ASTRAZENECA PLC
Form 6-K
March 29, 2016

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 March 2016

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): _____

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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) APPROVED IN JAPAN FOR PATIENTS WITH EGFR T790M MUTATION-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER

Full approval is based on two Phase II trials, AURA extension and AURA2, demonstrating objective response rates of 61.3% and 70.9%, respectively

Osimertinib targets mutation seen in significant proportion of patients with lung cancer in Japan

Japanese and recent US and EU approvals for osimertinib achieved within three years of clinical trials initiation

AstraZeneca today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Tagrisso (osimertinib, AZD9291) 80mg once-daily tablets for the treatment of patients with epidermal growth factor receptor (EGFR) T790M mutation-positive inoperable or recurrent non-small cell lung cancer (NSCLC) that is resistant to EGFR tyrosine kinase inhibitor (TKI) therapy.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We continue to move at an unprecedented pace with osimertinib, with the full approval in Japan following closely the recent US and EU approvals. As first-in-class lung cancer treatment directed at the T790M mutation, we are delighted that this targeted medicine is now available to patients in Japan to address the existing unmet medical need."

Dr. Tetsuya Mitsudomi, Division of Thoracic Surgery, Department of Surgery, Kinki University Faculty of Medicine said: "A significant proportion of Japanese patients with lung cancer have the EGFR mutation and about 60% of them are likely to develop the T790M resistance mutation following initial TKI treatment. Osimertinib enables us to respond to this disease progression in a precise and logical way as clearly demonstrated in clinical trials, with potential to make a meaningful difference to the lives of Japanese patients."

Approximately 30-40% of Asian patients with NSCLC have the EGFR mutation at diagnosis. Nearly two out of three patients with NSCLC whose disease progresses after treatment with an EGFR-TKI develop the T790M mutation, for which treatment options are currently limited. Osimertinib targets both the EGFR mutation involved in cancer development and T790M, a mutation that makes tumours resistant to existing treatment with EGFR-TKIs. Patients with EGFRm NSCLC, who experience disease progression, should be tested for their mutation status through a validated diagnostic test. AstraZeneca has collaborated with Roche to develop the cobas® EGFR Mutation Test v2 as the companion diagnostic for osimertinib.

The Japanese approval is based on data from the two multinational AURA Phase II trials (AURA extension and AURA2), with 22% of patients enrolled from Japan. The studies demonstrated efficacy in patients who had progressed on or after treatment with an EGFR-TKI and whose tumours tested positive for the EGFR T790M mutation. The overall objective response rate (ORR, a measurement of tumour shrinkage) was 61.3% (95% CI: 54.2% to 68.1%) in AURA extension (n=199), and 70.9% (95% CI: 64.0% to 77.1%) in AURA2 (n=199) (1 May 2015 cut-off).

In the two AURA Phase II studies (n=411), the most commonly reported adverse events assessed by the investigator were rash/acne (37.7%), diarrhoea (36.5%), dry skin/eczema, etc. (28.5%), nail disorder including paronychia, etc (23.4%). In Japanese patients (n=80), the incidence of interstitial lung disease (ILD; including pneumonitis etc.), as assessed by the investigator, for all grades was 6.3% (1 May 2015 cut-off). Warnings and precautions include ILD, QT interval prolongation, hepatic impairment and haematological changes.

AstraZeneca has agreed a Risk Management Plan with the Japanese Health Authority.

The full Japanese approval was granted seven months after the New Drug Application submission in August 2015. The Japanese approval for osimertinib was granted under the Priority Review mechanism of the MHLW, in recognition of the submitted data and the life-threatening nature of the disease. The Japanese approval follows US FDA Accelerated Approval in November 2015 and European Commission conditional marketing authorisation in February 2016. 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% of NSCLC patients in Europe and 30-40% 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 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 trial 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

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least 6 new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advance New Oncology as one of AstraZeneca's six Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms -- immuno-oncology, the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates -- and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

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

29 March 2016

-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: 29 March 2016

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