SANOFI SYNTHELABO SA
Form 6-K
June 18, 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 June 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-_____.

Investor Relations **Paris, June 18, 2003**

New indication for ARIXTRA® in the United States:
Extended prophylaxis of deep venous thrombosis
in patients undergoing hip fracture surgery

Sanofi-Synthelabo and Organon announced today that Arixtra® (fondaparinux sodium) has been approved by the U.S. Food and Drug Administration (FDA) for a new indication: Prophylaxis of deep venous thrombosis, which may lead to pulmonary embolism, in patients undergoing hip fracture surgery, including extended prophylaxis .

Arixtra® is already indicated in the United States for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism :

- in patients undergoing hip fracture surgery;
- in patients undergoing hip replacement surgery;
- in patients undergoing knee replacement surgery.

The file for this new indication for Arixtra® was submitted to the FDA on December 17, 2002 and was granted a six-month priority review in March 2003. This is the second time that Arixtra® had been granted a six-month priority review. The clinical study on which this indication is based was published by Eriksson et al in the June 9, 2003 issue of the *Archives of Internal Medicine* 2003;163:1337-1342.

Arixtra® is the only anti-thrombotic agent currently indicated in the United States for the extended prophylaxis of deep venous thrombosis in patients undergoing hip fracture surgery.

This new indication is based upon the findings of a study (Penthifra-Plus) which demonstrates that in patients undergoing hip fracture surgery who were initially treated during the peri-operative period with Arixtra® 2.5 mg SC once daily for 7 days followed by a 3-week extended prophylaxis period comparing Arixtra® 2.5 mg once daily with placebo, in or out of the hospital, Arixtra® was associated with a venous thromboembolism events (VTE) rate of 1.4% compared to a VTE rate of 35.0% for placebo for a relative risk reduction of 95.9% (95% CI=[-99.7; -87.2], p<0.0001). The rate of symptomatic VTE was 0.3% for Arixtra vs. 2.7% for placebo (p=0.021).

After an usual duration of administration of 5 to 9 days, in patients undergoing hip fracture surgery an extended prophylaxis course of up to 24 additional days is recommended.

As with other antithrombotics, the most common side effect during Arixtra® administration is bleeding. Arixtra® 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® includes a Boxed Warning regarding possible spinal/epidural haematomas when spinal anaesthesia or spinal puncture is used.

Arixtra® was launched in the United States on February 8, 2002, and in Europe as from March 27, 2002. The file for this new indication in Europe for Arixtra® was submitted to the EMEA in December 2002 and is currently under review.

Unlike heparins, which are from animal origin, Arixtra® is a synthetic compound and the first in a new class of antithrombotic agents that selectively inhibit factor Xa. It was discovered and is being co-developed by Sanofi-Synthelabo and Organon.

With this synthetic drug, Sanofi-Synthelabo and Organon intends to establish Arixtra® as a reference treatment in the antithrombotic field.

Further clinical investigations are being carried out to extend the use of Arixtra® for the treatment of venous thrombosis and pulmonary embolism, VTE prevention in medical and surgical high risk situations and for the treatment of patients with acute coronary syndrome.

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 U.S. Securities and Exchange Commission at www.sec.gov or directly from Sanofi-Synthélabo on the web site www. sanofi-synthelabo.

Investor Relations Department

Philippe Goupit *Director of Investor Relations*
Isabelle Laurent *Investor Relations Europe*
Arnaud Delépine *Investor Relations Europe*
Sanjay Gupta *Investor Relations US*

Contacts:

E-mail: investor-relations@sanofi-synthelabo.com

Europe	*US*
Tel: +33 1 53 77 45 45	*Tel: 1 212 551 42 93*
Fax: +33 1 53 77 42 96	*Fax: 1 212 551 49 10*

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: June 18, 2003

SANOFI-SYNTHELABO

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