ASTRAZENECA PLC
Form 6-K
December 18, 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 December 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-_____

TAGRISSO™ (OSIMERTINIB) RECEIVES POSITIVE CHMP OPINION FOR PATIENTS WITH EGFR T790M MUTATION-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER

CHMP positive recommendation is based on an objective response rate of 66% and median progression-free survival of 9.7 months

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending the marketing authorisation of TAGRISSO™ (AZD9291, osimertinib) 80mg once-daily tablets for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC).

This indication includes NSCLC patients whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor (TKI) and patients with a T790M mutation who have not been treated with an EGFR-TKI.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The CHMP's recommendation for osimertinib to receive marketing approval is a positive step for patients in Europe. This follows the recent US accelerated approval of osimertinib and its adoption in the UK under the Early Access to Medicines Scheme to meet urgent unmet need. Building on the breakthrough clinical evidence, we're investigating osimertinib's full potential as a monotherapy and in novel combinations with other precision medicines and immunotherapies from our comprehensive oncology pipeline."

AURA study clinical investigator Professor Jean-Charles Soria, Head of Drug Development Department, Gustave Roussy Cancer Center, Paris, France added; "In Europe, lung cancer kills over 260,000 people every year, so there is an urgent need for new treatments. As a treating physician, it is very gratifying to see the progression of osimertinib towards use in clinical practice for patients living with EGFRm T790M non-small cell lung cancer."

Osimertinib is an EGFR-TKI designed to inhibit both the activating, sensitising mutation (EGFRm), and T790M, a genetic mutation responsible for EGFR-TKI treatment resistance. Nearly two-thirds of patients with EGFRm NSCLC whose disease progresses after EGFR-TKI treatment develop the T790M resistance mutation, for which treatment options are limited.

The CHMP recommendation for osimertinib is based on data from two Phase II studies (AURA extension and AURA2) and the AURA Phase I expansion study, which demonstrated efficacy in 474 EGFRm T790M NSCLC patients who had progressed on or after an EGFR-TKI. In the combined Phase II studies, the objective response rate (ORR, a measurement of tumor shrinkage) was 66%, and in the Phase I study it was 62%. Progression-free survival (PFS) was 9.7 months in the combined Phase II studies and 11 months in the Phase I trial. Median duration of response (DOR) in the Phase I study was 9.7 months and in the combined Phase II studies, median duration of response was not reached.

The most common adverse events based on data from the two AURA Phase II studies were generally mild to moderate and included diarrhoea (42% all grades; 1.0% Grade 3/4), rash (41% all grades; 0.5% Grade 3/4), dry skin (31% all grades; 0% Grade 3/4), and nail toxicity (25% all grades; 0% Grade 3/4). Warnings and precautions include interstitial lung disease, QT interval prolongation and embryofoetal toxicity.

The positive CHMP recommendation has been received through the EMA's Accelerated Assessment and follows the recent US Accelerated Approval of osimertinib by the Food and Drug Administration (FDA). In Japan, osimertinib was granted Priority Review by the Pharmaceuticals and Medical Devices Agency (PMDA). Interactions with regulatory authorities in the rest of the world are ongoing.

About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths, and more than breast, prostate and colorectal cancers combined. Patients who have the EGFRm form of NSCLC, which occurs in 10-15 percent of NSCLC patients in Europe and 30-40 percent of NSCLC patients in Asia, are particularly sensitive to treatment with currently available EGFR-TKIs, which block the cell signalling pathways that drive the growth of tumour cells. However, tumours almost always develop resistance to treatment, leading to disease progression. In approximately two-thirds of patients treated with the approved EGFR-TKIs, gefitinib, erlotinib or afatinib, this resistance is caused by the secondary mutation, T790M.

About osimertinib

Osimertinib 80mg once-daily tablet is the first potential medicine indicated for the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC. Non-clinical in vitro studies have demonstrated that osimertinib has high potency and inhibitory activity against mutant EGFR phosphorylation across the range of clinically relevant EGFRm and T790M mutant NSCLC cell lines, with significantly less activity against EGFR in wild-type cell lines.

Osimertinib is being compared with platinum-based doublet chemotherapy in the confirmatory AURA3 Phase III study in patients with EGFR T790M-positive, locally advanced, or metastatic NSCLC who have progressed after EGFR-TKI therapy. It is also being investigated in the adjuvant and metastatic first-line settings, including in patients with brain metastases, and in combination with other compounds.

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 a 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.

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

18 December 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: 18 December 2015

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