SKYEPHARMA PLC
Form 6-K
March 29, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

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

For March, 2004

SkyePharma PLC

(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40F.

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-
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For Immediate Release

29 March 2004

SkyePharma PLC

European urology conference hears data on use of Xatral® OD in acute urinary retention

LONDON, UK, 29 March 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) draws attention to the recent announcement of the results of the ALFAUR (**ALF**uzosin in **A**cute **U**rinary **R**etention) study at the XIXth European Association of Urology Congress in Vienna, Austria. The results indicate that Sanofi-Synthélabo's Xatral® OD, a 10 mg once-daily formulation of the uroselective alpha1-blocker alfuzosin, may have a beneficial effect in the management of male patients suffering from acute urinary retention ("AUR"). AUR is a condition where a sudden inability to pass urine results in the bladder becoming painfully distended. AUR requires immediate management with urethral catheterization and can require emergency surgical intervention. The once-daily formulation in Xatral® OD was developed by SkyePharma for Sanofi-Synthélabo and incorporates SkyePharma's proprietary Geomatrix delivery technology.

ALFAUR was a double-blind, placebo-controlled trial involving 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, patients were randomised to receive Xatral® 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, Xatral® OD had a higher rate of successful voiding of the bladder after catheter removal compared with placebo (62% versus 48%, p=0.012). Treatment with Xatral® 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 (men over 65 years of age and/or with a urine retention volume of more than 1 litre).
- In the second phase, all patients who were successfully voided in the first phase were re-randomized to receive Xatral® 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 Xatral® OD administered for six months following a successful TWOC reduced the risk of BPH surgery by almost 30% compared with placebo. In addition this result was even more marked at month 1 and at month 3 (risk reduction of 61% and 53% respectively, p=0.04).

Sanofi-Synthélabo has marketed alfuzosin as Xatral® outside the USA for the treatment of the urinary symptoms of BPH since 1988. Xatral® OD, the once a day formulation developed by SkyePharma for Sanofi-Synthélabo, was launched in Europe in April 2000 and is now on the market throughout Europe and in certain territories in Africa, the Middle East, Asia, Latin America and Canada. No version of Xatral® had been marketed in the USA before the introduction of Uroxatral® (the US trade name for Xatral® OD) in November 2003. In 2003, Sanofi-Synthélabo's global sales of Xatral® in all forms were EUR222 million, including US sales of Uroxatral® of EUR9 million (US$11 million). Alfuzosin was recently approved in certain European countries for the related indication of AUR, and is in late-stage clinical trials for a US filing for this indication.

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Notes to Editors

About SkyePharma
SkyePharma PLC uses its world-leading drug delivery technology to develop easier-to-use and more effective formulations of drugs. The majority of challenges faced in the formulation and delivery of drugs can be addressed by one of the Company's proprietary technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit http://www.skyepharma.com.

About Geomatrix
Geomatrix controlled release systems control the amount, timing and location of drug release into the body. This is achieved by constructing a tablet with two basic components: a core containing the active drug or drugs, and one or two additional barrier layers

that control the drug's diffusion out of the core. Tablets with a wide range of predictable and reproducible drug release profiles can be made by combining different chemical components in the core and barrier layers, each with a different rate of swelling, gelling and erosion.

About Sanofi-Synthélabo
Sanofi-Synthélabo is a major global research-based pharmaceutical group with 32,500 employees in more than 100 countries and consolidated sales of over EUR8 billion in 2003. With an R&D portfolio of 55 compounds in development, Sanofi-Synthélabo is focused on a core group of four therapeutic areas: cardiovascular disease and thrombosis; diseases of the central nervous system; internal medicine; and oncology. For more information, visit http://www.sanofi-synthelabo.com.

About Benign Prostatic Hyperplasia (BPH)
BPH (also known as benign prostatic hypertrophy) is a common chronic condition that typically first affects males in middle age. Thereafter the incidence rises steeply with age. For example, the urinary symptoms of BPH affect 22% of men aged 50-59 but 45% of men aged 70-80. Currently 8 million men in the USA are affected. Gradual enlargement of the prostate gland causes progressive obstruction of the urethra. Patients feel the need for frequent micturition but this results in incomplete emptying of the bladder. 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 (AUR).

The increase in the average age of the population as the post-war "Baby Boom" reaches middle age is expected to drive a significant increase in both the prevalence of the condition and the size of the market for treatments for BPH. A 2002 analysis by Theta Reports estimated that by 2006 approximately 115 million men in the 50+ age bracket worldwide will suffer from BPH and that even though BPH is not life-threatening, the rising incidence will drive the value of the global market to nearly $10 billion.

About Acute Urinary Retention (AUR)
AUR, 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 is normally catheterised to reduce pain and to avoid the risk of causing, or exacerbating, renal failure. Prompt urethral catheterisation is essential.

In elderly men, the risk of having an episode of AUR is remarkably high. Over 1 in 10 men in their 70s will experience AUR 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.

About alfuzosin
Alfuzosin is not a primary treatment for enlarged prostate but addresses the urinary symptoms by selectively blocking alpha-1 adrenergic receptors in smooth muscle of the urinary tract, causing smooth muscle in the bladder neck and prostate to relax and thereby improving urine flow. Extensive clinical studies conducted by Sanofi-Synthélabo have demonstrated that alfuzosin has a high degree of selectivity for urinary tract smooth muscle, resulting in a low incidence of vasodilatory side-effects such as postural hypotension and syncope (fainting) that can affect patients treated with competing alpha blockers that are less selective. In addition alfuzosin has a low risk of sexual side-effects whereas erectile dysfunction and ejaculatory disorders are well-recognized side-effects of competing alpha-blockers (and also of alternative treatments for BPH). Alfuzosin is the only alpha-1 blocker that has been shown in clinical trials to result in a significant decrease in post-void residual urine volume, a known risk factor for acute urinary retention. IMS estimates that the US market for treatments for BPH is currently in excess of US$1.0 billion, two-thirds of which comes from sales of alpha-blockers.

Except for the historical information herein, the matters discussed in this news release include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. These include without limitation risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for its products, other regulatory risks, risks relating to SkyePharma's ability to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning SkyePharma's ability to manage growth, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization and maintain or expand sales and market share for its products, risks relating to the ability to ensure regulatory compliance, risks related to the research, development and regulatory approval of new pharmaceutical products, risks related to research and development costs and capabilities, market acceptance of and continuing demand for SkyePharma's products and the impact of increased competition, risks associated with anticipated top and bottom line growth and the possibility that upside potential will not be achieved, competitive products and pricing, and risks associated with the ownership and use of intellectual property rights. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

END

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.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: March 29, 2004