ASTRAZENECA PLC
Form 6-K
April 25, 2017

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 April 2017

Commission File Number: 001-11960

AstraZeneca PLC

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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 __

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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-_____

25 April 2017 13:30 BST

TAGRISSO RECEIVES FULL APPROVAL IN THE EU

Full approval follows Tagrisso's expedited Conditional Marketing Authorisation as first-in-class medicine for patients with locally-advanced or metastatic EGFR T790M mutation-positive non-small cell lung cancer

Tagrisso is a potential new standard of care in 2nd line and subsequent therapy in this hard-to-treat form of lung cancer

Approval is based on Phase III AURA3 data which demonstrate significant clinical superiority of Tagrisso over chemotherapy in EGFR T790M mutation-positive NSCLC patients, including those with CNS metastases

AstraZeneca today announced that the European Commission (EC) has granted full marketing authorisation for Tagrisso(osimertinib) 40mg and 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).

The full approval for Tagrissois based on the results of the Phase III AURA3 trial, which were presented last year. The EGFR T790M mutation can be detected with a validated test using either DNA derived from a biopsy or circulating tumour DNA (ctDNA) obtained from a plasma sample.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The full approval of Tagrissoin the EU is further evidence of our exciting progress in transforming the science of cancer care to deliver life-changing medicines to people most in need. Having demonstrated its superiority over chemotherapy in EGFR T790M mutation-positive non-small cell lung cancer, Tagrissohas the potential to become the new standard of care for patients with this difficult-to-treat form of lung cancer."

Data from the Phase III AURA3 trial showed that Tagrissodemonstrated statistically-significant improvements in progression-free survival (PFS) over standard platinum-based doublet chemotherapy in 419 patients with EGFR T790M-positive advanced NSCLC whose disease had progressed on or after EGFR TKI therapy. Among patients taking Tagrisso, the PFS was 10.1 months, compared to 4.4 months in the chemotherapy arm. The objective response rate (ORR) was 71% compared to 31% for chemotherapy. Among 144 patients with metastases to the central nervous system (CNS), PFS was 8.5 months versus 4.2 months.

The most common adverse reactions in the Tagrissogroup were diarrhoea (41% overall; 1% Grade ≥3), rash (34% overall; 1% Grade ≥3), dry skin (23% overall; 0% Grade ≥3), paronychia (22% overall; 0% Grade ≥3), stomatitis (15% overall; 0% Grade ≥3, and pruritus (13% overall; 0% Grade ≥3). Warnings and precautions include interstitial lung disease (ILD), keratitis, left ventricular ejection fraction (LVEF) and QTc interval prolongation.

In March 2017, the US Food and Drug Administration (FDA) granted Tagrissoa conversion from accelerated to full approval. Tagrissowas also recently approved in China through the new Priority Review Pathway, which grants an accelerated review timeline for innovative therapies.

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, more than breast, prostate and colorectal cancers combined. Patients who have EGFRm NSCLC, which occurs in 10-15% of NSCLC patients in the US and 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. Approximately two-thirds of patients develop resistance to approved EGFR-TKIs such as gefitinib, erlotinib and afatinib due to the secondary mutation, T790M.

About Tagrisso
Tagrisso (osimertinib) 40mg and 80mg once-daily oral tablet has been approved in over 45 countries, including the US, EU, Japan and China, for patients with EGFR T790M mutation-positive advanced NSCLC. Eligibility for treatment with Tagrisso is dependent on confirmation that the EGFR T790M mutation is present in the tumour.

Tagrisso is a third generation, irreversible EGFR-TKI designed to inhibit both EGFR sensitising and EGFR T790M resistance mutations and to have activity in the CNS.

Tagrissois also being investigated in the adjuvant and metastatic 1st line settings, including in patients with and without CNS metastases, in leptomeningeal metastases, and in combination with other treatments.

About AstraZeneca in Lung Cancer
AstraZeneca uses ground-breaking science to develop a wide range of therapies for patients with lung cancer. We are pioneering biomarker-guided therapies that aim to eliminate lung cancer by targeting molecular mutations in tumour cells and by boosting the power of the immune response against cancer. We are committed to transforming outcomes for patients with lung cancer, whose treatment options are currently limited.

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 six 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, Tumour Drivers and Resistance, DNA Damage Response 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, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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 and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary, AstraZeneca PLC

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: 25 April 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary