELOXATIN has successfully completed a Mutual Recognition Procedure in Europe in December 2003, 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).

In the US, ELOXATIN has been approved last week, for the first line treatment of metastatic carcinoma of the colon or rectum after an approval in August 2002 for second line treatment of patients. This new approval recommends now the use of ELOXATIN , in combination with infusional 5FU/LV, for the treatment of advanced carcinoma of colon or rectum in the US.

ELOXATIN is currently marketed by Sanofi-Synthelabo in more than 60 countries for the treatment of 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.

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 develops 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.

Clinical considerations about Eloxatin in the United States

In the United States, ELOXATIN (oxaliplatin for injection), used in combination with infusional 5-fluorouracil (5-FU) and leucovorin (LV), is indicated for the treatment of advanced carcinoma of the colon or rectum.

ELOXATIN should be administered under the supervision of a qualified 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.

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.

ELOXATIN is associated with pulmonary toxicity, which may be fatal, and with two types of primarily peripheral sensory neuropathy: an acute, reversible type of early onset and a persistent type (>14 days). Paresthesias occurred in 77% (all grades) of previously untreated patients. Acute and persistent neuropathy occurred in 56% and 48% (all grades) of previously treated patients, respectively. An acute syndrome of pharyngolaryngeal dysesthesia seen in 1%-2% (grade 3/4) of patients, characterized by subjective sensations of dysphagia or dyspnea without any laryngospasm or bronchospasm (no stridor or wheezing), may also occur.

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.

Full prescribing information including boxed warning is available upon request.

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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Paris, January 16, 2004

Following market rumors, and at the express request of the French Financial Market Regulatory Authority - Autorités des Marchés Financiers (AMF)- , Sanofi-Synthélabo indicates that, while it continues to evaluate any transaction that might consolidate its medium and long-term future, it is not engaged in any negotiation to that effect.

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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 20, 2004

SANOFI-SYNTHELABO

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