ASTRAZENECA PLC
Form 6-K
June 08, 2018

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 June 2018

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 __
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):
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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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
EU APPROVES TAGRISSO FOR 1ST-LINE NSCLC

08 June 2018 17:30BST

The EU approves Tagrisso for 1st-line treatment of EGFR-mutated non-small cell lung cancer

1st-line Tagrisso offers a potential new standard of care

Today the European Commission has granted marketing authorisation for Tagrisso (osimertinib) as monotherapy for the 1st-line treatment of adult patients with locally-advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations. The approval is based on results from the Phase III FLAURA trial published in the New England Journal of Medicine.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: "Today's approval is an exciting advance in bringing a potential new standard of care to patients with EGFR-mutated NSCLC in the EU. This milestone is also a step forward for our Company, marking another regional approval for Tagrisso in the 1st-line setting."

Dr. David Planchard, Associate Professor of Medicine, Head of Thoracic Group, Gustave Roussy cancer center, France said: "The FLAURA trial is changing medical practice in the 1st-line treatment of EGFR-mutated NSCLC. The progression-free survival benefit seen in the trial is unprecedented for patients with an EGFR mutation, and this benefit was consistent across all subgroups including in patients with or without central nervous system metastases. Further, the preliminary overall survival data, while not statistically significant at the time of the interim analysis, is promising, with a 37 percent reduction in the risk of death."

The approval follows the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency.

FLAURA efficacy results according to investigator assessment

Efficacy parameter	Tagrisso(N=279)	EGFR-TKI comparator (gefitinib or erlotinib) (N=277)
Progression-free survival (PFS)		
Number of events (62% maturity)	136 (49)	206 (74)
Median PFS (95% CI)	18.9 months (15.2, 21.4)	10.2 months (9.6, 11.1)
HR (95% CI); p-value	0.46 (0.37, 0.57); p < 0.0001	
Overall survival (OS)		
Number of deaths, (25% maturity)	58 (21)	83 (30)
Median OS in months (95% CI)	NC	NC
HR (95% CI); p-value	0.63 (0.45, 0.88); p=0.0068 (NS)*	
Objective response rate (ORR)		
Response rate (95% CI)	80% (75, 85)	76% (70, 81)
Odds ratio (95% CI); p-value	1.3 (0.9, 1.9); p=0.2421	
Duration of response (DoR)		
Median DoR (95% CI)	17.2 months (13.8, 22.0)	8.5 months (7.3, 9.8)

*Not statistically significant at current level of maturity.

Safety data for Tagrisso from the FLAURA, AURA3, AURA and AURA2 trials were evaluated. Tagrisso was well tolerated, with most adverse reactions Grade 1 or 2 in severity. In all patients, the most common adverse reactions were decreased leucocytes (68% [1.5% Grade ≥3]), decreased lymphocytes (67% [7.2% Grade ≥3]), decreased platelet count (54% [1.6% Grade ≥3]), diarrhoea (49% [1.2% Grade ≥3]), rash (47% [0.9% Grade ≥3]), decreased neutrophils (35% [4.1% Grade ≥3]), dry skin (33% [0.1% Grade ≥3]), paronychia (31% [0.3% Grade ≥3]), stomatitis (20% [0.2% Grade ≥3]), and pruritus (17% [0.1% Grade ≥3]).

In the EU, Tagrisso is already indicated for the treatment of patients with locally-advanced or metastatic EGFR T790M mutation-positive NSCLC. Today's approval follows the recent approvals of Tagrisso for the 1st-line

treatment of patients with metastatic EGFR-mutated (EGFRm) NSCLC in the US, Brazil and the Russian Federation. Tagrisso is also under regulatory review in Japan for use in the 1st-line treatment setting with a decision anticipated in the second half of 2018, with other global health authority reviews and submissions ongoing.

About NSCLC

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-fifth of all cancer deaths, more than breast, prostate and colorectal cancers combined. Approximately 10-15% of patients in the US and Europe, and 30-40% of patients in Asia have EGFR-mutated (EGFRm) NSCLC. These patients are particularly sensitive to treatment with EGFR-TKIs, which block the cell-signalling pathways that drive the growth of tumour cells. Tumours almost always develop resistance to EGFR-TKI treatment, however, leading to disease progression. Approximately half of patients develop resistance to approved EGFR-TKIs such as gefitinib, erlotinib and afatinib due to the EGFR T790M resistance mutation. There is also a need for medicines with improved CNS efficacy, since approximately 25% of patients with EGFRm NSCLC have brain metastases at diagnosis, increasing to approximately 40% within two years of diagnosis.

About Tagrisso

Tagrisso (osimertinib) is a third-generation, irreversible EGFR-TKI designed to inhibit both EGFR-sensitising and EGFR T790M-resistance mutations, with clinical activity against CNS metastases. Tagrisso 40mg and 80mg once-daily oral tablets have been approved in four countries, including the US and EU, for 1st-line EGFRm advanced NSCLC, and in more than 75 countries including the US, EU, Japan and China for patients with EGFR T790M mutation-positive advanced NSCLC. Tagrisso is also being tested in the adjuvant setting and in combination with other treatments.

About the FLAURA trial

The FLAURA trial assessed the efficacy and safety of Tagrisso 80mg once daily vs. standard-of-care EGFR-TKIs (either erlotinib [150mg orally, once daily] or gefitinib [250mg orally, once daily]) in previously-untreated patients with locally-advanced or metastatic EGFRm NSCLC. The trial was double-blinded and randomised, with 556 patients across 29 countries.

About AstraZeneca in Lung Cancer

AstraZeneca is committed to developing medicines to help every patient with lung cancer. We have three approved medicines and a growing pipeline that targets genetic changes in tumour cells and boosts the power of the immune response against cancer. Our unrelenting pursuit of science aims to deliver more breakthrough therapies with the goal of extending and improving the lives of patients across all stages of disease and lines of therapy.

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 Oncology as a key growth driver for AstraZeneca 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 therapy areas - Oncology,

Cardiovascular, Renal & Metabolism 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: 08 June 2018
By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary