SANOFI SYNTHELABO SA
Form 6-K
January 12, 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 12, 2004

Eloxatin (oxaliplatin for injection) approved in the United-States for the 1st line treatment of metastatic colorectal cancer

ELOXATIN now indicated for the treatment of advanced carcinoma of the colon or rectum in combination with infusional 5FU/LV.

Sanofi-Synthélabo (Euronext: SAN/NYSE: SNY) announced today that ELOXATIN (oxaliplatin for injection) in combination with 5FU/LV has been approved by the U.S. Food and Drug Administration (FDA) for the first-line treatment of advanced colorectal cancer. ELOXATIN was already approved in August 2002 for second line treatment of patients with metastatic carcinoma of the colon or rectum in the US.

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.

The supplemental New Drug Application (sNDA) for ELOXATIN in this indication had been submitted on July 11, 2003 in the United States and was granted a six-month priority review in September 2003.

Clinical data show that patients with advanced colorectal cancer treated with ELOXATIN given in combination with 5-FU/LV as first-line chemotherapy had a statistically significant improvement of nearly five months in median survival time compared to patients treated with a standard treatment of irinotecan in combination with 5-FU/LV.

The finding that the oxaliplatin-based regimen demonstrated a longer survival time for patients is a major step forward. said Richard M. Goldberg, M.D., Professor and Division Chief at University of North Carolina (Chapel Hill School of Medicine). *This is the greatest increase in survival time we have seen in a chemotherapy regimen used in advanced colorectal cancer and positions the oxaliplatin-based regimen as an emerging standard of care for patients with colorectal cancer.*

Clinical Trial Results

The study, upon which the FDA approval was based, was an NCI-sponsored trial, N 9741, coordinated by the North Central Cancer Treatment Group (NCCTG). The study demonstrated that patients treated first with ELOXATIN combined with infusional 5-fluorouracil and leucovorin (5-FU/LV), a regimen known as FOLFOX, had an overall median survival time of 19.4 months after the initiation of treatment, compared to 14.6 months in patients treated with a standard combination of irinotecan plus bolus 5-FU/LV, a regimen known as IFL. This represents a median survival advantage of 4.8 months for patients treated with FOLFOX, a 35% improvement.

In addition to the survival advantage, patients on FOLFOX also had a significantly higher overall tumor response rate in patients with measurable disease at baseline (45% vs. 33%) and a significantly longer time to disease progression (8.7 months vs. 6.9 months) than those on

IFL. The side effects experienced by the group taking FOLFOX also were less severe, more manageable, and more often reversible than those reported by the IFL group. The most commonly reported side effects in patients treated with FOLFOX included neutropenia (decrease in white blood cells) and paresthesia (numbness or tingling). Based on these results, the investigators concluded that FOLFOX should be considered a standard first-line therapy for advanced colorectal cancer.

In March 2003, ELOXATIN was incorporated into the National Comprehensive Cancer Network (NCCN) colorectal cancer treatment guidelines.

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).

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

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. As with other platinum compounds, hypersensitivity and anaphylactic/anaphylactoid reactions have been reported.

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. In patients previously untreated/treated for advanced colorectal cancer, the most frequently reported adverse events (all grades) with ELOXATIN in combination with infusional 5-FU/LV were fatigue (70%/68%), diarrhoea (56%/67%), nausea (71%/65%), and vomiting (41%/40%). Changes in hematology parameters were also seen (all grades): anemia (27%/81%), leukopenia (85%/76%), neutropenia (81%/73%), and thrombocytopenia (71%/64%).

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 12th , 2004

Dear Madam, Dear Sir,

Please find below the estimated dates for key financial announcements in 2004 :

Thursday, January 22, 2004	>>	2003 sales press release
Monday, February 16, 2004	>>	2003 results press release
Thursday, April 22, 2004	>>	1st quarter 2004 sales press release
Monday, May 24, 2004	>>	Shareholders General Meeting
Wednesday, July 21, 2004	>>	1st half 2004 sales press release
Tuesday, August 31, 2004	>>	1st half 2004 results press release
Thursday, October 21, 2004	>>	9 months 2004 sales press release

Yours sincerely,

Philippe Goupit

Investor Relations Department

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Paris, January 12th , 2004

Dear Madam, Dear Sir,

On the occasion of the **2003 Full Year sales** publication, a **conference call** for financial analysts, institutional investors and journalists will be held on **Thursday, January 22nd, 2004 at 3.00 p.m.** (Paris time). This conference call will be in English.

France :	**00 33 (0) 1 70 70 81 98**	**code : 459621**
United Kingdom :	**00 44 (0) 207 984 75 82**	**code : 459621**
USA :	**00 1 718 354 11 58**	**code : 459621**

A recorded version of the conference will be made available through Wednesday February 11th, 2004 by dialing :

France :	**00 33 (0) 1 70 70 82 10**	**code : 459621#**
United Kingdom :	**00 44 (0) 207 784 10 24**	**code : 459621#**
USA :	**00 1 718 354 11 12**	**code : 459621#**

A live audio webcast of this conference will be made available at our internet site (www.sanofi-synthelabo.com) and a recorded version will be archived through Wednesday, February 11th, 2004.

Yours sincerely,

Philippe Goupit

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 12, 2004

SANOFI-SYNTHELABO

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