SANOFI SYNTHELABO SA
Form 6-K
July 15, 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 July 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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):____

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-_____.

[SANOFI~SYNTHELABO LOGO]

~ Investor Relations

Paris, July 14, 2003

New Major Results on ARIXTRA(R) presented
at the International Society on Thrombosis and Haemostasis (ISTH):

ARTEMIS and PEGASUS trials

ARTEMIS shows that ARIXTRA(R) significantly lowers the risk of venous thromboembolism in acutely ill medical patients

PEGASUS shows that ARIXTRA(R) provides benefit in preventing venous thromboembolism in patients undergoing major abdominal surgery

The results of two major trials on Arixtra(R) (fondaparinux sodium) - ARTEMIS and PEGASUS - were presented today at the 19th Congress of the International Society on Thrombosis and Haemostasis (ISTH) in Birmingham, UK.

Here is a brief overview of the results.

ARTEMIS results

The results of the ARixtra(R) for ThromboEmbolism prevention in a Medical Indications Study (ARTEMIS) presented today demonstrate that the use of Arixtra(R) 2.5 mg administered once daily significantly reduces the risk of venous thromboembolism (VTE) in acutely ill hospitalised medical patients from 10.5% in the control group to 5.6% in the Arixtra(R) group (odds reduction = 49.5 % - p=0.029). There was a low rate of major bleeding (0.2%) in this population with Arixtra(R). Arixtra(R) therapy also showed a trend in reducing overall mortality patients, from 6.0% in the control group to 3.3% in the Arixtra(R) group, as assessed at day 32.

Regulatory submissions for this new indication should occur at the end of 2003 or beginning of 2004.

PEGASUS results

The results of the PEntasaccharide in GenerAl SUrgery Study (PEGASUS) presented today demonstrate that Arixtra(R) has at least comparable efficacy and safety than the low-molecular-weight heparin (LMWH) dalteparin for the prevention of venous thromboembolism (VTE) following major abdominal surgery. The PEGASUS study showed that the incidence of VTE was 4.6% in the Arixtra(R) group and 6.1% in the control group (p=0.14), with a trend in favor of Arixtra(R). Among patients undergoing abdominal cancer surgery, which represented around 70% of the overall study population, the incidence of VTE was significantly reduced in the Arixtra(R) group (4.7%) compared with the control group (7.7%) (p=0.02). This improved efficacy was achieved with comparable safety. Major bleeding rate was similar in both groups.
Regulatory submissions for this new indication should occur at the end of 2003 or beginning of 2004. These two new targeted indication as well as the treatment of VTE indication should allow Arixtra(R) to get access to 80 % of the current LMWH market - in number of patients - versus only 15% today.

ADDITIONAL INFORMATION

Arixtra(R) was launched in the United States on February 8, 2002, and in Europe as from March 27, 2002.

Prophylaxis of VTE
Arixtra(R) 2.5 mg has been extensively investigated in prophylaxis of VTE following major orthopedic surgery. In four phase III trials performed in patients undergoing hip fracture, hip or knee replacement surgery, Arixtra(R) more than halved the incidence of VTE (relative risk reduction of more than 55%

- p <0.001) with a similar safety profile compared to enoxaparin across all surgery types.

Extended prophylaxis of VTE
A recent trial in extended prophylaxis in hip fracture patients (PENTHIFRA-PLUS) found that Arixtra(R) administered for four weeks compared to one week markedly reduces the incidence of further VTE complications by 96% (p <0.001) and reduced the rate of symptomatic VTE to 0.3%. This trial allowed Arixtra(R) to be granted a new indication in the United States in June 2003 : "Prophylaxis of deep venous thrombosis, which may lead to pulmonary embolism, in patients undergoing hip fracture surgery, including extended prophylaxis". The file for this new indication in Europe was submitted to the EMEA in December 2002 and is currently under review.

Treatment of VTE
In December 2002, the results of the MATISSE program represented another step forward in the demonstration of the efficacy and safety of Arixtra(R). The key findings of the MATISSE program were that a fixed 7.5 mg once-daily subcutaneous dose of Arixtra(R) was at least comparable in efficacy and safety as current therapy. As an added benefit to physicians and patients, Arixtra(R) is more convenient to use in the initial treatment of DVT and PE. Regulatory submissions for this new indication and dosage forms should occur in the 3rd quarter of 2003.

Treatment of patients with acute coronary syndrome
Further clinical investigations are being carried out to extend the use of Arixtra(R) for the treatment of patients with acute coronary syndrome.

The life cycle management program on Arixtra(R) is going on according to plan.

As with other antithrombotics, the most common side effect during Arixtra(R) administration is bleeding. Arixtra(R) is contraindicated in patients with severely impaired kidney function or in patients who weigh less than 50 kg (110 pounds), because they may have an increased risk for major bleeding. Patients greater than 75 years of age also may be more likely to experience major bleeding complications. As with other antithrombotics, labeling for Arixtra(R) includes a Boxed Warning regarding possible spinal/epidural haematomas when spinal anaesthesia or spinal puncture is used.

Please refer to the approved Package Insert for the indication and safety profile.

Arixtra(R) is the first totally synthetic agent to selectively inhibit a specific key enzyme in the coagulation process called Factor Xa (<