

SANOFI SYNTHELABO SA

Form 6-K

March 31, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 6-K  
REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

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For the month of March 2004

Commission File Number: 001-31368

**SANOFI-SYNTHÉLABO**

(Translation of registrant's name into English)

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  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

If "Yes" marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

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## Investor Relations

### **Alfuzosin 10 mg OD (Xatral® OD) shows beneficial effect in patients with acute urinary retention** *Need for BPH-related surgery reduced*

**Vienna, March 25, 2004** - The results of the ALFAUR (ALFuzosin in Acute Urinary Retention) study, announced today at the XIXth European Association of Urology (EAU) Congress in Vienna, Austria, indicate that the uroselective  $\alpha_1$ -blocker alfuzosin 10 mg once daily (OD) may have a beneficial effect in the management of male patients suffering from acute urinary retention (AUR), a sudden inability to pass urine that results in a painful distension of the bladder, requires immediate management with urethral catheterization and could necessitate surgical intervention.

ALFAUR was a double-blind, placebo-controlled trial including 363 patients with a first episode of AUR related to benign prostatic hyperplasia (BPH).

The ALFAUR trial was conducted in two phases.

In the first phase of the study patients were randomised to receive alfuzosin 10 mg OD or placebo for a period of 2 to 3 days from the beginning of catheterization to a trial without catheter (TWOC). In this phase of the trial, alfuzosin 10 mg OD had a higher rate of successful voiding of the bladder after catheter removal compared with placebo (61.9% versus 47.9 percent,  $p=0.012$ ). Alfuzosin 10 mg OD almost doubled the likelihood of a successful TWOC in these patients and its beneficial effect was particularly marked in patients with a high risk of TWOC failure, i.e. men over 65 years of age and/or with a retention volume of more than 1,000 ml.

In the second phase of the ALFAUR study, all patients who were successfully voided in the first phase were re-randomized to receive alfuzosin 10 mg OD or placebo for a further period of six months to evaluate whether alfuzosin was able to reduce the need for BPH-related surgery defined by the recurrence of AUR or symptomatic impairment. The results of this phase of the study showed that:

- Ø alfuzosin 10mg OD administered for six months following a successful TWOC reduces the risk of BPH surgery by almost 30% compared to placebo,
- Ø this result is even more marked at month 1 and month 3 (respectively 61% and 53% risk reduction;  $p=0.04$ )

The ALFAUR trial demonstrates that alfuzosin, through its action on risk factors and sympathetic overactivity, allows for rapid catheter removal in patients with AUR and also significantly reduces the recurrence of AUR and the need for BPH-related surgery



in comparison with placebo in the medium term. This is clinically meaningful for physicians and offers patients hope for better treatment, said S. Alan McNeill, MD, Department of Urology, Western General Hospital in Edinburgh, leading investigator of the ALFAUR trial.

Acute urinary retention, the sudden inability to urinate, is most commonly a complication of chronic benign prostatic hyperplasia. Typically the patient complains of severe pain and an inability to satisfactorily empty the bladder. The patient should be catheterised to reduce pain and avoid the risk of causing, or exacerbating, renal failure. Prompt urethral catheterisation is essential.

In elderly men, the risk of having an episode of acute urinary retention is remarkably high. Over 1 in 10 men in their 70s will experience acute urinary retention within the next five years. The risk for men in their 80s is nearly 1 in 3. Men who have moderate to severe symptoms of AUR have three times the risk of men with mild symptoms.

On the basis of the ALFAUR study results, men with acute urinary retention can now expect a diminished need of having BPH-related surgery in urgency conditions which increase the mortality and morbidity of the intervention. With the on-going ALTESS study, we will see whether this beneficial effect could prevent the occurrence of a first episode of AUR in BPH patients said Steven A. Kaplan, MD, Given Foundation Professor of Urology and Vice-chairman, College of Physicians and Surgeons at Columbia University, New York.

The ALFAUR trial was made possible by a grant from Sanofi-Synthelabo Research.

*In accordance with article 7 of the COB rule no. 2002-04, this document was transmitted to the Autorité des marchés financiers (AMF) before its publication.*

### **Forward-Looking Statements**

*This press release contains statements that constitute forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-Looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to future operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words expect, anticipates, believes, intends, estimates and similar expressions. Although Sanofi-Synthelabo's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi-Synthelabo, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. The following factors, among other risks and uncertainties that are described in our Form 20-F as filed with the SEC on June 25, 2003 and in the Reference Document filed with the French Commission des Opérations de Bourse (now the Autorité des Marchés Financiers) on April 23, 2003, could cause actual results to differ materially from those described in the forward-looking statements: the ability of Sanofi-Synthelabo to expand its presence profitably in the United States; the success of Sanofi-Synthelabo's research and development programs; the ability of Sanofi-Synthelabo 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 Europe. Sanofi-Synthelabo 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 SEC at [www.sec.gov](http://www.sec.gov) as well as of the Reference Document filed with the French Autorité des Marchés Financiers at [www.amf-france.org](http://www.amf-france.org) or directly from Sanofi-Synthélabo on our web site at: [www.sanofi-synthelabo.com](http://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: March 31, 2004

SANOFI-SYNTHÉLABO

By: /s/ Marie-Hélène Laimay

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