ASTRAZENECA PLC
Form 6-K
December 13, 2012

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 the month of December 2012

Commission File Number: 001-11960

AstraZeneca PLC

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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 X 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 X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

AstraZeneca Announces Top-Line Results of OSKIRA-4 Phase IIb Study of Fostamatinib as a Monotherapy for Rheumatoid Arthritis

13 December 2012

AstraZeneca today announced top-line results of OSKIRA-4, a Phase IIb monotherapy study of fostamatinib, the first kinase inhibitor with selectivity for SYK (spleen tyrosine kinase) in development as an oral treatment for rheumatoid arthritis (RA).

OSKIRA-4 was a six month study evaluating improvements in signs and symptoms of RA in 280 patients who had never previously used a disease-modifying anti-rheumatic drug (DMARD), were DMARD intolerant or had an inadequate response to DMARDs and were randomised to receive fostamatinib as a monotherapy, adalimumab as a monotherapy, or placebo. Three dose regimens of fostamatinib were evaluated in OSKIRA-4: 100mg twice daily, 100mg twice daily for a month followed by 150mg once daily, and 100mg twice daily for a month followed by 100mg once daily.

OSKIRA-4 had two primary objectives - a superiority comparison to placebo at 6 weeks and a non-inferiority analysis against adalimumab monotherapy at 24 weeks as measured by change from baseline in DAS28 score (a composite endpoint assessing signs and symptoms of RA).

In the OSKIRA-4 study, fostamatinib as a monotherapy met the first primary objective, showing a statistically significant superior DAS28 score change from baseline compared to placebo at 6 weeks at the 100mg twice daily dose and the 100mg twice daily for a month followed by 150mg once daily dose, but not at the 100mg twice daily for a month followed by 100mg once daily dose.

The OSKIRA-4 study did not meet its second primary objective as all f
ostamatinib monotherapy doses were inferior to adalimumab monotherapy at week 24 based on DAS28.

The safety and tolerability findings for fostamatinib as reported in the OSKIRA-4 study were generally consistent with those previously observed in the TASKi Phase II programme.

Martin Mackay, President of AstraZeneca Research and Development said: "This Phase IIb dose finding study was designed to evaluate the effect of fostamatinib independent of methotrexate and to inform the further development of fostamatinib as a monotherapy treatment for RA. A more comprehensive assessment of the benefit/risk profile of fostamatinib used in combination with a DMARD is being undertaken in the pivotal studies that form the OSKIRA Phase III programme which are on track to report in the first half of 2013, and would form the basis of regulatory submissions."

Regulatory filings in the US and EU for use in combination with a DMARD based on the OSKIRA Phase III programme, are expected in the second half of 2013.

A more detailed analysis of the OSKIRA-4 findings will be published in due course.

NOTES TO EDITORS

About the OSKIRA programme

Ongoing Phase III trials in the OSKIRA (Oral Syk Inhibition in Rheumatoid Arthritis) programme, include three pivotal studies assessing the efficacy and safety of fostamatinib; two 12-month studies examining the effect of fostamatinib on patients responding inadequately to DMARDs including methotrexate (OSKIRA-1, OSKIRA-2); a six-month study assessing the effect of fostamatinib on patients who have previously responded inadequately to an anti-TNF therapy (OSKIRA-3); and a long-term extension study looking at the ongoing safety and tolerability of fostamatinib (OSKIRA-X). The three pivotal studies have as their primary endpoint the proportion of patients with ACR20 compared to placebo (ACR20 = American College of Rheumatology 20% response criteria). The OSKIRA-1 study also has a co-primary endpoint of change from baseline to week 24 in modified total Sharp score (mTSS), an x-ray endpoint assessing structural progression.
These Phase III studies are expected to be completed in the first half of 2013.

For more information about OSKIRA-4 visit: http://clinicaltrials.gov/ct2/show/NCT01264770

About Fostamatinib

Fostamatinib (previously referred to as R788), is the first kinase inhibitor with selectivity for SYK in development as an oral treatment for rheumatoid arthritis. Fostamatinib blocks signalling in multiple cell types involved in inflammation and tissue degradation in rheumatoid arthritis and it is hypothesized that it may hinder key steps in the progression of the disease. In February 2010, AstraZeneca and Rigel Pharmaceuticals announced a worldwide license agreement whereby AstraZeneca will develop and commercialise fostamatinib.

About Rheumatoid Arthritis (RA)

RA is a painful, systemic, chronic inflamatory disease which can cause damage to the joints and vital organs as well as affecting other parts of the musculoskeletal system such as connective tissues, muscles and tendons. The disease affects approximately one in 100 people worldwide.

If not adequately treated, RA is a major cause of disability and is associated with reduced life expectancy. In the US alone the total annual societal cost of RA is estimated to amount to $39.2 billion, with even greater indirect costs to individuals and society including costs from diminished work capacity, loss of productivity, loss in earnings and loss in tax contributions.

About Rigel Pharmaceuticals

Rigel Pharmaceuticals, Inc. is a clinical-stage drug development company that discovers and develops novel, small-molecule drugs for the treatment of inflammatory and autoimmune diseases, as well as muscle disorders. Rigel's pioneering research focuses on intracellular signaling pathways and related targets that are critical to disease mechanisms. Rigel's productivity has resulted in strategic collaborations with large pharmaceutical partners to develop and market its product candidates. Current product development programs include fostamatinib, an oral SYK inhibitor that is in Phase III clinical trials for rheumatoid arthritis with its partner AstraZeneca; R343, an inhaled SYK inhibitor for asthma and R333, a topical JAK/SYK inhibitor for discoid lupus - both of which have commenced Phase II clinical trials; and R548, an oral JAK3 inhibitor for the treatment of transplant rejection and other immune disorders. Visit
www.rigel.com.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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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: 13 December 2012 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary