SANOFI SYNTHELABO SA
Form 6-K
November 19, 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 November 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, November 19, 2003

ARIXTRA® in the European Union: New treatment duration for the prophylaxis of Venous Thromboembolic Events in patients undergoing major orthopaedic surgery

Sanofi-Synthélabo and Organon announced today that Arixtra® (fondaparinux sodium) has received marketing authorization from the European Commission for ***an extended duration of prophylactic treatment of Venous Thromboembolic Events (VTE) in patients undergoing hip fracture surgery.***

Arixtra® is indicated in the European Union for the ***Prevention of Venous Thromboembolic Events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as hip fracture, major knee or hip replacement surgery*** .

The new labelling provides that for all these indications, the treatment should be continued until the risk of venous thrombo-embolism has diminished, usually until the patient is ambulant, at least 5 to 9 days after surgery. Experience shows that in patients undergoing hip fracture surgery, the risk of VTE continues beyond 9 days after surgery. In these patients the use of prolonged prophylaxis with Arixtra® should be considered for up to an additional 24 days.

This extended treatment duration will allow clinicians to give what has been demonstrated to be the most effective prophylaxis for the appropriate amount of time in hip fracture patients who have the highest risk of suffering VTE. This is a fact already recognised in recent guidelines issued by clinical expert societies in a number of European countries.

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

The clinical study on which this indication is based, Penthifra-Plus, was published by Eriksson et al in the June 9, 2003 issue of the Archives of Internal Medicine 2003;163: 1337-1342. This international randomised double-blind, placebo-controlled study demonstrates that patients undergoing hip fracture surgery treated with four weeks of Arixtra 2.5 mg SC once daily, in or out of the hospital, had a VTE rate of only 1.4%. The rate of symptomatic VTE was also reduced to 0.3% with Arixtra® extended prophylaxis, the lowest level ever reached in this high risk patient group, with no pulmonary embolisms the most feared outcome of VTE. There were no differences between Arixtra® and the placebo in the incidence of clinically relevant bleeding.

As with other antithrombotics, the most common side effect during Arixtra® administration is bleeding. Arixtra® is contraindicated in patients with severely impaired kidney function (< 20 mL/min creatinine Clearance) and should be used with caution in patients with mild and moderate renal impairment or in patients who weigh less than 50 kg or in patients greater than 75 years of age because they may have an increased risk for major bleeding.

Arixtra® was launched in the United States on February 8, 2002, and in Europe as from March 27, 2002. The file for this new treatment duration in Europe for Arixtra® was submitted to the EMEA in December 2002, and the Committee for Proprietary Medicinal Products (CPMP) adopted a positive opinion in July 2003. Arixtra® has received marketing approval for extended prophylaxis in the US in June 2003, after a six-month priority 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 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.

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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: November 19, 2003

SANOFI-SYNTHELABO

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