ASTRAZENECA PLC
Form 6-K
April 19, 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 __

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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

19 April 2018 07:00 BST

US FDA APPROVES TAGRISSO AS 1ST-LINE TREATMENT FOR EGFR-MUTATED NON-SMALL CELL LUNG CANCER

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

Tagrisso delivered unprecedented median progression-free survival of 18.9 months versus 10.2 months compared with current standard of care

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved Tagrisso (osimertinib) for the 1st-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) mutations, (exon 19 deletions or exon 21 L858R mutations), as detected by an FDA-approved test. The approval 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.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: "Today's FDA approval of Tagrisso in the 1st-line setting is an exciting milestone for patients and our company. Tagrisso delivered unprecedented median progression-free survival data across all pre-specified patient subgroups, including patients with or without CNS metastases, and could prolong the lives of more patients without their tumours growing or spreading."

Dr. Suresh S. Ramalingam, Principal Investigator of the FLAURA trial, from Winship Cancer Institute of Emory University, Atlanta, said: "The approval of osimertinib in the 1st-line setting represents a major advance in the treatment of patients with EGFR mutations and a significant change in the treatment paradigm. Osimertinib provides robust improvements in progression-free survival with no unexpected safety signals compared to the previous generation of EGFR inhibitors."

The FLAURA trial compared Tagrisso to current 1st-line EGFR tyrosine kinase inhibitors (TKIs), erlotinib or gefitinib, in previously-untreated patients with locally-advanced or metastatic EGFR-mutated (EGFRm) NSCLC. Tagrisso met the primary endpoint of progression-free survival (PFS) (see table below). PFS results with Tagrisso were consistent across all pre-specified patient subgroups, including in patients with or without central nervous system (CNS) metastases. Overall survival data were not mature at the time of the final PFS analysis.

FLAURA Efficacy Results According to Investigator Assessment

| | Tagrisso (N=279) | EGFR-TKI (gefitinib or erlotinib) (N=277) |
|---|---|---|
| Progression-Free Survival (PFS) | | |
| Median PFS | 18.9 months | 10.2 months |
| (95% confidence interval [CI]) | (15.2, 21.4) | (9.6, 11.1) |
| Hazard Ratio (95% CI) | 0.46 (0.37, 0.57) | |
| P-value | P < 0.0001 | |
| Objective Response Rate (ORR)* | | |
| ORR | 77% | 69% |
| (95% CI) | (71, 82) | (63, 74) |
| Complete response | 2% | 1% |

| | | |
|---|---|---|
| Partial response | 75% | 68% |
| Duration of Response (DoR)* | | |
| Median DoR | 17.6 months | 9.6 months |
| (95% CI) | (13.8, 22.0) | (8.3, 11.1) |

*Confirmed responses

Safety data for Tagrisso in the FLAURA trial were in line with those observed in prior clinical trials. Tagrisso was generally well tolerated, with Grade 3 or higher adverse events (AEs) occurring in 34% of patients taking TAGRISSO and 45% in the comparator arm. The most common adverse reactions (≥20%) in patients treated with Tagrisso were diarrhoea (58%), rash (58%), dry skin (36%), nail toxicity (35%), stomatitis (29%), fatigue (21%) and decreased appetite (20%).

In the US, Tagrisso is already approved for the 2nd-line treatment of patients with metastatic EGFRm NSCLC, whose disease has progressed on or after a 1st-line EGFR-TKI therapy and who have developed the secondary T790M mutation, as detected by an FDA-approved test. In 2017, Tagrisso was granted Breakthrough Therapy and Priority Review designations by the US FDA in the 1st-line treatment setting. Tagrisso is under regulatory review in the European Union and Japan for use in the 1st-line treatment setting with regulatory decisions anticipated in the second half of 2018.

Tagrisso received its first approval for 1st-line use based on the FLAURA data in Brazil in patients with metastatic EGFRm NSCLC on April 16, 2018

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 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 investigated 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 platform 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: 19 April 2018

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