SKYEPHARMA PLC
Form 6-K
August 06, 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 August, 2004

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

6 August, 2004

SkyePharma's Partner Astralis Presents US Phase I Results for Novel Psoriasis Treatment

LONDON, UK, 6 August 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) welcomes the recent announcement by its partner Astralis Ltd (OTC Bulletin Board: ASTR) that Dr Jose O'Daly, the Chairman and Chief Executive of Astralis, is presenting the results of a Phase I clinical trial of Psoraxine(R) at the 2004 National Conference of the US National Psoriasis Foundation, being held on August 6-8 in San Diego, California. Psoraxine(R) is a novel injectable treatment for moderate psoriasis, a common chronic skin condition.

The US Phase I trial commenced in September 2003. The study, conducted in Princeton, New Jersey and Dallas, Texas, was a Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose-Ranging Study to evaluate the safety of Psoraxine(R). Administered via a single intramuscular injection, Psoraxine(R) was given to 21 patients (5 or 6 patients per treatment arm) with moderate and clinically stable plaque psoriasis. Psoraxine(R) was generally well tolerated in patients with active but stable plaque psoriasis, with similar safety profiles among patients who received single doses of placebo or Psoraxine(R) at doses of 50 mg, 150 mg, or 300 mg. None of the patients evaluated developed skin anergy to standard recall antigens during the study. Therefore the study provided preliminary evidence of a specific response to the Psoraxine(R) antigen, without the suppression of normal immunologic response to other common antigens.

The Phase I trial was primarily a safety study using a sub-optimal treatment regimen, and was not intended or expected to demonstrate efficacy. However efficacy trends were observed. The number of patients in the Psoraxine(R) groups that exhibited improvements in the total and partial PASI scores at Day 14 was greater than the number of patients in the placebo group. A decrease from baseline mean severity was observed in the Psoraxine(R) groups at Day 14 and an increase in severity observed in the placebo group. The score for itching also showed an improvement in the Psoraxine(R) groups as compared to the placebo group.

Michael Ashton, SkyePharma's Chief Executive, said: "The Phase I trial results are encouraging. Although we must caution that this was not an efficacy trial, we now look forward to the outcome of the ongoing Phase II trial for Psoraxine(R), which will provide the first efficacy data using a practical dosing schedule. We hope that this trial will replicate the very promising results seen in the previous studies of the first generation version 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."

A Phase II clinical trial of Psoraxine(R) commenced in April 2004. The primary objective of this trial is to evaluate the safety and efficacy of multiple administrations of Psoraxine(R) at three alternative dose levels, compared with placebo. The trial is also designed to detect and evaluate any specific immunological changes that may be induced by repeated exposure to Psoraxine(R) and to generate data towards a better understanding of the mechanism of action. A total of 120 patients at twelve clinical sites in the US will participate in the study. Under the trial protocol, each patient will receive a series of six intramuscular injections, once every two weeks for a total of 3 months, and subsequently will undergo evaluation for an additional two months without treatment. Patient enrolment is expected to be completed by the end of this month.

Through a service agreement, SkyePharma is providing development, manufacturing, pre-clinical and clinical development services to Astralis for the second generation version of Psoraxine(R), 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(R). SkyePharma is a substantial investor in Astralis.

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Notes for editors

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.

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(R)
Psoraxine(R) is a protein-based therapy that is believed to stimulate cells from the patient's immune system to reverse the inflammatory process responsible for psoriasis symptoms. Jose O'Daly MD, PhD, Chairman of the Board and Chief Executive of 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(R) 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(R) 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.

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: August 06, 2004