

ASTRAZENECA PLC  
Form 6-K  
June 03, 2004

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Report of Foreign Issuer

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

For May 2004

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

- Item 1. Press release entitled, Successful Outcome of the Mutual Recognition Procedure for Exanta™ (Ximelagatran) in Europe, dated 5 May 2004.

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

- Item 2. Press release entitled, New Seroquel Data Shows Efficacy and Tolerability in Bipolar Depression , dated 6 May 2004.
  - Item 3. Press release entitled, London Stock Exchange Announcement AstraZeneca PLC: AGM Resolutions , dated 7 May 2004.
  - Item 4. Press release entitled, AstraZeneca Sells Interest in Advanta BV , dated 12 May 2004.
  - Item 5. Press release entitled, Companies Act 1985 Section 198: Disclosure of Interest in Voting Shares in Public Companies , dated 14 May 2004.
  - Item 6. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 19 May 2004.
  - Item 7. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 20 May 2004.
  - Item 8. Press release entitled, AstraZeneca Makes Global Bond Market Debut , dated 20 May 2004.
  - Item 9. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 21 May 2004.
  - Item 10. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 24 May 2004.
  - Item 11. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 25 May 2004.
  - Item 12. Press release entitled, Repurchase of Shares in AstraZeneca PLC , dated 26 May 2004.
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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: 02 June 2004

By: /s/ G H R Musker

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Name: G H R Musker

Title: Company Secretary & Solicitor

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### Item 1

#### **SUCCESSFUL OUTCOME OF THE MUTUAL RECOGNITION PROCEDURE FOR EXANTA™ (XIMELAGATRAN) IN EUROPE**

AstraZeneca announced today that it has successfully completed the Mutual Recognition Procedure (MRP) in Europe for Exanta™ (ximelagatran) for short-term use in the prevention of venous thromboembolic events in major elective orthopaedic surgery (hip or knee replacement) the proof of concept indication for this new anticoagulant.

France acted as the Reference Member State for the MRP, with approval in this first market achieved in December 2003. National Marketing Authorisations for an additional 14 countries will be issued in the coming months. UK and Ireland have been withdrawn from the MRP and regulatory discussions will be held to agree the appropriate route to secure approval of Exanta in orthopaedic

surgery in these countries.

Dr Hamish Cameron, Vice President, Head of Exanta, AstraZeneca, said, As Exanta is the first new oral anticoagulant in nearly 60 years, completion of this first regulatory review in orthopaedic surgery is a historic milestone as we approach the introduction of this innovative new therapy.

Completion of the MRP for this first indication for Exanta was based on the extensive clinical programme and in particular the METHRO III study. The approved treatment regimen involves an early postoperative start of Exanta, with initial injectable dosing administered 4-8 hours after the completion of surgery, followed by oral Exanta 24mg twice daily for up to 11 days. This approach reflects the changing trends in clinical practice across Europe with increasing use of spinal anaesthesia as well as enabling oral treatment, to be easily continued following discharge from hospital.

More than half of patients undergoing major orthopaedic surgery can develop thromboembolic complications in the absence of preventative anticoagulant treatment, and while effective treatments are available, no treatment regimen to date has successfully balanced efficacy and bleeding risk with oral dosing.

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Exanta is the first oral therapy in a new class of direct thrombin inhibitors to protect patients against thrombosis. Exanta is currently under regulatory review in the E.U. for key chronic-use indications including the prevention of stroke and other thromboembolic complications associated with atrial fibrillation and the treatment of venous thromboembolism (VTE). In the US, FDA submissions were filed in December 2003 for stroke prevention in patients with atrial fibrillation and long-term secondary prevention of VTE, as well as for use of Exanta in prevention of VTE in major elective orthopaedic surgery (knee replacement).

The worldwide market for anticoagulants is around \$4 billion and growing at 13 per cent annually, while the worldwide anti-thrombotic market is around \$12 billion, growing at 15 per cent annually.

Exanta is a trademark of the AstraZeneca group of companies. European MRP countries include: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, United Kingdom, Iceland and Norway

METHRO: **ME**lagatran for **THR**ombin inhibition in **Orth**opaedic surgery is a study that compared injectable low molecular weight heparins initiated the evening before surgery, with preoperative (METHRO II) or post-operative (METHRO III) initiation of melagatran (active form) followed by oral ximelagatran in 4,688 patients undergoing total hip or knee replacement.

5 May 2004

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**NEW SEROQUEL DATA SHOWS EFFICACY AND TOLERABILITY  
IN BIPOLAR DEPRESSION**

AstraZeneca announces important new data from its first large-scale clinical trial to examine SEROQUEL (quetiapine) as a treatment for depressive episodes in patients with bipolar I and II disorders. The results, presented at the 157<sup>th</sup> American Psychiatric Association (APA) congress, show that SEROQUEL is an effective and well-tolerated agent for the treatment of bipolar depression and improves a broad range of anxiety and mood symptoms associated with bipolar depression.

The BOLDER study showed that SEROQUEL was superior to placebo in reducing depressive symptoms, as measured by Montgomery-Asberg Depression Rating Scale (MADRS) scores, in patients with bipolar disorder. Patients treated with SEROQUEL exhibited a statistically significant improvement across all efficacy measures, including those measuring anxiety, as early as week one. The improvements were noted at every assessment during the eight-week trial. In addition, approximately 50 percent of patients receiving SEROQUEL achieved remission from their bipolar depression symptoms.

The study was a double-blind, placebo controlled trial involving 542 patients with bipolar I and II disorders, who were randomised to receive eight weeks of treatment with either a fixed dose of SEROQUEL (300mg/d, 600mg/d administered once-daily) or placebo. The results of the trial found that patients taking SEROQUEL achieved a significantly greater improvement ( $p < 0.001$ ) in mean MADRS and Hamilton Rating Scale for Depression (HAM-D) scores versus placebo at every time point, starting at week one and through week eight (MADRS: -16.7 and -16.4 vs -10.3 in 600mg, 300mg and placebo group, respectively; HAM-D: -13.8 and -13.4 vs -8.5 in 600mg, 300mg and placebo group, respectively). Significantly ( $p < 0.001$ ) more patients taking SEROQUEL were considered responders ( 50 percent decrease from baseline MADRS score) from week two through to the end of the study.

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After eight weeks, significantly more patients taking SEROQUEL achieved remission from their depressive symptoms compared to the placebo group (53 percent vs 28 percent respectively  $p < 0.001$ ) as evaluated on the MADRS scale. Patients taking SEROQUEL had significantly greater improvement in mean Hamilton Rating Scale for Anxiety (HAM-A) score versus placebo at every assessment point starting at week one through week eight (-8.6 and -8.7 vs -5.5;  $p < 0.05$  at 600mg, 300mg and placebo, respectively).

Treatment-emergent mania did not differ between SEROQUEL and placebo (3 percent vs 4 percent respectively). Significant improvements were also seen on measures of quality of life and quality of sleep at all time points throughout the eight-week study ( $p < 0.001$ ). Bipolar depression and anxiety symptoms were assessed using the MADRS, HAM-D and HAM-A. The primary endpoint for bipolar depression was change in baseline on the MADRS scale.

Bipolar disorder is a serious mental illness that affects almost four percent of the adult population and is the sixth leading cause of disability in the world. More than half of those with bipolar disorder stop taking their medication at some point during their illness, subjecting themselves to a high risk of relapse and an increased risk of suicide. A medication's overall efficacy and tolerability profile is therefore vital to helping patients comply with their medication.

SEROQUEL is currently approved worldwide for the treatment of mania associated with bipolar disorder and schizophrenia. SEROQUEL has been licensed for the treatment of schizophrenia since 1997 and is available in 81 countries. Licences for bipolar mania have also been received in 23 other countries. SEROQUEL is the fastest growing product among the three leading brands in the atypical antipsychotic market. Sales during 2003 reached \$1.5 billion and the product currently ranks second in the US antipsychotic market for new prescription share, having recently overtaken olanzapine.

Thursday, 6<sup>th</sup> May 2004

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

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**Item 3**

**London Stock Exchange Announcement**

**AstraZeneca PLC: AGM Resolutions**

In accordance with paragraphs 9.31 and 16.7 of the Listing Rules, copies of the relevant resolutions passed at the Annual General Meeting of AstraZeneca PLC on 29 April 2004 have been submitted to the UK Listing Authority and will shortly be available for inspection at the UK Listing Authority's Document Viewing Facility at 25 The North Colonnade, Canary Wharf, London E14 5HS.

Graeme Musker  
Company Secretary  
7 May 2004

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**Item 4**

**ASTRAZENECA SELLS INTEREST IN ADVANTA BV**

AstraZeneca PLC and its joint venture partner, (Royal Cosun), announced today that they have reached an agreement to sell Advanta BV to Syngenta AG, for 400 million Euro plus a final net asset value adjustment. Completion will be subject to the necessary regulatory approvals and settlement will be in cash. The profit realised on the disposal of AstraZeneca's 50 per cent interest, will be recorded as an exceptional item in AstraZeneca's accounts below Group Operating Profit and does not form part of the Company's 2004 anticipated earnings per share range of \$2.00 to \$2.15 per share, reaffirmed in the announcement of the Company's first quarter results on 29 April 2004.

12 May 2004

**Notes for Editors:**

**Advanta BV is a leading international seeds business**

Announcements related to this transaction are also being issued today by Cosun,; Syngenta AG and Fox Paine, its collaboration partner in the transaction.

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**Item 5**

COMPANIES ACT 1985 SECTION 198  
DISCLOSURE OF INTEREST IN VOTING SHARES IN PUBLIC COMPANIES

ON 13 MAY 2004 WE WERE INFORMED BY THE CAPITAL GROUP COMPANIES, INC., A REGISTERED INVESTMENT MANAGER IN THE U.S., THAT ON 11 MAY 2004 ITS INTEREST IN THE USD0.25 ORDINARY SHARES OF ASTRAZENECA PLC HAD INCREASED TO 264,669,595 SHARES (15.74 PER CENT OF THE CURRENT ISSUED ORDINARY CAPITAL) FROM THE PREVIOUSLY NOTIFIED LEVEL OF 254,143,676 SHARES (15.01 PER CENT). THE REASON FOR THIS ANNOUNCEMENT IS THAT, WITHIN THE SAID HOLDING OF 15.74 PER CENT OF THE ISSUED ORDINARY CAPITAL OF ASTRAZENECA PLC, CAPITAL GUARDIAN TRUST COMPANY, AN AFFILIATE OF THE CAPITAL GROUP COMPANIES, INC., HAS INCREASED ITS INTEREST IN THESE SHARES TO 101,574,866 SHARES (6.04 PER CENT).

G H R MUSKER  
COMPANY SECRETARY  
14 MAY 2004

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**Item 6**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 18 May 2004, it purchased for cancellation 350,000 ordinary shares of AstraZeneca PLC at a price of 2650 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,681,411,912.

G H R Musker  
Company Secretary  
19 May 2004

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**Item 7**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 19 May 2004, it purchased for cancellation 500,000 ordinary shares of AstraZeneca PLC at a price of 2629 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,680,911,912.

G H R Musker  
Company Secretary  
20 May 2004

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**Item 8**

**ASTRAZENECA MAKES GLOBAL BOND MARKET DEBUT**

AstraZeneca PLC today announced a successful global bond market debut issuing a total of \$750 million. The proceeds of the issue will be used for general corporate purposes.

The global bond is rated Aa2 (stable) by Moody's and AA+ (stable) by Standard & Poor's credit rating agencies. The transaction is a 10-year benchmark SEC registered global offering and represents AstraZeneca's first offer in the bond markets.

This transaction is the first opportunity for bond investors to participate in AstraZeneca's credit and enables us to enhance our financial flexibility by diversifying our sources of funding, said Jonathan Symonds, Chief Financial Officer of AstraZeneca.

Formed in 1998 by the merger between Sweden's Astra and UK's Zeneca, AstraZeneca is currently listed on the London, New York and Stockholm stock exchanges. It is one of the world's leading pharmaceutical companies and employs over 60,000 employees worldwide. Global sales for 2003 were over \$18.8 billion.

The joint bookrunners for the transaction were Citigroup; Goldman, Sachs & Co, and J P Morgan

20 May 2004

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This press release contains forward-looking statements in the first and third paragraphs. Such statements may be subject to risks and uncertainties that could cause the actual results to differ materially from these statements. We refer you to AstraZeneca's publicly available filings with the U.S. Securities and Exchange Commission for information about these and other risks and uncertainties. AstraZeneca assumes no obligation to update forward-looking statements to reflect actual results, changed assumptions or other factors. This release does not constitute, or form part of, any offer or invitation to sell or issue, or any solicitation of any offer, to purchase or subscribe for any ordinary shares in, or securities of, AstraZeneca PLC nor shall it form the basis of, or be relied on in connection with, any contract therefore.

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**Item 9**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 20 May 2004, it purchased for cancellation 600,000 ordinary shares of AstraZeneca PLC at a price of 2597 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,680,316,461.

G H R Musker  
Company Secretary  
21 May 2004

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**Item 10**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 21 May 2004, it purchased for cancellation 600,000 ordinary shares of AstraZeneca PLC at a price of 2586 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,679,716,461.

G H R Musker  
Company Secretary  
24 May 2004

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**Item 11**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 24 May 2004, it purchased for cancellation 600,000 ordinary shares of AstraZeneca PLC at a price of 2580 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,679,116,461.

G H R Musker  
Company Secretary  
25 May 2004

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**Item 12**

**REPURCHASE OF SHARES IN ASTRAZENECA PLC**

AstraZeneca PLC announced that on 25 May 2004, it purchased for cancellation 600,000 ordinary shares of AstraZeneca PLC at a price of 2563 pence per share. Upon the cancellation of these shares, the number of shares in issue will be 1,678,516,461.

G H R Musker  
Company Secretary  
26 May 2004