

SKYEPHARMA PLC  
Form 6-K  
March 30, 2004

**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 March, 2004

SkyePharma PLC

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(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

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(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-

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**For Immediate Release**

**30 March, 2004**

## **SkyePharma's Partner Astralis Initiates US Phase II Trial for Novel Psoriasis Treatment**

LONDON, UK, 30 March 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes the recent announcement by its partner Astralis Ltd (OTC Bulletin Board: ASTR) that it has initiated a Phase II clinical trial in the USA for Psoraxine , a novel injectable treatment for moderate psoriasis, a common chronic skin condition. This follows the successful completion of a US Phase I trial, which commenced in September 2003. A first generation version of Psoraxine was studied extensively in Venezuela, where nearly 3,000 patients participated in open-label clinical studies, the vast majority showing a positive response with few side-effects.

Michael Ashton, SkyePharma's Chief Executive, said "The US Food & Drug Administration's decision to authorize the Phase II trial for Psoraxine is an encouraging step forward. We are optimistic that this trial will replicate the very promising results seen in the previous studies in Venezuela. There is still significant unmet medical need in psoriasis and we are convinced that there is a substantial opportunity for a safe and effective new treatment."

The randomised double-blind, placebo-controlled US study will evaluate the safety and efficacy of repeated doses of Psoraxine in 120 patients with moderate to severe plaque psoriasis. Patients at 10 US sites will receive a course of six intramuscular injections, administered every two weeks, with an 8-week follow-up period and the trial will involve three dose levels in addition to a placebo control arm. The study will also examine specific immunological changes in order to further elucidate the mode of action of Psoraxine .

Through a service agreement, SkyePharma is providing development, manufacturing, pre-clinical and clinical development services to Astralis for a second generation version of Psoraxine , up to the completion of Phase II clinical studies. In the event that Phase II studies are successfully completed, Astralis will offer SkyePharma the option to acquire the worldwide licensing and distribution rights to Psoraxine . SkyePharma is a substantial investor in Astralis.

### **For further information please contact:**

#### **SkyePharma PLC**

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#### **About SkyePharma**

SkyePharma PLC 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](http://www.skyepharma.com).

#### **About psoriasis**

Psoriasis is a chronic, genetically linked skin disorder that affects approximately 2-3% of the world's population. For example, there are 7 million patients in the USA, with around 250,000 new cases diagnosed every year. The prevalence in Europe is similar. About 25% of patients are classified as moderate to severe, with over 10% of their body area affected. Psoriasis symptoms result from the overproduction of skin by epidermal cells induced by cells from the immune system. These blood cells over-stimulate the epidermis and act as though the skin was damaged, manufacturing skin cells at a much faster rate than is required by undamaged skin. The overproduction of skin cells can cause symptoms ranging from itchy rash-like patches to painful plaques or pustules, accompanied by massive inflammation.

Psoriasis is normally episodic, with patients experiencing flares of increasing severity followed by periods of remission. Disease severity in psoriasis is measured by the PASI (Psoriasis Area and Severity Index) score, based on subjective assessment by the patient and objective measurements by the clinician. The PASI score ranks from 0-72 with zero indicating symptom-free. The FDA hurdle for demonstrating the efficacy of psoriasis treatments is a 75% reduction in PASI score.

#### **About Psoraxine**

Psoraxine is a protein-based therapy that is believed to stimulate cells from the patient's immune system to reverse the

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inflammatory process responsible for psoriasis symptoms. Jose O'Daly MD, PhD, Chairman of the Board and Head of R&D for Astralis, is a Venezuelan parasitologist. While developing an improved vaccine for leishmaniasis, a parasitic infection transmitted by sandflies and endemic in much of South America, he noticed that vaccinated patients affected by psoriasis saw their symptoms resolve. The version of Psoraxine used in the clinical studies in Venezuela was based on a cellular extract from several species of the Leishmania parasite. Since 1992, nearly 3,000 patients have been treated with a course of injections in open-label studies. A clinically significant reduction in PASI score was reported for a great majority of the patients treated. The only significant side-effect in these studies was pain at the injection site. The second generation version of Psoraxine being used in the US trials is a purified protein fraction.

### **About Astralis**

Astralis Ltd, an emerging biotechnology company based in Fairfield, New Jersey, focuses on the research and development of novel treatments for immune system disorders and skin diseases. For further information visit [www.astralisltd.com](http://www.astralisltd.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.*

## **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: March 30, 2004