SANOFI SYNTHELABO SA
Form 6-K
November 03, 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 3, 2003

# Sanofi-Synthélabo launches UROXATRAL® in the United States for effective relief of the signs and symptoms of enlarged prostate

Sanofi-Synthelabo announced today that Uroxatral® (alfuzosin hydrochloride extended-release tablets) has been launched in the United States. Uroxatral® is a new 10 mg, once-daily prescription alpha$_1$-blocker that provides effective relief of the signs and symptoms of benign prostatic hyperplasia (BPH).

The launch of Uroxatral® further expands Sanofi-Synthelabo s key strategic product portfolio and establishes the company s commitment to building its internal medicine franchise.

Uroxatral® exhibits selectivity for alpha$_1$-adrenergic receptors in the lower urinary tract[(1)]. Uroxatral® works by relaxing the muscle surrounding the prostate, bladder neck and prostatic urethra to effectively treat the symptoms of BPH a non-cancerous enlargement of the prostate. Symptoms can include a frequent or urgent need to urinate, hesitancy in urinating and reduced urinary flow.

In three clinical trials, Uroxatral® demonstrated a statistically significant reduction in prostate symptoms severity versus placebo at the last assessment (week 12)[(1)]. Uroxatral® showed an improvement in peak urine flow rate versus placebo at last assessment (week 12) [(1)].

Men who are trying to cope with bothersome and noticeable symptoms should know that urinary problems may not necessarily be a part of aging. The symptoms related to benign enlargement of the prostate can be effectively treated with Uroxatral®, which can bring much needed relief to the millions of men suffering from bothersome urinary problems, said Claus G. Roehrborn, MD, Professor and Chairman, Department of Urology, University of Texas, Southwest Medical Center. Rather than live with these symptoms, men should see their doctors about treatment options and their side effect profiles. BPH treatment is sometimes associated with sexual side effects. Sexual side effects such as ejaculatory dysfunction (EjD) and erectile dysfunction (ED) should be considered in the management of patients with enlarged prostate.

The symptoms of BPH can have a significant impact on a man s day-to-day activities, added Dr. Roehrborn. Furthermore, left untreated, the symptoms may progress, which can lead to serious health problems including urinary tract infections, bladder and kidney damage, bladder stones, incontinence and acute urinary retention.

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Uroxatral® exhibits a low incidence of vasodilatory side effects (dizziness: 5.7% versus placebo 2.8%) and a low incidence of hypotension (0.4% versus placebo 0.0%) and syncope (0.2% versus placebo 0.0%) [(1)].

**Important Information About BPH Enlarged Prostate**
Affecting more than eight million men in the United States, BPH is a non-cancerous enlargement of the prostate, a progressive condition that can cause urinary symptoms, such as frequent and urgent need to urinate during the day and night, decreased urinary flow, and weak urinary stream. More than half of all men over age 60 suffer from BPH, and after age 80 men have an 80 percent chance of developing BPH[(2)]. The U.S. BPH market is approaching $1 billion (IMS MAT Sales July 2003) up 14 percent.

**Important Information About Lower Urinary Tract Symptoms And Sexual Dysfunction**
In a recent multinational survey study of nearly 14,000, lower urinary tract symptoms related to an enlarged prostate which affect 90 percent of men over age 50 are strongly correlated to sexual dysfunction. Erectile and ejaculatory dysfunction are more common in men with lower urinary tract symptoms than in men with other conditions known to be associated with erectile dysfunction, such as diabetes, hypertension, cardiac disease and hyperlipidemia. Men with severe urinary symptoms reported 50 percent less sexual activity and 33 percent reduction in overall sexual satisfaction [(3)].

**Important Safety Information**
Uroxatral® should not be used in patients with moderate to severe hepatic insufficiency (Childs-Pugh categories B and C), since Uroxatral® blood levels are increased in these patients. Uroxatral® should not be used in combination with CYP3A4 inhibitors such as ketoconazole, itraconazole, and ritonavir. Caution should be used in patients with severe renal insufficiency (creatinine clearance <30 mL/min). Uroxatral® should not be used in combination with other alpha-blockers. If symptoms of angina pectoris should newly appear or worsen, the use of Uroxatral® should be discontinued. In a study of QT effect in 45 healthy males, the QT effect appeared less with Uroxatral® 10 mg than with 40 mg, and the effect of Uroxatral® 40 mg did not appear as large as that of the active control moxifloxacin at its therapeutic dose. This should be considered in clinical decisions to prescribe Uroxatral® for patients with a known history of QT prolongation or patients who are taking medications known to prolong QT. There has been no signal of Torsades de Pointe in the extensive post marketing experience with Uroxatral® worldwide. There are no known pharmacokinetic/pharmacodynamic studies of the effects of other alpha-blockers on cardiac repolarization.

Carcinoma of the prostate and BPH cause many of the same symptoms. These two diseases frequently coexist. Therefore, patients thought to have BPH should be examined prior to starting therapy with Uroxatral® to rule out the presence of carcinoma of the prostate. Postural hypotension with or without symptoms may develop within a few hours following administration of Uroxatral®. As with all alpha-blockers, there is a potential for syncope. Patients should be warned of the possible occurrence of such events and should avoid situations where injury could result should syncope occur. In clinical trials, the most common side effects occurring in ≥ 2% of patients and more frequently than placebo were dizziness (5.7% versus 2.8%), upper respiratory tract infection (3.0% versus 0.6%), headache (3.0% versus 1.8%), and fatigue (2.7% versus 1.8%)[(1)].

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**About Sanofi-Synthelabo**
Sanofi-Synthelabo is a major global research-based pharmaceutical group with 32,500 employees in more than 100 countries. The company is headquartered in Paris and listed in Paris (Euronext : SAN) and in New York (NYSE : SNY). With consolidated sales of EUR 7.4 billion in 2002, Sanofi-Synthelabo ranks 7th in Europe and among the world s top 20 pharmaceutical companies. With an R&D portfolio of 55 compounds in development, Sanofi-Synthelabo is focused on a core group of four therapeutic areas: cardiovascular disease and thrombosis; diseases of the central nervous system; internal medicine; and oncology.

*Full prescribing information for Uroxatral is available at www.uroxatral.com.*


(1) Uroxatral® (alfuzosin HCI extended-release tablets) package insert, 2003. Sanofi-Synthelabo Inc., New York, NY.
(2) Medina JJ, Parra RO, Moore RG. Benign prostatic hyperplasia (the aging prostate). *Med Clin North Am.* 1999;83:1213-1229.
(3) Rosen R. & al. Lower Urinary Tract Symptoms and Male Sexual Dysfunction: The Multi-National Survey of the Aging Male (MSAM-7). *European Urology* 2003 In Press


*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 3, 2003

SANOFI-SYNTHELABO

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