SKYEPHARMA PLC
Form 6-K
February 05, 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 February, 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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SKYEPHARMA'S PARTNER MUNDIPHARMA LAUNCHES DEPOCYTE IN EUROPE

LONDON, UK, 5 February 2004 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) and its marketing partner Mundipharma International Holdings Limited ("Mundipharma") today announce the European launch of DepoCyte®, a major advance in the treatment of lymphomatous meningitis. Mundipharma has exclusive marketing and distribution rights for this product for most European and Eastern European countries.

SkyePharma's chief executive officer, Michael Ashton, said: "Lymphomatous meningitis is both under-diagnosed and under-treated and DepoCyte® offers great potential to bring relief of suffering from this devastating complication of cancer."

Ake Wikstrom, European Regional Director for Mundipharma, said: "Through existing early experience of the product, physicians in Germany, Belgium and Spain have already witnessed the major benefits DepoCyte®can bring to patients. Mundipharma looks forward to contributing to the improved care of patients with lymphomatous meningitis across Europe through the launch of DepoCyte®."

DepoCyte® (marketed 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 it is rapidly metabolised. Patients therefore require spinal (intrathecal) injections every two days - these are uncomfortable for the patient and carry significant risks including the introduction of infection. SkyePharma's proprietary DepoFoam delivery technology encapsulates cytarabine in water solution within minute particles of lipid. After injection, these particles gradually degrade, prolonging the release of the drug and extending the period between injections to two weeks. This brings much less disruption to the life of the patient, reduces the associated risks accompanying frequent injections and also brings savings in hospital costs with the reduced admission rate. But perhaps most importantly, sustained maintenance of high levels of cytarabine in the cerebrospinal fluid may also prolong the time to neurological progression.

Lymphomatous meningitis is a comparatively uncommon condition with approximately 10,000 cases reported worldwide each year. Consequently DepoCyte® 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. 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. DepoCyte® is being launched to doctors at a pan-European symposium of the senior specialists in the field of lymphomatous meningitis (February 6-8).

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Notes for editors:

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, with death 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 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 Mundipharma

Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies; privately owned companies and joint ventures that cover the world's pharmaceutical markets. The companies have particular expertise in bringing to patients the benefits of novel drug delivery systems such as those used to enhance medicines for the relief of severe pain. For further information, visit www.mundipharma.co.uk.

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: February 5, 2004