

SKYEPHARMA PLC  
Form 6-K  
May 31, 2007

**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, 2007

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  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-

---

**TWICE DAILY ZYFLO CR (ZILEUTON) EXTENDED-RELEASE TABLETS APPROVED BY  
THE FDA FOR ASTHMA**

## Edgar Filing: SKYEPHARMA PLC - Form 6-K

LONDON, UK, Thursday, May 31, 2007 - **SkyePharma PLC (LSE: SKP)** today announces that the U.S. Food and Drug Administration (FDA) has approved Critical Therapeutics, Inc.'s (Nasdaq: CRTX) New Drug Application (NDA) for twice-daily ZYFLO CR (zileuton) extended-release tablets. ZYFLO CR uses SkyePharma PLC's proprietary Geomatrix® drug delivery technology, which controls the amount and rate of drug released into the body.

ZYFLO CR and ZYFLO® (zileuton tablets) are the only FDA-approved leukotriene synthesis inhibitors for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO CR and ZYFLO are not indicated for use in the reversal of bronchospasm in acute asthma attacks, but can be continued during acute exacerbations of asthma. Leukotrienes are inflammatory mediators in asthma that can trigger asthma symptoms, including inflammation, swelling, bronchoconstriction and mucus secretion. Critical Therapeutics expects to begin marketing ZYFLO CR in the U.S. together with its co-promotion partner, Dey, L.P. (DEY) in the autumn of 2007.

Frank Condella, Chief Executive Officer of SkyePharma, said: "The approval of ZYFLO CR is another successful application of our Geomatrix oral controlled-release technology. We continue our focus on oral and inhalation products as we build our business moving forward."

Upon the launch of ZYFLO CR, Critical Therapeutics and DEY's combined sales force of 240 representatives will begin promoting ZYFLO CR to approximately 15,000 allergists, pulmonologists and primary care physicians across the U.S. SkyePharma will receive a high mid single digit royalty on sales of ZYFLO CR.

### **For further information please contact:**

|                                   |   |                  |
|-----------------------------------|---|------------------|
| SkyePharma PLC                    | Frank Condella<br>Ken Cunningham<br>Peter Grant | +44 20 7491 1777 |
| Financial Dynamics (UK Enquiries) | David Yates<br>Deborah Scott                    | +44 20 7831 3113 |
| Trout Group (US Enquiries)        | Christine Labaree<br>Seth Lewis                 | +1 617 583 1308  |

### **About SkyePharma PLC**

Using its proprietary drug delivery technologies, SkyePharma develops new formulations of known molecules to provide a clinical advantage and life-cycle extension. The Company has eleven approved products in the areas of oral, inhalation and topical delivery that are marketed throughout the world by leading pharmaceutical companies.

For more information, visit [www.skyepharma.com](http://www.skyepharma.com)

### **About ZYFLO CR and ZYFLO**

ZYFLO CR and ZYFLO are the only FDA-approved leukotriene synthesis inhibitors for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. ZYFLO CR and ZYFLO are not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with ZYFLO CR and ZYFLO CR can be continued during acute exacerbations of asthma.

The recommended dose of ZYFLO CR is two 600 mg extended-release tablets twice

## Edgar Filing: SKYEPHARMA PLC - Form 6-K

daily, within one hour after morning and evening meals, for a total daily dose of 2400 mg. The recommended dose of ZYFLO is one 600 mg immediate-release tablet four times a day for a total daily dose of 2400 mg.

ZYFLO CR and ZYFLO are contraindicated in patients with active liver disease or transaminase elevations greater than or equal to three times the upper limit of normal. A small percentage of patients treated with ZYFLO CR (2.5%) and ZYFLO (1.9%) in placebo-controlled trials showed an increased release of a liver enzyme known as ALT and bilirubin (an orange or yellowish pigment in bile). As a result, the level of liver enzymes in patients treated with ZYFLO CR and ZYFLO should be measured by a simple blood test. It is recommended that physicians perform this test before administering ZYFLO CR and ZYFLO and repeat the test on a regular basis while patients are on the medication. Patients taking ZYFLO CR and theophylline should reduce the theophylline dose by 50%. Patients taking ZYFLO CR and propranolol or warfarin should be monitored and doses adjusted as appropriate. Most common side effects associated with the use of ZYFLO CR and ZYFLO are sinusitis, nausea and pharyngolaryngeal pain and abdominal pain, upset stomach and nausea, respectively.

For full prescribing information for ZYFLO CR, please visit [www.zyflocr.com](http://www.zyflocr.com) or call Critical Therapeutics at +1-866-835-8216 to request medical information.

For full prescribing information for ZYFLO, please visit [www.zyflo.com](http://www.zyflo.com) or call +1-866-835-8216 to request medical information.

ZYFLO® and ZYFLO CR are trademarks of Critical Therapeutics, Inc. Geomatrix® is a registered trademark of SkyePharma PLC.

### 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/ John Murphy

Name: John Murphy  
Title: Company Secretary

Date: May 31, 2007