SANOFI SYNTHELABO SA
Form 6-K
September 17, 2003

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 September 2003
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, September 17, 2003

FDA grants priority review to ELOXATIN®
for the 1st line treatment of metastatic colorectal cancer

SANOFI-SYNTHELABO announced today that the U.S. Food and Drug Administration (FDA) has granted a six-month priority review to ELOXATIN® (oxaliplatin), for the 1st line treatment of metastatic colorectal cancer (MCRC).

The supplemental New Drug Application (sNDA) for ELOXATIN® in this indication had been submitted on July 11, 2003 in the United States.

The filing for this new indication was based on a NCI-sponsored trial, N 9741. The trial was coordinated by the North Central Cancer Treatment Group (NCCTG). Patients receiving the FOLFOX regimen (oxaliplatin + 5-FU/LV) versus the IFL regimen (irinotecan + 5-FU/LV), have a statistically significant improvement in terms of response rate (RR), progression free survival (PFS), overall survival (OS) and safety profile. The overall survival was 19.5 months with the FOLFOX regimen versus 14.8 months with the IFL regimen (p = 0.0001) giving an improvement of 4.7 months in favor of oxaliplatin-based treatment, representing a survival gain of more than 30%.

Further development in colorectal cancer
In addition to these important results, new data were also presented at the 39th annual meeting of the American Society of Clinical Oncology (ASCO), in June 2003, in adjuvant treatment following surgery, the early stage of the disease MOSAIC study. 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 was reduced by 23% vs. current standard treatment alone. The filing in the United States and in Europe for the adjuvant treatment of colorectal cancer should occur in the second half of the year 2003.

About Colorectal Cancer
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.

About Eloxatin®
ELOXATIN® is currently marketed by Sanofi-Synthelabo in more than 60 countries for 1st and/or 2nd line metastatic colorectal cancer and is becoming a cornerstone drug in the therapeutic strategies for all stages of this disease, including early stages. Moreover an extensive worldwide clinical development program is ongoing to explore the benefit of ELOXATIN® in other types of cancers, primarily gastric and pancreatic cancer.

Global sales of ELOXATIN® for the first semester 2003 reached EUR 384 million. Oxaliplatin was developed in association with Debiopharm S.A.

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. Data that demonstrate a clinical benefit, such as improvement of disease-related symptoms or increased survival were not available at approval.

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

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.

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, 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.

Investors and security holders may obtain a free copy of documents filed by Sanofi-Synthélabo with the french « Commission des Opérations de bourse » (COB) at www.cob.fr and with the U.S. Securities and Exchange Commission at www.sec.gov or directly from Sanofi-Synthélabo on the web site www. sanofi-synthelabo. com

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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: September 17, 2003

SANOFI-SYNTHELABO

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