

SKYEPHARMA PLC  
Form 6-K  
December 02, 2003

**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 December, 2003

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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**For Immediate Release**

**2 December, 2003**

**SKYEPHARMA PLANS JOINT DEVELOPMENT WITH NOVARTIS OF NEW PRODUCT FOR**

## TREATMENT OF ASTHMA AND COPD

LONDON, UK, 2 December 2003 -- SkyePharma PLC (LSE: SKP, Nasdaq: SKYE) today announced an agreement with Novartis Pharma AG to jointly develop a new product for the treatment of asthma and chronic obstructive pulmonary disease (COPD). The product will combine Novartis' novel long-acting bronchodilator QAB149 with two SkyePharma technologies:

- SkyeHaler<sup>®</sup>, a breath-activated multi-dose dry powder inhaler (MDDPI) device, to be marketed by Novartis as the Certihaler
- SkyeProtect<sup>®</sup>, a powder formulation that protects the drug from atmospheric moisture to ensure product stability and dose-to-dose reproducibility

The product has already successfully completed a technical feasibility study at SkyePharma. Novartis will make an initial payment to SkyePharma on signature of the agreement. If the co-development project progresses successfully, Novartis will also make future payments on attainment of development milestones and will pay SkyePharma royalties on eventual sales.

Michael Ashton, chief executive of SkyePharma, said: "We are delighted by the decision of Novartis to select our formulation expertise and SkyeHaler<sup>®</sup> technology for this exciting new compound. This agreement further confirms our position as a leader in the development of products for the important and fast-growing respiratory market."

Patients with asthma and COPD use bronchodilators to open the airways in the lung, thereby improving their ability to breathe. Most bronchodilators are short-acting but in recent years long-acting bronchodilators have been introduced that have an extended duration of action and only need to be taken twice a day. QAB149 is a long-acting bronchodilator that is currently in Phase II trials for asthma. QAB149 was reviewed at the Novartis R&D Day on 19 November 2003 (for details, see [www.novartis.com](http://www.novartis.com) and use the internal search tool for QAB149).

An agreement has already been made to use SkyePharma MDDPI and formulation technology with Novartis' long-acting bronchodilator Foradil<sup>®</sup> (formoterol fumarate). Foradil<sup>®</sup> Certihaler<sup>®</sup> was co-developed by SkyePharma and Novartis and was submitted for regulatory review in the US and Europe in December 2002. In October 2003 the US Food and Drug Administration (FDA) issued an "approvable" letter for Foradil<sup>®</sup> Certihaler<sup>®</sup>, meaning that the product can be approved by the FDA subject to resolution of certain outstanding issues.

**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 nine approved products incorporating three of SkyePharma's five 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).

*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, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization 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.*

**For further information please contact:**

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END

**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: December 2, 2003