ASTRAZENECA PLC
Form 6-K
December 02, 2014

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 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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-_____

NEW DRUG APPLICATION FOR IRESSA ACCEPTED BY
US FOOD AND DRUG ADMINISTRATION

AstraZeneca today announced that the US Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for IRESSA® (gefitinib) as a targeted monotherapy for the first line treatment of patients with advanced or metastatic epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC), as identified through a companion diagnostic test. The Prescription Drug User Fee Act goal date for IRESSA will be in the third quarter 2015.

IRESSA is an EGFR tyrosine kinase inhibitor that acts by blocking the transmission of signals involved in the growth and spread of tumours. AstraZeneca's NDA submission for IRESSA was based on data from the Phase III IFUM1 (IRESSA Follow-Up Measure) clinical trial, providing evidence of IRESSA's efficacy in Caucasian patients. This was supported by results from the IPASS2 (IRESSA Pan-ASia Study) clinical trial, as well as other collaborative group studies.

IRESSA is already approved in 90 countries for the treatment of adult patients with locally advanced or metastatic NSCLC with activating mutations of the EGFR tyrosine kinase.

1 Douillard JY, et al. Efficacy, safety and tolerability results from a phase IV, open-label, single arm study of 1st-line gefitinib in Caucasian patients with epidermal growth factor receptor mutation-positive non-small-cell lung cancer. European Multidisciplinary Conference in Thoracic Oncology, Lugano, Switzerland, May 9-11, 2013; abstract 68O.

2 Maemondo M, et al. Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. N Engl J Med 2010;362:2380-8.

About IRESSA
IRESSA is a targeted monotherapy for the treatment of patients with advanced or metastatic epidermal growth factor receptor mutation positive (EGFRm) non-small cell lung cancer (NSCLC). IRESSA acts by inhibiting the tyrosine kinase enzyme in the EGFR, thus blocking the transmission of signals involved in the growth and spread of tumours. EGFR mutations occur in approximately 10-15 percent of NSCLC patients in Europe and 30-40 percent of NSCLC patients in Asia.

IRESSA was launched in 2002 and is now approved in 90 countries worldwide.

In the US, AstraZeneca is working with Qiagen to develop a companion diagnostic test to guide the use of IRESSA in the treatment of patients with advanced NSCLC.

In Europe, the collaboration between AstraZeneca and Qiagen has resulted in IRESSA becoming the first EGFR tyrosine kinase inhibitor to have a European label allowing the use of circulating tumour DNA (ctDNA) obtained from a blood sample, to be used for the assessment of EGFR mutation status in those patients where a tumour sample is not an option.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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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2 December 2014

-ENDS-

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 December 2014

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary