ASTRAZENECA PLC
Form 6-K
November 13, 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 November 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™ (AZD9291) APPROVED BY THE US FDA FOR PATIENTS WITH EGFR T790M MUTATION-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER

One of fastest development programmes - from start of clinical trials to approval in just over two and a half years to meet unmet patient need

With objective response rate of 59% and duration of response of 12.4 months, TAGRISSO provides important new option for patients

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved TAGRISSO™ (AZD9291) 80mg once-daily tablets for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

AZD9291 is the only approved medicine indicated for patients with metastatic EGFR T790M mutation-positive non-small cell lung cancer. This indication is approved under the FDA's accelerated approval process based on tumour response rate and duration of response (DoR).

AZD9291 is an EGFR-TKI, a targeted cancer therapy, designed to inhibit both the activating, sensitising mutations (EGFRm), and T790M, a genetic mutation responsible for EGFR-TKI treatment resistance. Nearly two-thirds of NSCLC patients who are EGFR mutation-positive and experience disease progression after being treated with an EGFR-TKI develop the T790M resistance mutation, for which there have been limited treatment options.

Pasi A Jänne MD, PhD, Director, Lowe Center for Thoracic Oncology at Dana-Farber Cancer Institute, Scientific Director, Belfer Center for Applied Cancer Science and Professor of Medicine, Harvard Medical School, said: "In the AURA clinical studies, AZD9291 has demonstrated compelling early efficacy and tolerability in patients with EGFRm T790M metastatic non-small cell lung cancer. This treatment has the potential to become the standard of care for patients living with EGFRm T790M non-small cell lung cancer. The accelerated approval of AZD9291 highlights its clinical promise for a targeted group of patients and gives healthcare providers an important new option."

Pascal Soriot, Chief Executive Officer, AstraZeneca, said: "The FDA approval of TAGRISSO marks an important milestone for lung cancer patients who urgently need new treatment options. We have built on our heritage in this area and acted on the breakthrough clinical evidence to ensure this next-generation medicine reaches patients in record time. As we advance our comprehensive lung cancer portfolio, we have the opportunity to treat greater numbers of patients across all stages of this disease through precision medicines, immunotherapies and novel combinations."

AstraZeneca has collaborated with Roche to develop the cobas® EGFR Mutation Test v2 as the companion diagnostic for AZD9291. The cobas® EGFR Mutation Test v2 is intended to identify a range of EGFR mutations in patients with non-small cell lung cancer, including T790M.

AZD9291 was granted Fast Track, Breakthrough Therapy, Priority Review and Accelerated Approval status by the FDA. In Europe and Japan, AZD9291 was granted Accelerated Assessment and Priority Review status respectively. Interactions with regulatory authorities in the rest of the world are ongoing.

The FDA approval of AZD9291 is based on data from the two AURA Phase II studies (AURA extension and AURA2) which demonstrated efficacy in 411 EGFRm T790M NSCLC patients that had progressed on or after an EGFR TKI. In those trials, overall objective response rate ((ORR) a measurement of tumor shrinkage) was 59% (95% CI: 54% to 64%). In a supportive Phase I study in 63 patients, ORR was 51% and median duration of response was 12.4 months.

The AZD9291 tolerability profile showed that no individual severe grade 3+ adverse events occurred at ≥ 3.5%.The most common adverse events 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). There are no contraindications for AZD9291. Warnings and precautions include interstitial

lung disease, QT interval prolongation, cardiomyopathy and embryofoetal toxicity.

AZD9291 Development Programme
AZD9291 is being studied in the confirmatory trial, AURA3, an open label, randomised Phase III study designed to assess the efficacy and safety of AZD9291 versus platinum-based doublet chemotherapy in patients with EGFR T790M positive, locally advanced, or metastatic NSCLC who have progressed following prior therapy with an EGFR-TKI. AZD9291 is also being investigated in the adjuvant setting and in the metastatic first-line setting, including in patients with brain metastases, as well as in combination with other compounds.

NOTES TO EDITORS

About Non-Small Cell Lung Cancer
Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths, more than breast, prostate and colorectal cancers combined. Lung cancer has a five-year survival rate that is less than 20%. Approximately 85% of all lung cancers in the US are NSCLC; 10% to 15% of these are EGFR mutation-positive. Approximately two-thirds of patients treated with EGFR TKI therapy will acquire resistance related to the T790M mutation.

About AZD9291
AZD9291 80mg once-daily tablet is the first medicine indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small-cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.
Non-clinical in vitro studies have demonstrated that AZD9291 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 has recently been published by the World Health Organisation (WHO) as the proposed International Non-proprietary Name (INN) for AZD9291, and may become formally adopted during November 2015. In the US, the American Medical Association accepted osimertinib as the United States Adopted Name (USAN).

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 hematological 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 Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

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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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

13 NOVEMBER 2015

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 November 2015

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