ASTRAZENECA PLC
Form 6-K
July 14, 2015

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 July 2015

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-_____

IRESSA APPROVED BY US FDA FOR FIRST-LINE TREATMENT OF
PATIENTS WITH ADVANCED EGFR MUTATION-POSITIVE

NON-SMALL CELL LUNG CANCER

AstraZeneca announced that the US Food and Drug Administration (FDA) has approved IRESSA (gefitinib) tablets, 250mg once daily, for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations, as detected by an FDA-approved test.

IRESSA is an oral, EGFR tyrosine kinase inhibitor (TKI), which works by blocking the activity of the EGFR tyrosine kinase enzyme responsible for regulating signalling pathways implicated in the growth and survival of cancer cells. IRESSA was granted Orphan Drug Designation by the FDA in August 2014 for the treatment of EGFR mutation-positive NSCLC.

Antoine Yver, Head of Oncology, Global Medicines Development at AstraZeneca said: "The approval of IRESSA provides physicians and patients in the US with a new choice of first-line treatment for metastatic non-small cell lung cancer. AstraZeneca is at the forefront of research into targeted therapies for EGFR mutated lung cancer and is committed to improving the outlook for patients at all stages of the disease."

AstraZeneca has partnered with QIAGEN to provide the therascreen® EGFR companion diagnostic test for IRESSA in the US. The test rapidly identifies EGFR mutation status through a tumour tissue sample, in order to guide the use of IRESSA in the treatment of patients with metastatic NSCLC.

The FDA approval of IRESSA is based on data from the Phase IV IFUM1 (IRESSA Follow-Up Measure) study, assessing IRESSA as a first-line treatment for Caucasian patients with locally advanced or metastatic EGFR mutation-positive NSCLC. This was supported by results from the IPASS2 (IRESSA Pan-ASia Study) clinical trial.

IRESSA is approved in 91 countries for the treatment of adult patients with locally advanced or metastatic EGFR mutation-positive NSCLC. The safety profile of IRESSA is well established through a large, global clinical programme and extensive real world evidence. The most commonly reported adverse events for IRESSA are diarrhoea and skin reactions including rash, acne, dry skin and pruritus.

AstraZeneca is also studying IRESSA in combination with other investigational medicines, including the company's anti-PD-L1 monoclonal antibody, durvalumab (MEDI4736) to assess its potential as a combination treatment for a broader range of lung cancer patients.

1 Douillard JY et al. First-line gefitinib in Caucasian EGFR mutation-positive NSCLC patients: a phase-IV, open-label, single-arm study. Br J Cancer 2014 Jan 7; 110, 55-62. doi: 10.1038/bjc.2013.721.

2 Masahiro F, et al. Biomarker analyses and final overall survival results from a phase III, randomized, open-label, first-line study of gefitinib versus carboplatin/paclitaxel in clinically selected patients with advanced non-small-cell lung cancer in Asia (IPASS). J Clin Oncol 2011Jul 20; 29(21):2866-74. doi: 10.1200/JCO.2010.33.4235.

About the IFUM Study
The IFUM study was a multicentre, single arm study to characterise the efficacy and safety of gefitinib 250mg (once daily) as first-line treatment in Caucasian patients who have EGFR mutation-positive locally advanced or metastatic NSCLC. A total of 106 EGFR mutation-positive patients were enrolled to the study. The overall response rate (ORR) by investigators' assessment was 70% (95% confidence interval (CI) 61% to 78%). ORR by a Blinded Independent Centre Review (BICR) was 50% (95% CI 41% to 59%).

The most common adverse events (AEs) in the IFUM study were rash (44.9%), diarrhoea (30.8%), vomiting (13.1%), asthenia, cough and dry skin (all 11.2%), and nausea (10.3%). Two patients (1.9%) experienced a serious AE that the investigator characterised as related to treatment, and 4 patients (3.7%) experienced drug related AEs that led to

treatment discontinuation.

About IRESSA
IRESSA is a targeted monotherapy for the treatment of patients with advanced or metastatic epidermal growth factor receptor mutation-positive 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 to 15 percent of NSCLC Caucasian patients and 30 to 40 percent of NSCLC patients in Asia.

IRESSA is approved in 91 countries worldwide.

In the US, AstraZeneca has partnered with QIAGEN to develop a companion diagnostic test to guide the use of IRESSA. In Europe, the collaboration between AstraZeneca and QIAGEN has resulted in IRESSA becoming the first EGFR tyrosine kinase inhibitor to have a European label supporting 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 in Oncology
Oncology is a therapeutic area in which AstraZeneca has deep-rooted heritage. It will be potentially transformational for the company's future, becoming the sixth growth platform. Our vision is to help patients by redefining the cancer treatment paradigm and one day eliminate cancer as cause of death. By 2020, we are aiming to bring six new cancer medicines to patients.

Our broad pipeline of next-generation medicines is focused on four main disease areas - lung, ovarian, breast, and haematological cancers. These are being targeted through four key platforms - immuno-oncology, the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates.

In lung cancer, AstraZeneca is at the forefront of development of targeted therapies, with more than 10 years' experience in providing treatments for this challenging disease. In 2002, AstraZeneca was the first company to launch an EGFR TKI for patients with pre-treated metastatic NSCLC. We are committed to addressing the urgent unmet need for more effective treatments and are developing therapies that target all stages of the disease from primary treatment through to recurrence and re-treatment, in order to achieve sustained disease control. By making targeted, personalised treatment a reality at every stage, we hope to take important steps towards ultimately eradicating death from lung cancer.

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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14 July 2015

-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: 14 July 2015

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