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:

- alfuzosin 10mg OD administered for six months following a successful TWOC reduces the risk of BPH surgery by almost 30% compared to placebo,
- 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.

Senior Vice President, Corporate Communications : **Nicole CRANOIS** - Director of Media Relations : **Jean-Marc PODVIN**
Tel.: + 33 1.53.77.42.23 - Fax : + 33 1.53.77.42.65 - 174, avenue de France - 75013 PARIS - www.sanofi-synthelabo.com

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-Synthélabo'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-Synthélabo, 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-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 Europe. 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 SEC at www.sec.gov as well as of the Reference Document filed with the French Autorité des Marchés Financiers at www.amf-france.org or directly from Sanofi-Synthélabo on our web site at: www.sanofi-synthelabo.com.

Senior Vice President, Corporate Communications : **Nicole CRANOIS** - Director of Media Relations : **Jean-Marc PODVIN**
Tel.: + 33 1.53.77.42.23 - Fax : + 33 1.53.77.42.65 - 174, avenue de France - 75013 PARIS - www.sanofi-synthelabo.com