SKYEPHARMA PLC
Form 6-K
June 16, 2003

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 the month of June, 2003

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

16 June, 2003

FDA approves Sanofi-Synthelabo's Uroxatral

LONDON, ENGLAND, June 16, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announced today that the US Food and Drug Administration (FDA) has approved Sanofi-Synthelabo's New Drug Application (NDA) for alfuzosin hydrochloride extended-release tablets, to be marketed in the US as UroXatral. The 10 mg once-daily extended-release formulation was developed for Sanofi-Synthelabo by SkyePharma and involves SkyePharma's proprietary Geomatrix oral controlled-release drug drug delivery technology. SkyePharma earns a royalty on Sanofi-Synthelabo's global sales of the once-daily formulation of alfuzosin.

Alfuzosin is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Alfuzosin selectively blocks alpha1-adrenergic receptors in the lower urinary tract. Blockade of these adrenoreceptors can cause smooth muscle in the bladder neck and prostate to relax, resulting in an improvement in urine flow and a reduction in the symptoms of BPH. BPH is a very common disorder, leading to urinary symptoms of varying severity. The resulting symptoms affect 22% of men aged 50-59 years, but up to 45% of men aged 70-80 years. These symptoms may have an impact on men's day-to-day activities and may ultimately lead to serious complications such as acute urinary retention.

Clinical efficacy data for alfuzosin from placebo-controlled trials have demonstrated efficacy compared to placebo in urinary flow improvement and in improvement in urinary symptoms without the need for dose titration. In the clinical trials, the most common side effects occurring more frequently than placebo were dizziness, upper respiratory tract infection, headache and fatigue.

Alfuzosin is marketed in more than 80 countries throughout Europe, Latin America, Africa and Asia. Outside of the United States, the once-daily formulation (Xatral OD) is registered in 70 countries worldwide and is currently marketed in 14 countries in Europe and in more than 35 other countries. Total sales of alfuzosin reached 182 million euros in 2002 and 49 million euros in the first quarter of 2003.

Sanofi-Synthelabo has indicated that the launch of UroXatral in the United States will occur in the second half of 2003.

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 oral 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 rates of swelling, gelling and erosion.

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 52 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.

This press release may contain forward-looking statements regarding SkyePharma PLC and its technologies. Actual results may differ materially from those described in the press release as a result of a number of factors, including but not limited to the following: There can be no assurance that SkyePharma will exercise its option to sign a technology access and license agreement for micro-encapsulation technology, nor that any product will be successfully developed incorporating micro-encapsulation technology, or that final results of human clinical trials will result in the regulatory approvals required to market products, or that final regulatory approval will be received in a timely manner, if at all, or that patient and physician acceptance of these products will be achieved. The Company undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

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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.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: June 16, 2003