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

SkyePharma Welcomes Publication of Studies on
Additional Potential Therapeutic Applications for Paxil CR™

LONDON, ENGLAND, June 16, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes the recent publication of studies on three potential additional therapeutic applications for Paxil CR™ (paroxetine HCl) Controlled Release. Data from double blind placebo controlled studies on the use of Paxil CR™ in treating social anxiety disorder and premenstrual dysphoric disorder (PMDD) were presented at the 156th Annual Meeting of the American Psychiatric Association in San Francisco (22nd-24th May). The 4th June issue of the Journal of the American Medical Association (JAMA) included a paper on a double blind placebo controlled study of Paxil CR™ in the treatment of menopausal hot flashes (known as "hot flushes" in some countries).

The social anxiety study examined 370 patients who were treated with doses of Paxil CR™ between 12.5 mg and 37.5 mg a day or with placebo. A significantly larger number of patients treated with Paxil CR™ achieved remission than with placebo and the drop-out rate with Paxil CR™ was comparable to placebo. Social anxiety is a condition characterised by extreme reluctance to engage in social activity and can have profound impact on patients' lives. The condition is believed to affect about 10 million patients in the USA.

In the PMDD studies, over 1000 patients were enrolled in three separate studies and were treated with either Paxil CR™ at a daily dose of 12.5 or 24 mg or with placebo. Even at the lowest dose, there was a significant improvement in patients' emotional and physical symptoms over placebo and the drug was well-tolerated. PMDD is a condition that affects about 5% of menstruating women and is characterised by severe and disabling mood swings and physical symptoms around the end of the menstrual cycle.

The JAMA paper reported the results of a study of 165 women experiencing menopausal hot flashes treated with Paxil CR™ at 12.5 mg or 25 mg a day or with placebo. After 6 weeks of treatment there was a significant improvement in the frequency and severity of hot flashes in over 60% of those treated with Paxil CR™ against 38% on placebo. Paxil CR™ was well tolerated with the incidence of adverse events near placebo level. This finding is interesting because of the concerns raised recently by the Women's Health Initiative study over the risks associated with hormone replacement therapy, the current main treatment for menopausal hot flashes.

GlaxoSmithKline launched Paxil CR™ in the USA in April 2002. Paxil(R) , a leading anxiolytic-antidepressant, was reformulated using SkyePharma's Geomatrix™ oral drug delivery technology. SkyePharma receives ongoing royalty payments on net sales. Paxil CR™ is approved by the U.S. Food and Drug Administration (FDA) for the treatment of major depressive disorder and panic disorder. The FDA is currently reviewing Paxil CR™ as a treatment for social anxiety disorder and for premenstrual dysphoric disorder.

Michael Ashton, SkyePharma's chief executive officer commented, "Paxil CR™ , the flagship of our Geomatrix™ oral drug delivery platform technology, has been very successful since its US launch last year. According to IMS market data, Paxil CR™ currently accounts for over 36% of new prescriptions for the entire Paxil(R) /Paxil CR™ franchise in the U.S. Clinical studies have demonstrated that Paxil CR™ significantly reduces the incidence of nausea, a common and troublesome side-effect that results in poor compliance with many SSRI antidepressants. The low drop-out rate for patients on Paxil CR™ may increase the likelihood that patients will obtain the full therapeutic benefit. The new studies reported recently imply several potential new applications for Paxil CR™ , expanding the market opportunity for the product."

Paxil CR™ is a controlled-release formulation of GlaxoSmithKline's leading antidepressant Paxil(R) . In 2002, worldwide sales of Paxil(R) (including Paxil CR™) were over £2.0 billion, £1.4 billion of which was in the U.S. The Geomatrix™ formulation is a multi-layered tablet that controls the dissolution and absorption of the drug in the body. Paxil CR™ offers flexible dosing and is available in three different dosing strengths: 12.5 mg, 25 mg and 37.5 mg.

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 drugs' 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 GlaxoSmithKline

GlaxoSmithKline, one of the world's leading research-based pharmaceutical and health care companies, is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information visit http://www.gsk.com.

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.

For further information please contact:

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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