

SKYEPHARMA PLC
Form 6-K
December 19, 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 December, 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 ☒ 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 ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

**For Immediate Release
19 December, 2003**

SkyePharma PLC

**NEW STUDY SHOWS PATIENTS TREATED WITH PAXIL® CR FOR DEPRESSION ARE LESS
LIKELY TO DISCONTINUE THERAPY**

LONDON, UK, 19 December 2003 -- SkyePharma PLC (LSE: SKP, Nasdaq: SKYE) welcomes the publication of a new study in the December 2003 issue of "Managed Care Interface" showing that patients with depression who were prescribed controlled-release paroxetine (GlaxoSmithKline's Paxil® CR) were less likely to discontinue therapy than patients receiving immediate-release selective serotonin reuptake inhibitors (SSRIs). Paxil® CR, a modified version of GlaxoSmithKline's SSRI antidepressant Paxil®, incorporates SkyePharma's Geomatrix® oral controlled release delivery technology. Paxil® CR was designed to reduce the incidence of nausea, the most common side-effect of SSRI antidepressants, especially in patients initiating therapy. Paxil® CR has been available in the US market since April 2002 and SkyePharma receives a royalty on GlaxoSmithKline's sales. In the three months ending 30 September 2003, sales of Paxil® CR were GBP110 million (\$177 million), representing 30% of the US Paxil®/Paxil® CR franchise total.

The database study looked at more than 80,000 patients in managed care organizations across the United States and found that patients taking controlled-release paroxetine were 28 percent less likely to discontinue therapy during a 180-day period than patients taking immediate-release SSRIs. American Psychiatric Association (APA) treatment guidelines recommend that patients with depression remain on antidepressant therapy for a minimum of six months. However more than 40 percent of patients discontinue treatment within the first 90 days.

The clinical benefit of increased length of treatment is well-documented, indicating that depression and/or anxiety relapses are less likely with patients who remain on therapy longer. A decrease in relapse rates could substantially reduce the current costs associated with this disease in America, which currently total in excess of \$80 billion annually. Previously-published clinical trial data¹ shows that controlled-release paroxetine is associated with improved tolerability and a lower adverse event drop-out rate as compared with immediate-release paroxetine, suggesting a rationale for the extended treatment duration of patients taking controlled-release paroxetine.

"With controlled-release paroxetine, more patients remain on therapy during the critical maintenance-phase period than with immediate-release SSRIs, enhancing the quality of depression management," said Dr. Quentzel, Chief of Primary Care Psychiatry at Beth Israel Medical Center in New York, NY. "Controlled-release paroxetine offers primary care physicians and mental health providers an encouraging option to help reduce treatment discontinuation."

The study examined claims data obtained from the PharMetrics Integrated Outcomes Database, including data from 61 different managed care organizations, encompassing more than 36 million lives and nearly 1 billion claims. Patients were required to be at least 18 years of age and to have six months of enrolment before their index date, defined as the date of the first SSRI prescription. Only patients experiencing new therapy with SSRIs between April 1, 2002 and December 31, 2002 were included in the study. A total of 82,337 patients were eligible for study inclusion. Most patients had prescriptions for sertraline (Pfizer's Zoloft®), followed by immediate-release paroxetine (GlaxoSmithKline's Paxil®, now also available generically), citalopram (Forest Laboratories' Celexa), and fluoxetine (Eli Lilly's Prozac®, now also available generically). Eight percent of eligible patients received controlled-release paroxetine (GlaxoSmithKline's Paxil® CR).

In the time-to-discontinuation analysis, patients were deemed to have discontinued therapy when more than 15 days beyond the days' supply elapsed between prescriptions. The discontinuation analysis indicated that patients receiving controlled-release paroxetine were 28 percent less likely to discontinue therapy as compared with patients receiving immediate-release SSRIs. Furthermore, during the 180-day follow-up period, patients receiving controlled-release paroxetine were 16.5 percent less likely to switch or augment therapy as compared with patients receiving immediate-release SSRIs.

"Not only does non-compliance in antidepressant therapy make it more difficult to effectively treat patients, but early therapy change or discontinuation also places a financial burden on the health system." said investigator Timothy Regan, Senior Manager with Applied Health Outcomes, the outcomes research firm that conducted the study. "The improvements in length of therapy seen with controlled-release paroxetine are expected to yield substantial economic and clinical benefits for patients and managed care organizations."

1 Golden et al., J. Clin. Psychiatry, 63:7 (July 2002)

Notes for Editors:

About SkyePharma

SkyePharma develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now nine approved products incorporating three of SkyePharma's five technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit 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 rate of swelling, gelling and erosion.

About Managed Care Interface

Managed Care Interface, launched in 1988, is a monthly peer-reviewed journal for the US managed care industry. Each month, Managed Care Interface publishes fully refereed articles in a broad spectrum of interest, including Pharmacy Practice, Pharmacoeconomics, Disease Management, and Health Care Policy.

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: December 19, 2003