

SKYEPHARMA PLC  
Form 6-K  
September 02, 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

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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

2 September, 2003

**SkyePharma's DepoCyt®/DepoCyte®  
to be featured at major cancer conference**

LONDON, ENGLAND, 2 September, 2003 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces today that its cancer drug DepoCyt®/DepoCyte® will be the subject of a presentation at a conference, "Targetting Cancer Drugs - Advances In Compounds, Delivery Methods And Personalisation", to be held in London on 10-11 September. The presentation will be given on 11 September by Professor Stephen Howell of the University of California San Diego. Professor Howell, a consultant to SkyePharma, was instrumental in the development of DepoCyt®/DepoCyte®.

"Lymphomatous meningitis is a devastating complication of lymphoma that rapidly degrades the patient's quality of life," stated Professor Howell. "By slowly releasing an anticancer drug over a long period of time following injection, DepoCyt®/DepoCyte® markedly improves both the effectiveness and the ease of treatment."

Michael Ashton, SkyePharma's Chief Executive, said "We are proud to have worked with Professor Howell to develop a treatment for this dreaded condition. Our sustained-release delivery technology is the key to improved efficacy and greater convenience for the patient. DepoCyt® is already on the market in the US and our marketing partner Mundipharma is about to launch it in Europe."

DepoCyte® (known as DepoCyt® in the USA) is a sustained-release injectable formulation of cytarabine and is approved in both the USA and Europe for the treatment of lymphomatous meningitis, a serious late-stage complication of lymphoma, a form of cancer affecting the lymphatic system. Lymphomatous meningitis is a subset of neoplastic meningitis (see explanation below). Cytarabine is known to be an effective treatment for neoplastic meningitis but is rapidly metabolised and so patients require spinal (intrathecal) injections twice a week. SkyePharma's proprietary DepoFoam® delivery technology encapsulates cytarabine within minute lipid particles. After injection, these particles gradually degrade, prolonging the release of the drug and extending the period between injections to two weeks. This improves both the effectiveness of the treatment and the patient's quality of life; it also reduces the overall cost of treating this disease.

Lymphomatous meningitis is a comparatively uncommon condition with approximately 10,000 cases reported worldwide each year. Consequently DepoCyt® has been granted "Orphan Drug" status in the USA. SkyePharma is currently conducting a Phase IV study, the data from which will be submitted in applications to the FDA and EMEA to expand the treatment indication for DepoCyt®/DepoCyte® to neoplastic meningitis associated with solid tumours. This is a more common condition and would increase the number of patients eligible for treatment with DepoCyt®/DepoCyte® approximately threefold.

DepoCyt® was approved by the US Food & Drug Administration in April 1999 and is marketed in North America by Enzon Pharmaceuticals Inc. Rights in Japan were licensed to Nippon-Shinyaku in 2001 although the product is not yet on the market. DepoCyte® was approved by the European Medicines Evaluation Authority in August 2001. European marketing and distribution rights for DepoCyte® were recently licensed to Mundipharma International Holdings Limited ("Mundipharma") for most European and Eastern European countries.

## **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 neoplastic meningitis

In many forms of cancer, secondary tumours (metastases) form in the meninges, the membrane that surrounds the brain and spinal cord. From autopsy data, neoplastic meningitis affects up to 20% of all cancer patients (Posner, Neurological Complications of Cancer, 1995) but the condition is only diagnosed in 4-7% of cancer patients. The symptoms are pain and progressive neurological deterioration and few patients survive more than a few months, either from neurological dysfunction or from the primary tumour. The goal of therapy for neoplastic meningitis is palliation, not cure. The principal treatments are normally radiotherapy and chemotherapy to clear the cerebrospinal fluid of malignant cells and to prevent or slow recurrence. Most cytotoxic drugs do not cross the blood-brain barrier so the main chemotherapy treatments are methotrexate or cytarabine, injected intrathecally. These drugs reduce pain and slow neurological degradation but have the disadvantage of rapid clearance from the circulation and so require frequent injections.

#### About DepoFoam

DepoFoam is SkyePharma's proprietary sustained release injectable delivery technology. This is fully commercialised and approved by regulatory agencies in both the USA and Europe. DepoFoam consists of tiny lipid-based particles which contain discrete water-filled chambers dispersed through the lipid matrix. The particles are 10-30 microns in diameter and are suspended in saline. The suspension resembles skimmed milk and can be injected through a fine needle. The water-filled chambers containing active drug account for most of the weight of the particles. The lipids are naturally occurring substances (or close analogues) such as lecithin and triglycerides. The small amount of lipid is cleared rapidly in the body as the particles deliver their drug payload over a period that can be modified from 1 to 30 days. For example in DepoCyt®/DepoCyte® the circulating half-life of the drug cytarabine is increased from 3.4 hours to 141 hours.

#### About Professor Howell

Stephen Howell MD is Professor of Medicine at the University of California, San Diego (UCSD) and Program Leader of the Cancer Pharmacology Program at the Rebecca and John Moores UCSD Cancer Center. He is also Director of the Laboratory of Pharmacology and Director of the Clayton Foundation Drug Resistance Laboratory at the UCSD Cancer Center. Professor Howell was co-inventor of DepoFoam and a co-founder of DepoTech Inc. (acquired by SkyePharma in 2000). He is a consultant to SkyePharma and is also a member of the Scientific Advisory Board of Xenova Group plc.

*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 DepoCyt®/DepoCyte® and 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 DepoCyt®/DepoCyte®, 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:

##### **SkyePharma PLC**

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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: September 2, 2003