SKYEPHARMA PLC
Form 6-K
May 07, 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 May, 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
7 May 2004

SkyePharma PLC

DEPOMORPHINE CLINICAL TRIAL DATA PRESENTED AT AMERICAN PAIN SOCIETY MEETING

LONDON, UK, 7 May 2004 -- SkyePharma PLC (LSE: SKP, Nasdaq: SKYE) today announces that data from the clinical trials of DepoMorphine , its novel sustained-release injectable formulation of morphine for control of moderate-to-severe post-operative pain, is being presented through posters at the 2004 annual meeting of the American Pain Society, taking place in Vancouver 6-9 May. SkyePharma has licensed DepoMorphine to Endo Pharmaceuticals for North America and to Medeus Pharma for Europe. DepoMorphine was filed with the US Food & Drug Administration ("FDA") in July 2003 and with the European regulatory agencies in December 2003.
Michael Ashton, Chief Executive of SkyePharma, said: "Our clinical trial programme for DepoMorphine involved over 1000 patients in four different pain models. The data presented at the American Pain Society demonstrates the great potential of DepoMorphine to improve the control of post-operative pajn. We and our partners look forward to the benefits this product will bring for many patients after surgery."

The four posters being presented are as follows:

"A Novel, Single-Dose, Long-Acting, Epidural Morphine Provides Up To 48 Hours Of Pain Relief After Abdominal Surgery"
Authors: D. Gambling (Sharp Mary Birch Hospital for Women, San Diego, California), T. Hughes (Woodland Memorial Hospital, Woodland, California), G. Martin (Dept of Anesthesiology, Duke University Medical Center, North Carolina), G. Manvelian (SkyePharma)

"Encapsulated Epidural Morphine Provides Up To 48 Hours Of Postoperative Pain Relief After Total Hip Arthroplasty"
Authors: E. Viscusi (Dept of Anesthesiology, Thomas Jefferson Hospital, Philadelphia, Pennsylvania), G. Martin (Dept of Anesthesiology, Duke University Medical Center, Durham, North Carolina), C. Hartrick (Dept of Anesthesia, William Beaumont Hospital, Royal Oak, Michigan), N. Singla (Dept of Anesthesia, Huntington Memorial Hospital, Pasadena, California), G. Manvelian (SkyePharma)

"Evaluation Of A Novel, Encapsulated, Epidural Morphine For Pain Control After Elective Knee Arthroplasty"
Authors: C. Hartrick (Dept of Anesthesia, William Beaumont Hospital, Royal Oak, Michigan), G. Martin (Dept of Anesthesiology, Duke University Medical Center, Durham, North Carolina), G. Kantor (Palm Beach Gardens Medical Center, Palm Beach Gardens, Florida), G. Manvelian (SkyePharma)

"Improved Postoperative Pain Control Following Elective C-Section With A Single-Dose, Encapsulated, Epidural Morphine"
Authors: B. Carvalho (Dept of Anesthesia, Stanford University School of Medicine, Stanford, California), E. Riley (Dept of Anesthesia, Stanford University School of Medicine, Stanford, California), G. Manvelian (SkyePharma)

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Notes for editors:

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 ten 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 DepoMorphine
DepoMorphine is a sustained-release injectable formulation of morphine sulphate. DepoMorphine 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 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.

DepoMorphine is designed for the control of moderate-to-severe post-operative pain. 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.

On 16 September 2003 the US Food & Drug Administration ("FDA") formally accepted for filing a New Drug Application ("NDA") for DepoMorphine . The FDA is due to make its initial response in May. On 20 November 2003 SkyePharma submitted an application to the UK Medicines and Healthcare products Regulatory Agency ("MHRA"). After national approval in the UK, SkyePharma intends to seek approval in other European Union countries under the Mutual Recognition procedure.

SkyePharma has completed seven clinical trials of DepoMorphine . The Phase IIb and Phase III clinical development programme for DepoMorphine involved four separate pain models and included more than 1000 patients. In the two Phase III trials, in hip surgery and lower abdominal surgery, DepoMorphine demonstrated sustained 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). DepoMorphine 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, DepoMorphine 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. DepoMorphine 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 DepoMorphine was typical for an epidural opioid agent.

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 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. For example in DepoCyt®/DepoCyte® the circulating half-life of the drug cytarabine is increased from 3.4 hours to 141 hours.

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.

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.

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: May 7, 2004