SKYEPHARMA PLC
Form 6-K
October 20, 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 October, 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

20 October, 2003

SkyePharma Welcomes FDA Approval of Additional Indication for Paxil CR

Paxil CR Becomes the First and Only Controlled-Release SSRI Antidepressant Approved for Social Anxiety Disorder

LONDON, ENGLAND, October 20, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes the recent announcement by its partner GlaxoSmithKline (NYSE: GSK), that the US Food & Drug Administration ("FDA") has approved an additional therapeutic indication for Paxil CR (paroxetine hydrochloride Controlled Release) for the treatment of social anxiety disorder. Paxil CR is already approved and on the market in the US for the treatment of depression, panic disorder and, most recently, premenstrual dysphoric disorder (PMDD). SkyePharma developed the controlled release formulation used in Paxil CR and receives a royalty on GlaxoSmithKline's sales.

Social anxiety disorder ("SAD", also known as social phobia) is a condition in which affected individuals have an intense and exaggerated fear of scrutiny by other people in common everyday social interaction situations such as meetings, parties, speaking in public and talking to strangers or authority figures. Affected individuals exhibit symptoms such as rapid heartbeat, tremor, nausea and diarrhoea in these circumstances, often leading them to avoid such situations altogether, thereby adversely affecting their life, work and social relationships. This highly debilitating condition is believed to affect more than 10 million Americans and is the third most common psychiatric disorder behind depression and alcoholism. Despite the devastating consequences of SAD, relatively few patients are diagnosed and most are not even aware that this is a medical condition that can be treated successfully. Paxil CR is the first and only controlled-release selective serotonin reuptake inhibitor (SSRI) antidepressant to be approved for treating SAD. The low level of treatment-associated side-effects with Paxil CR is expected to contribute to the effectiveness of therapy since adverse events are a major factor behind the recognised problem of poor compliance with other antidepressants.

Michael Ashton, SkyePharma's chief executive officer, commented "We are extremely excited by this recent milestone, which is testimony to the breadth of therapeutic efficacy for Paxil CR when targeting incapacitating depressive conditions such as SAD. Even though SAD is a common condition, it is under-treated, with less than 1% of all US prescriptions for SSRI antidepressants currently being written for SAD, so we believe that there is a substantial opportunity for a superior treatment. Based on US IMS data through August 2003, 72% of all prescriptions for SAD involve an SSRI antidepressant, and nearly 30% of SSRI prescriptions for the condition are already written for Paxil CR . Clinical studies have demonstrated that Paxil CR significantly reduces the incidence of nausea in the first few weeks of treatment, 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. We look forward to a similar regulatory outcome for the remaining indication of Paxil CR still under review, intermittent treatment of PMDD."

Data from a 12 week multi-center, double-blind placebo-controlled trial was presented by GlaxoSmithKline at the 156th annual meeting of the American Psychiatric Association in San Francisco in May 2003. 370 patients diagnosed with SAD were given a flexible dose regimen of Paxil CR (12.5 mg - 37.5 mg per day) or placebo. The two primary efficacy variables were the mean change from baseline in the Liebowitz Social Anxiety Scale (LSAS) and percent of responders defined by a CGI-Global Improvement score of one (very much improved) or two (much improved). The Sheehan Disability Scale (SDS) was also utilized to measure functional impairment. Paxil CR resulted in statistically significant improvement in symptoms from placebo in the efficacy scales and significant improvements were seen in total functional impairments measures as

well as each of the subcategories: family life, work life and social life. Additional results from this study demonstrated that Paxil CR achieved high remission rates. Furthermore Paxil CR was well-tolerated, with a low patient drop-out rate due to adverse events comparable with placebo (3% vs. 2%).

In Paxil CR GlaxoSmithKline's leading antidepressant Paxil® was reformulated using SkyePharma's Geomatrix 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 CR is currently approved by the FDA for the treatment of major depressive disorder, panic disorder and continuous premenstrual dysphoric disorder (PMDD). 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 sales of Paxil CR) were US$1.07 billion. The FDA is currently reviewing Paxil CR as an intermittent treatment for PMDD.

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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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: October 20, 2003