ASTRAZENECA PLC
Form 6-K
April 27, 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 April 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 __

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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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
AZ: positive CHMP for Tagrisso first-line nsclc

27 April 2018 12:30 BST

TAGRISSO RECEIVES POSITIVE EU CHMP OPINION FOR 1ST-LINE TREATMENT OF EGFR-MUTATED NON-SMALL CELL LUNG CANCER

Recommendation based on FLAURA trial data showing unprecedented median progression-free survival of 18.9 months for Tagrisso versus 10.2 months compared with current standard of care

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion, recommending a change to the terms of the Marketing Authorisation for Tagrisso (osimertinib) to include 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 recommendation is based on results from the Phase III FLAURA trial, which were presented at the European Society of Medical Oncology 2017 Congress and published in the New England Journal of Medicine.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "This positive recommendation acknowledges Tagrisso's potential as a new 1st-line standard of care for patients with EGFR-mutated NSCLC in Europe. It reflects the strength of the FLAURA data that show Tagrisso delivered a statistically-significant and clinically-meaningful improvement in progression-free survival over the EGFR-TKI comparator arm across all pre-specified patient subgroups, including those with or without central nervous system metastases."

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 were in line with those observed in prior clinical trials. Tagrisso was well tolerated, with fewer Grade 3 or higher adverse events (AEs) than with standard EGFR-TKIs (34% vs. 45%). In all patients, the most common adverse reactions were rash (58% [1.1% Grade ≥3] for Tagrisso vs. 78% [6.9% Grade ≥3] for the comparator arm), diarrhoea (58% [2.2% Grade ≥3] for Tagrisso vs. 57% [2.5% Grade ≥3] for the comparator arm) and dry skin (36% [<1% Grade ≥3] for Tagrisso vs. 36% [1.1% Grade ≥3] for the comparator arm).

The positive opinion from the CHMP will now be reviewed by the European Commission, which has the authority to approve medicines for the 28 EU member countries plus Iceland, Norway and Liechtenstein. Earlier this month, Tagrisso was approved in the US for the 1st-line treatment of patients with metastatic NSCLC whose tumours have EGFR mutations (exon 19 deletions or exon 21 L858R mutations). In addition to the EU, Tagrisso is under regulatory review in Japan for use in the 1st-line treatment setting with a decision anticipated in the second half of 2018. Other global health authority reviews and submissions are also 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 the US and Brazil 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: 27 April 2018

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