SKYEPHARMA PLC
Form 6-K
October 04, 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 October, 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 4 October, 2006

SkyePharma PLC

SkyePharma Reports Positive Phase III and EU Filing for Lodotra

LONDON, ENGLAND, 4 October, 2006 -- SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) today announces positive results of a Phase III clinical trial for Lodotra , a new, modified-release tablet that has been developed in partnership with Nitec Pharma to optimize the efficacy of orally administered low-dose prednisone in Rheumatoid Arthritis (RA). Lodotra uses SkyePharma's proprietary GEOCLOCK technology and has been filed with regulatory authorities in August by Nitec Pharma AG, which is a specialist pharmaceutical company focused on the treatment of chronic inflammatory diseases.

Lodotra provides all the benefits of standard immediate release (IR) prednisone but has the additional, clinically important advantage of significantly reducing morning symptoms combined with a convenient dosing regimen.

The diurnal rhythm in RA is characterised by elevated night time levels of inflammatory cytokines such as IL6, which leads to extreme stiffness and pain in the hours immediately after waking. It has been established that these morning symptoms can be addressed with prednisone administered at 2am. However, until now this has been impossible without disturbing sleep. Lodotra is an oral medication that has a unique delivery system ensuring rapid release of the prednisone from the tablet core about 4 hours after ingestion. Administration of Lodotra at bed time results in a release of prednisone at about 2am for a more effective treatment of the morning symptoms of RA.

The trial involved 288 patients in 26 centres in Europe, and was a randomized, double-blind, active-controlled, parallel-group Phase III study. The study compared the efficacy and safety of Lodotra given to patients before sleep the evening before, with standard immediate-release (IR) prednisone (following the current recommended regimen where prednisone is administered in the morning at 8am) over a period of 12 weeks. The duration of morning stiffness (the primary clinical endpoint of the study) was significantly reduced in the Lodotra group while under standard IR prednisone no change in morning stiffness was shown. In half the patients a reduction of more than one hour or one third was observed and those patients also showed a reduction in pain of one third. Lodotra was also shown to be well tolerated and just as safe as the standard regimen. Importantly, IL6 levels were shown to be reduced in the Lodotra group but remained constant in the standard prednisone group indicating that this reformulation of prednisone was exerting a specific inhibitory action on what is thought to be a key biological marker of the inflammatory process in RA.

Frank Condella, CEO, SkyePharma said:
"We are extremely pleased with this validation of our GEOCLOCK technology in this area of high unmet need, through these successful Phase III trials and the filing in the EU. Lodotra should be the first commercial exploitation of our GEOCLOCK technology which has the potential to be applied across a wide range of therapeutic needs."

Prof. Frank Buttgereit, Charite Berlin; principal investigator in the study commented:
"These results confirm the hypothesis that the adaptation of the timing of oral glucocorticoids to the circadian rhythms in RA could lead to a more effective therapy without increasing the dose of prednisone. The benefit of Lodotra results in a clinically relevant reduction of morning stiffness added to all known therapeutic effects of IR prednisone. The new administration mode is also convenient for the patient and was well tolerated."

Jochen Mattis, co-founder and Head of Marketing of Nitec Pharma said:
"We are delighted to have such positive results in a Phase III trial and have already submitted a dossier for marketing authorisation in Europe in August. We also plan to seek marketing authorisation for North America and the Far East. We

will also be seeking marketing partners to realise the commercial value of Lodotra worldwide, in addition to the agreement we already have with Merck KGaA in Germany and Austria."

Lodotra has originally been developed through a partnership between SkyePharma and Merck KGaA until 2004 when Nitec Pharma was spun out of Merck.

For further information please contact:

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Tim Anderson / Mark Court / Rebecca Skye Dietrich

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 Nitec Pharma AG
Nitec Pharma is a specialist pharmaceutical company created in 2004 in a spin out from Merck KGaA, financed by Atlas Venture and Global Life Science Ventures. Lodotra was originally developed by Merck in cooperation with SkyePharma using SkyePharma's proprietary GEOCLOCK technology.

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: October 4, 2006