SKYEPHARMA PLC
Form 6-K
September 03, 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 September, 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
3 September, 2003

SkyePharma Welcomes FDA Approval

of New Indication for Paxil CR

LONDON, ENGLAND, September 3, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes yesterday's announcement by its partner GlaxoSmithKline that the US Food & Drug Administration ("FDA") has approved an additional therapeutic application for Paxil CR (paroxetine hydrochloride Controlled Release) for the treatment of premenstrual dysphoric disorder ("PMDD"). PaxilCR is a leading selective serotonin reuptake inhibitor ("SSRI") antidepressant and Paxil C is already on the market in the US for the treatment of depression and panic disorder. SkyePharma developed the controlled release formulation used in Paxil CR and receives a royalty on GlaxoSmithKline's sales.

In studies on the use of Paxil CR in the treatment of PMDD reported at the 156th Annual Meeting of the American Psychiatric Association in San Francisco (22nd-24th May), over 1000 patients were enrolled in three separate studies and were treated with either Paxil C at a daily dose of 12.5 or 25 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.

In Paxil CR GlaxoSmithKline's leading antidepressant Paxil® was reformulated using SkyePharma's Geomatri oral drug delivery technology in which a multi-layered tablet controls the rate of dissolution and site of absorption of the drug in the body. GlaxoSmithKline launched Paxil CR in the USA in April 2002. Paxil C is currently approved by the U.S. Food and Drug Administration (FDA) for the treatment of major depressive disorder and panic disorder. Paxil CR offers flexible dosing and is available in three different dosing strengths: 12.5 mg, 25 mg and 37.5 mg. In the first half of 2003, US sales of Paxil® (including Paxil CR) were US$1.07 billion. SkyePharma receives ongoing royalty payments on GlaxoSmithKline's net sales of Paxil CR . The FDA is currently reviewing Paxil CR as a treatment for social anxiety disorder and for the intermittent dosing of PMDD.

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 38% of new prescriptions and over 30% of all prescriptions for the entire Paxil®/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 PMDD indication for Paxil CR should expand the market opportunity for the product since the older version of Paxil® was never approved for this indication."

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 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.

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.

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: September 3, 2003