SKYEPHARMA PLC
Form 6-K
April 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 April, 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 April, 2004**

SkyePharma to Receive Milestone Payment

from Endo for Propofol IDD-D™
Phase III trials to start by mid-year

LONDON, ENGLAND, 7 April, 2004 -- SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces today that it has successfully completed the review of the Phase II trial results of Propofol IDD-D™ with the US Food & Drug Administration ("FDA"). Propofol IDD-D™ is licensed in North America to Endo Pharmaceuticals ("Endo", Nasdaq: ENDP) and, under the terms of the December 2002 agreement as amended between SkyePharma and Endo, a US$5 million milestone payment to SkyePharma is now due.

SkyePharma and Endo have agreed upon the Phase III trial programme and expect Propofol IDD-D™ to commence Phase III trials around the middle of this year.

Propofol IDD-D™ is a 2% intravenous formulation of propofol as the sole active ingredient and employs SkyePharma's patented Insoluble Drug Delivery(IDD-D™) technology. In contrast with currently marketed versions of propofol, SkyePharma believes that Propofol IDD-D™ will not support significant microbial growth and therefore will not require incorporation of a preservative. Propofol IDD-D™ is intended for the maintenance of anaesthesia in adults during surgery and for sedation of adults hospitalized in an intensive-care setting.

Propofol IDD-D™ has been studied in a Phase II clinical trial. The study, involving 79 female patients undergoing laparoscopic gynaecological surgery, was designed to show clinical effect of Propofol IDD-D™ versus AstraZeneca's Diprivan, a currently marketed version of 1% propofol. The study results provided evidence of comparable pharmacokinetics, efficacy and safety of the two formulations which will need to be confirmed in phase III trials.

For further information please contact:

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Tim Anderson / Mark Court

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 propofol
Propofol is a widely-used intravenous anaesthetic and sedative, supplied as a 1% injectable emulsion. It is used for induction of short-term anesthesia (typically 30-60 minutes) or, at a lower dose, for sedation. Originally introduced as AstraZeneca's Diprivan, the patent has now expired and there are now several generic versions of propofol on the market in Europe and one in the USA. The world market for propofol was worth in excess of US$700 million in 2003, of which Diprivan accounted for about US$450 million.

About Propofol IDD-D™

Propofol IDD-D™ is SkyePharma's proprietary phospholipid-stabilised 2% oil-in-water emulsion of propofol. The designation "IDD-D™" stands for " Insoluble Drug Delivery - Droplet", one of a family of SkyePharma technologies for the formulation of water-insoluble drugs. The 2% formulation reduces the lipid load and volume of fluid administered to the patient compared with currently-marketed 1% formulations. Importantly the formulation used in Propofol IDD-D™ has been designed not to support the growth of a wide range of micro organisms. In contrast with existing propofol products (such as Diprivan and generic versions of this product), Propofol IDD-D™ does not need to contain preservatives like EDTA (which can cause zinc depletion) or metabisulphite (which can cause allergic reactions). Despite the incorporation of these preservatives, current versions of propofol can only be used within 6 hours after opening a vial because of the risk of microbial contamination. The enhanced antimicrobial protection in Propofol IDD-D™ may allow for a longer "hang-time" in the Intensive Care Unit and provide potential use as a multi-dose vial in anaesthesia. This could bring advantages for the hospital such as reduced nursing time, less wastage of propofol active ingredient and no need for regular replacement of expensive disposables and tubing sets. Propofol IDD-D™ is truly unique and is not a generic version of Diprivan.

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: April 07, 2004