SKYEPHARMA PLC
Form 6-K
June 20, 2005

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 June, 2005

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-
_____

FOR IMMEDIATE RELEASE
20 June 2005

SkyePharma PLC

Foradil® Certihaler Approved in Germany

LONDON, UK, 20 June 2005 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces today that the German pharmaceutical regulatory authority has approved FORADIL® CERTIHALER (formoterol fumarate inhalation powder) for the treatment of asthma and chronic obstructive pulmonary disease ("COPD"). FORADIL® CERTIHALER was co-developed by SkyePharma PLC and Novartis Pharma AG. FORADIL® CERTIHALER is a trademark of Novartis. FORADIL® CERTIHALER was submitted for regulatory review in Europe on a country-by-country basis beginning in December 2002 and has now been approved in Switzerland, Austria, Finland, Portugal and the Netherlands as well as in Germany. It has also been approved in five countries in Latin America. FORADIL® CERTIHALER was also submitted for regulatory review in the US in December 2002. The US Food and Drug Administration (FDA) has assessed the product as approvable and Novartis is preparing to provide the agency with additional data that were requested. The US Foradil® franchise has been licensed by Novartis to Schering-Plough Corporation.

Michael Ashton, SkyePharma's Chief Executive Officer, commented: "The sixth European approval for FORADIL® CERTIHALER is a further milestone in the validation of our pulmonary delivery technologies - already recognised by other unrelated collaborations in the pulmonary area with major pharmaceutical companies such as AstraZeneca and GlaxoSmithKline. We are now manufacturing launch material for our partner and look forward to the initiation of commercial sales."

FORADIL® CERTIHALER embodies two proprietary SkyePharma technologies, the SKYEHALER , a novel breath-actuated multi-dose dry powder inhaler ("MDDPI") device, and SKYEPROTECT , a powder formulation that protects the drug from atmospheric moisture to ensure product stability and dose-to-dose reproducibility.

Formoterol, the active ingredient in FORADIL® CERTIHALER , is a long-acting beta2-agonist bronchodilator that combines a rapid onset of action (within 5 minutes) with a long-lasting bronchodilation effect for 12 hours. This feature offers important benefits for patients who suffer from asthma and COPD. A major independent study published in October 2003 in the European Respiratory Journal(1) showed that formoterol (delivered by an alternative device) was superior to the widely-used short-acting bronchodilator salbutamol in relief of asthma symptoms under real-life conditions. The breath-actuated FORADIL® CERTIHALER dry-powder inhaler contains 60 doses, giving patients the convenience of 30 days of therapy in a single inhaler. This evolution of the FORADIL® line was developed to provide a valuable and convenient option for asthma and COPD patients who require maintenance therapy with a long-acting bronchodilator.

SkyePharma will earn a royalty on future sales of FORADIL® CERTIHALER in all markets. SkyePharma will also manufacture and supply FORADIL® CERTIHALER .

1 "Formoterol as relief medication in asthma: a worldwide safety and effectiveness trial", Pauwels et al., European Respiratory Journal 2003; 22: 787-794

For further information please contact:

SkyePharma PLC **+44 207 491 1777**
Michael Ashton, Chief Executive Officer
Peter Laing, Director of Corporate Communications **+44 205 491 5124**

Sandra Haughton, US Investor Relations **+1 212 753 5780**

Buchanan Communications **+44 207 466 5000**
Tim Anderson / Mark Court

Notes to 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 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.

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: June 20, 2005