

ASTRAZENECA PLC  
Form 6-K  
March 11, 2003

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For March, 2003

Commission File Number: 001-11960

**AstraZeneca PLC**

15 Stanhope Gate, London W1K 1LN, England

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

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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**AstraZeneca PLC**

INDEX TO EXHIBITS

1. Press release entitled, “AstraZeneca submits Iressa™ (gefitinib, ZD1839) for approval in Europe for advanced non-small cell lung cancer” dated 11 February 2003.
2. Press release entitled, “AstraZeneca submits information amendment for Crestor® (rosuvastatin calcium) NDA to FDA” dated 13 February 2003.
3. Press release entitled “Results of Exanta™ (ximelagatran) trial in prevention of stroke in atrial fibrillation (Sportif III) to be presented at ACC meeting” dated 17 February 2003.
4. Press release entitled “Research Update on AZD3582” dated 18 February 2003.
5. Press release entitled “AstraZeneca’s New Statin, Crestor™, receives approval in Canada – Company intends immediate launch” dated 19 February 2003.
6. Press release entitled “Repurchase of Shares in AstraZeneca PLC” dated 26 February 2003.
7. Press release entitled “AstraZeneca Issues 2002 Annual Report” dated 27 February 2003.

**Item 1**

**ASTRAZENECA SUBMITS IRESSA™ (gefitinib, ZD1839)  
FOR APPROVAL IN EUROPE FOR  
ADVANCED NON-SMALL CELL LUNG CANCER**

AstraZeneca announced today the submission in Europe of a Marketing Authorisation Application for IRESSA™ (gefitinib, ZD1839) for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients previously treated with platinum-based and docetaxel chemotherapy.

IRESSA is the first in a new class of anti-cancer drugs known as Epidermal Growth Factor Receptor (EGFR) inhibitors and was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of inoperable or recurrent NSCLC in July 2002. Sales for IRESSA in 2002 totalled \$67 million.

The submission for IRESSA in Europe is based on data from two Phase II trials, IDEAL 1 and IDEAL 2 (IRESSA Dose Evaluation in Advance Lung Cancer). These data confirmed that IRESSA 250mg per day monotherapy provides clinically-significant anti-tumour activity in patients with previously treated advanced NSCLC. Results also provided further confirmation of IRESSA's favourable safety profile, with the majority of side effects (diarrhoea and skin rash) reported as mild and reversible. Final results from these trials were presented internationally in September, 2002.

In the year 2000, there were approximately 370,000 new cases of lung cancer in Europe and more than 340,000 deaths from the disease. Only one in every 10 people with lung cancer is alive five years after diagnosis. The market for NSCLC is valued at \$1.6 billion, and is forecast to grow to \$8 billion by 2011.

The IRESSA submission today follows the submission (4 February) of the European Marketing Authorisation Application for the use of FASLODEX™ (fulvestrant) in the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following prior endocrine therapy.

AstraZeneca continues its tradition of research excellence and innovation in oncology that led to the development of its current anti-cancer therapies including ARIMIDEX, CASODEX, FASLODEX, NOLVADEX, TOMUDEX and ZOLADEX, as well as a range of novel targeted products such as anti-proliferatives, anti-angiogenics, vascular targeting and anti-invasive agents. AstraZeneca is also harnessing rational drug design technologies to develop new compounds that offer advantages over current cytotoxic and hormonal treatment options. The company has over 20 different anti-cancer projects in research and development.

AstraZeneca is a major international healthcare business engaged in the research, development, manufacture and marketing of prescription pharmaceuticals and the supply of healthcare services. It is one of the top five pharmaceutical companies in the world with healthcare sales of over \$17.8 billion and leading positions in sales of oncology, gastrointestinal, anaesthesia (including pain management), cardiovascular, central nervous system (CNS) and respiratory products.

IRESSA™, ARIMIDEX, CASODEX, FASLODEX, NOLVADEX, TOMUDEX and ZOLADEX are trademarks of the AstraZeneca group of companies.

11 February 2003

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**Item 2**

**AstraZeneca Submits Information Amendment  
For CRESTOR® (rosuvastatin calcium) NDA to FDA**

AstraZeneca announced today the submission of an information amendment to its New Drug Application (NDA) for CRESTOR® (rosuvastatin calcium) Tablets in response to the US Food and Drug Administration (FDA) approvable letter of May 2002.

The additional data provide further support for the proposed use of CRESTOR® Tablets for the treatment of patients for the management of hypercholesterolaemia, mixed dyslipidaemia and isolated hypertriglyceridaemia.

13 February 2003

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**Item 3**

**RESULTS OF EXANTA™ (ximelagatran) TRIAL IN PREVENTION  
OF STROKE IN ATRIAL FIBRILLATION (SPORTIF III)  
TO BE PRESENTED AT ACC MEETING**

AstraZeneca announced today that headline results of the recently completed SPORTIF III (Stroke Prevention Oral Thrombin Inhibitor in Atrial Fibrillation) trial comparing Exanta™ (ximelagatran), with warfarin, the current standard of care, are encouraging. The data support the emerging positive benefit / risk profile for Exanta in this indication and will be presented in the Late-Breaking Clinical Trial section of the American College of Cardiology (ACC) meeting in Chicago on 2 April 2003.

The Exanta regulatory submission for prevention of stroke in atrial fibrillation, which remains on track in Europe and the US, also includes SPORTIF V and other trials in the extensive clinical trial programme.

Exanta is set to be the first new fixed-dose oral anticoagulant since the introduction of warfarin over 50 years ago and is currently being investigated in an extensive clinical trials programme for a number of key indications.

Exanta is a trademark, property of the AstraZeneca Group of Companies

17 February 2003

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**Item 4**

**RESEARCH UPDATE ON AZD3582**

AstraZeneca and NicOx today announced that AZD3582, in development for the treatment of acute and chronic nociceptive pain, showed efficacy in a recently completed Phase II clinical study, but did not reach its primary end point with respect to gastro-intestinal ulcers.

The majority of the secondary objectives, including protection against gastro-intestinal damage (when ulcers and erosions are combined), were achieved and overall AZD3582 was well tolerated.

AstraZeneca remains committed to the completion of the ongoing AZD3582 Phase II development programme.

AstraZeneca, together with NicOx, will review the data generated from the several ongoing AZD3582 Phase II clinical studies in the programme in order to decide on the further development plans for AZD3582 and the CINOD class.

18 February 2003

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**Item 5**

**ASTRAZENECA'S NEW STATIN, CRESTOR™, RECEIVES  
APPROVAL IN CANADA – COMPANY INTENDS  
IMMEDIATE LAUNCH**

AstraZeneca announced today it has received approval for CRESTOR™ (rosuvastatin) 10-40 mg from the Therapeutic Products Directorate of Health Canada for the management of primary hypercholesterolaemia, mixed dyslipidaemia, and familial hypercholesterolaemia in Canada. The company will launch Crestor in Canada immediately.

The global statin market is currently worth US \$18 billion annually and is growing at about 20 per cent a year. The Canadian statin market is valued at Canadian \$1 billion a year and is also growing at 20 per cent annually. There are estimated to be 10 million people with dyslipidaemia in Canada.

The clinical development programme for CRESTOR now involves over 15,000 patients and includes a number of head-to-head comparative studies. In multiple clinical studies, CRESTOR has been shown to be more effective in lowering LDL-cholesterol (LDL-C or 'bad' cholesterol) than the currently prescribed statins. It has demonstrated reductions of 52 per cent to 63 per cent across the dose range, and compared to the same doses of atorvastatin, CRESTOR provided a significant 8.4 per cent greater reduction in LDL-C. CRESTOR 10mg gets significantly more patients to their European LDL-C goal than atorvastatin 10mg (82 per cent v 51 per cent respectively), simvastatin 20mg (80 per cent v 48 per cent) and pravastatin 20mg (80 per cent v 16 per cent). In addition to the dramatic reductions seen in LDL-C, CRESTOR produces a significant increase in HDL-C ('good' cholesterol), as well as reducing total cholesterol and triglycerides.

In addition to the approval in Canada today, CRESTOR was approved in the Netherlands last year and subsequently entered the European Mutual Recognition Procedure, which will lead to further approvals in

16 other countries in Europe -- beginning in the first half of 2003. CRESTOR has also recently been approved in Singapore and is awaiting approval in the USA, Japan and in other markets.

Coronary heart disease (CHD) is a major cause of morbidity and the leading cause of death in the Western world. LDL-C is the most significant contributory risk factor to atherosclerosis, a common cause of CHD and elevated levels of cholesterol is one of the most important risk factors in predicting CHD risk in the population.

AstraZeneca licensed worldwide rights to CRESTOR from Shionogi & Co Ltd, Osaka, Japan, the company that discovered the drug, in April 1998. AstraZeneca carried out a comprehensive clinical development programme leading to submission.

19 February 2003

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**Item 6**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announces that on 25 February 2003, it purchased for cancellation 860,000 ordinary shares of AstraZeneca PLC at a price of 2072 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,717,806,329.

G H R Musker  
Company Secretary  
26 February 2003

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**Item 7**



**ASTRAZENECA ISSUES 2002 ANNUAL REPORT**

AstraZeneca today published its Annual Report and Form 20-F for 2002. The document is available on the company's website - [www.astrazeneca.com](http://www.astrazeneca.com), click on Investor Relations - Financial Reports.

In addition to the annual report, all shareholders will, for the first time, receive a copy of AstraZeneca's 2002 Summary Corporate Responsibility Report, which provides the main points of the company's approach to corporate responsibility as well as 2002 performance highlights. Detailed statistics and further information about our policies and commitment to corporate responsibility are available on our web site – [www.astrazeneca.com](http://www.astrazeneca.com), click on About Us – Corporate Responsibility.

27 February 2003

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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.

AstraZeneca PLC

Date: 1 March 2003

By: /s/ G H R Musker  
Name: G H R Musker  
Title: Company Secretary & Solicitor