

SKYEPHARMA PLC  
Form 6-K  
October 24, 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

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(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

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(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  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

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 PLC

### FDA accepts New Drug Application for zileuton CR

LONDON, ENGLAND, 24 October, 2006 -- SkyePharma PLC (LSE: SKP; NASDAQ: SKYE) today announces that Critical Therapeutics, Inc (NASDAQ: CRTX) has recently received acceptance from the FDA for its New Drug Application (NDA) for the twice-daily, controlled-release formulation of zileuton (zileuton CR).

Zileuton CR is an investigational drug developed for the prevention and chronic treatment of asthma in adults and children 12 years of age and older. Critical Therapeutics (CRTX) submitted the NDA in late July and, pending regulatory approval, expects to launch zileuton CR in the second half of 2007. The anticipated PDUFA date is 31 May 2007.

#### Frank Condella, CEO, SkyePharma said:

"This is another important step in a successful collaboration and continued validation of our Geomatrix™ technology. We look forward to the product reaching the market, which we hope will begin to generate revenue in the next 12 months."

#### 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 eleven 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](http://www.skyepharma.com).

#### About Critical Therapeutics

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Critical Therapeutics, Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of products for respiratory, inflammatory and critical care diseases. The Company owns worldwide rights to the asthma drug ZYFLO(R) (zileuton tablets), as well as other formulations of zileuton. ZYFLO is the only 5-lipoxygenase inhibitor approved for marketing by the U.S. Food and Drug Administration. The Company's commercialization efforts for ZYFLO are carried out by its specialty sales force. Critical Therapeutics also is developing treatments directed toward the severe inflammatory response in acute diseases and conditions that lead to admission to the emergency room or intensive care unit, and acute exacerbations of other chronic diseases that frequently lead to hospitalization. For more information, please visit [www.crtx.com](http://www.crtx.com).

### **About zileuton**

Zileuton is a highly potent oral anti-inflammatory drug. It works by inhibiting the enzyme 5-lipoxygenase. This enzyme, which is involved in the formation of leukotrienes, is a key part of the inflammatory cascade that follows allergic challenge. Inhibition of this enzyme therefore helps minimize bronchoconstriction and mucus secretion in asthma. In its pivotal trials in adult asthma, zileuton was shown to bring the greatest benefit to those with the most severe disease. Zileuton is not intended for acute relief of asthma symptoms but chronic treatment with zileuton allows reduction of other therapies such as oral steroids which have undesirable side-effects.

*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

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Name: Douglas Parkhill

Title: Company Secretary

Date: October 24, 2006