

SKYEPHARMA PLC
Form 6-K
May 09, 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 May, 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 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-

For immediate release

SKYEPHARMA RECEIVES FDA APPROVAL FOR TRIGLIDE

9 May 2005

A NOVEL FORMULATION OF FENOFIBRATE

LONDON, UK, 9 May 2005 -- SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announces today that the US Food and Drug Administration ("FDA") has approved Triglide , its novel formulation of fenofibrate. This approval will trigger a \$15 million milestone payment from our partner First Horizon Pharmaceutical Corporation ("First Horizon", Nasdaq: FHRX).

In May 2004, SkyePharma announced that it had granted First Horizon exclusive U.S. marketing and distribution rights for a cardiovascular product (now identified as fenofibrate IDD®-P). Under this agreement, SkyePharma will receive up to \$50 million in milestone payments, \$30 million of which are sales-based milestone payments. In addition SkyePharma will receive 25% of First Horizon's net sales of the product. \$5 million was paid to SkyePharma upon signature of the agreement. SkyePharma will manufacture and supply the product from its Lyon manufacturing facility. SkyePharma will also make a contribution of up to \$5 million to First Horizon's initial marketing expenses to establish the product.

Michael Ashton, SkyePharma's Chief Executive Officer, said: 'We are delighted with the approval of Triglide . This approval further reinforces our strategy to improve quality of earnings via increased royalties. We are confident that First Horizon's 400-strong representative force with their focus on cardiovascular physicians and high-prescribing primary care practitioners will be able to successfully create a substantial franchise in this therapeutic area.'

Fenofibrate is an oral treatment for lipid disorders such as elevated cholesterol and triglycerides. The main drawback of fenofibrate is insolubility in water, resulting in variable uptake from the stomach and requiring the patient to take the tablets with food. Triglide the new formulation developed by SkyePharma, has a comparable absorption under fed and fasting conditions and therefore allows patients to take the drug at any time, improving compliance and simplicity for both patients and prescribers. This represents the first approval for a product utilizing SkyePharma's solubilization IDD®-P technology.

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 ten 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.

For further information please contact:

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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, SkyePharma's marketing partners' ability to market a pharmaceutical product on a large scale and manage their sales and marketing organisation 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

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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: May 9, 2005