SKYEPHARMA PLC
Form 6-K
April 28, 2006

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 April, 2006

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 **28 April, 2006**

SkyePharma PLC

SKYEPHARMA ANNOUNCES FIRST EUROPEAN

APPROVAL OF DEPODUR

Innovative Single Epidural Injection

48 Hours of Post-Surgical Pain Relief

LONDON, UK, 28 April 2006 -- SkyePharma PLC (LSE: SKP, Nasdaq: SKYE)) announces today that the UK Medicines and Healthcare products Regulatory Agency ("MHRA") has approved SkyePharma's DepoDur for the treatment of pain following major surgery. Previously referred to as DepoMorphine , DepoDur is a novel single dose sustained-release injectable formulation of morphine.

Frank Condella, Chief Executive of SkyePharma, said: "We are delighted with the approval of DepoDur in the UK and are confident that this will lead to additional approvals in other European markets under the Mutual Recognition Process DepoDur represents another successful outcome resulting from the major commitment SkyePharma has made to product development, including funding the product through Phase III trials and building and on-going funding of a purpose-built manufacturing plant in San Diego, USA. Our clinical trial programme for DepoDur involved over 1000 patients in four different pain models and demonstrated the great potential of the product to improve the control of post-operative pain.

"DepoDur was developed and is manufactured by SkyePharma Inc. the San Diego based injectable business, which SkyePharma has announced is in the process of being divested, "This approval, along with the availability of EU rights for DepoDur , provides further value to our injectable business."

DepoDur was licensed to Zeneus for distribution in the EU. Recently, SkyePharma bought back the rights to the product.

DepoDur is licensed to Endo Pharmaceuticals (Nasdaq: ENDP) for sale in the USA.

For further information please contact:

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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 twelve approved products incorporating SkyePharma's technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit www.skyepharma.com.

About DepoDur

DepoDur is a single dose extended-release injectable formulation of morphine sulphate. DepoDur employs

SkyePharma's proprietary DepoFoam technology and is supplied as a ready-to-use suspension. It is given as a single epidural injection before or during surgery and provides pain relief for up to 48 hours following surgery. There is no need for an in-dwelling catheter for continuous infusion, thereby overcoming a major drawback to the otherwise theoretically desirable epidural route of administration for opioid analgesics.

DepoDur is designed for the control of pain after major surgery. SkyePharma expects that its main use will be in control of post-operative pain in hospitalised patients undergoing major surgical procedures requiring general or regional anaesthesia such as major abdominal surgery, orthopaedic surgery and caesarean section. Currently there are an estimated 6 million such procedures every year in the USA and 5 million in Europe.

DepoDur is supplied in a 2 ml vial containing a 10 mg/ml suspension in sterile saline and is administered as a single dose epidural injection at the lumbar level prior to surgery (or after clamping of the umbilical cord during caesarean section). The recommended dose is 10 mg for caesarean section, 10-15 mg for lower abdominal surgery and 15 mg for major orthopaedic surgery of the lower extremities. Some patients may benefit from a dose of 20 mg. It should be appreciated that as with all opioids the incidence of serious adverse respiratory events is dose-related. Respiratory depression is the chief hazard of all opioid preparations and occurs more frequently in elderly or debilitated patients. For elderly patients (age >65 years), the low end of the dosing range for DepoDur is recommended together with vigilant peri-operative monitoring.

On 20 November 2003 SkyePharma submitted an application for DepoDur to the UK Medicines and Healthcare products Regulatory Agency ("MHRA"). Following national approval in the UK, SkyePharma now intends to seek approval in other European Union countries under the Mutual Recognition procedure. SkyePharma has licensed DepoDur to Endo for North America and is now seeking a partner for the product in the EU.

SkyePharma has completed seven clinical trials of DepoDur . The Phase IIb and Phase III clinical development programme for DepoDur involved four separate pain models and included more than 1000 patients. In the two Phase III trials, in hip surgery and lower abdominal surgery, DepoDur demonstrated extended dose-related analgesia and achieved its primary endpoint (superiority over study comparators in terms of total demand for opioid analgesics after surgery) with a high degree of statistical significance ($p < 0.0001$ and $p = 0.0003$, respectively). DepoDur also achieved statistical significance on several secondary endpoints. Importantly, statistical significance was achieved for the current pain intensity scores at rest and with activity over a 48 hour period and for the ratings of overall pain control.

In two related Phase IIb trials, DepoDur was significantly better than study comparators in the caesarean section study ($p = 0.0209$) and approached statistical significance in the knee arthroplasty study ($p = 0.0902$), which used a novel endpoint: time-weighted pain intensity recall score over 48 hours. DepoDur achieved a high degree of statistical significance in total demand for opioid analgesics after surgery ($p = 0.001$), a secondary endpoint in this trial but the primary endpoint in the three other studies.

In all four of these studies the safety profile of DepoDur was typical for an epidural opioid agent. As with all opioid preparations, respiratory depression is the chief hazard associated with DepoDur . The most common adverse events reported during clinical trials were decreased oxygen saturation, hypotension, urinary retention, vomiting, constipation, nausea, pruritus, pyrexia, anemia, headache and dizziness.

About DepoFoam

DepoFoam is SkyePharma's proprietary extended-release injectable delivery technology. This is fully commercialised and approved by regulatory agencies in both the USA and Europe. DepoFoam consists of lipid-based particles containing 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 phospholipids 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.

About post-operative pain

After a major surgical operation, the level of pain is usually very high for the first one to two days but the intensity of pain gradually subsides and by the end of the second day pain can normally be satisfactorily controlled with oral analgesics. For the immediate post-operative period, opioid analgesics like morphine (used alone or in combination with other non-opioid analgesics) are likely to remain the "gold standard" for relief of severe acute pain. However the relatively short duration of pain relief with opioids means that they require either continuous infusion or patient-controlled analgesia ("PCA") in which a pump delivers a series of doses of a short-acting opioid analgesic in response to the patient pressing a button (under computer control to prevent over-dosing). Both of these approaches require the patient to have an in-dwelling epidural or intravenous catheter. Such catheters can fall out or interfere with patient mobility and are a potential source of infections. Epidural catheters are also contra-indicated with concomitant use of anticoagulants because of the risk of bleeding in the spinal column that can potentially result in paralysis. There is a growing trend toward routine use of anticoagulants in patients undergoing orthopaedic surgery in order to prevent the formation of blood clots.

About the European licensing system for pharmaceuticals

The European system for the registration of medicinal products is based on three complementary procedures: National, Centralised and Mutual Recognition.

1. National procedure
Used to authorise medicinal products for local use in individual European Union ("EU") member states. National authorisation can form the basis for a subsequent application to other member states via the Mutual Recognition procedure.

2. Centralised procedure

Applications are submitted directly to the European Agency for the Evaluation of Medicinal Products ("EMEA"). Within the EMEA, the Committee for Proprietary Medicinal Products ("CPMP") appoints two member states to assess the documentation forwarded and prepare detailed evaluation reports to form the basis for evaluation by other members and consequent discussions in the CPMP. The time limit for the evaluation procedure is 210 days. The CPMP considers the completed assessment and delivers a favourable or unfavourable opinion as to whether to grant the authorisation. Marketing authorisation is valid throughout the EU and also in Norway, Iceland and Liechtenstein. The Centralised procedure is compulsory for medicinal products derived from biotechnology and optional for new active substances and other innovative medicinal products.

3. Mutual Recognition procedure

Allows a pharmaceutical company that has obtained a National marketing authorisation in one EU member state to apply to one or more other member states to recognise the product. If the original National marketing authorisation cannot be mutually recognised by another member state, the points in dispute are referred to the CPMP for arbitration. A CPMP decision is binding on all member states.

Certain statements in this news release are forward-looking statements and are made in reliance on the safe harbour provisions of the U.S. Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that these expectations will materialize. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward-looking statements based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. Factors that could cause differences between actual results and those implied by the forward-looking statements contained in this news release include, without limitation, risks related to the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new

products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to SkyePharma's ability to manage growth. 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: April 28, 2006