ASTRAZENECA PLC
Form 6-K
November 28, 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 November 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 __

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-_____

28 November 2017 07:00 GMT

THE EUROPEAN MEDICINES AGENCY ACCEPTS REGULATORY SUBMISSION FOR TAGRISSO IN 1ST-LINE EGFR-MUTATED NON-SMALL CELL LUNG CANCER

Acceptance is based on positive Phase III FLAURA trial results

AstraZeneca today announced that the European Medicines Agency has accepted a variation to the Marketing Authorisation Application (MAAv) for Tagrisso (osimertinib), a third-generation, irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) with clinical activity against central nervous system (CNS) metastases, for the 1st-line treatment of adult patients with locally-advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have EGFR mutations (exon 19 deletions or exon 21 (L858R) substitution mutations).

The MAAv submission is based on data from the Phase III FLAURA trial, in which Tagrisso significantly improved progression-free survival (PFS) compared to current 1st-line EGFR-TKIs, erlotinib or gefitinib, in previously-untreated patients with locally-advanced or metastatic EGFRm NSCLC.

About NSCLC
Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-quarter 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 currently-available EGFR-TKIs, which block the cell-signalling pathways that drive the growth of tumour cells. However, tumours almost always develop resistance to EGFR-TKI treatment leading to disease progression. Approximately half of patients develop resistance to approved EGFR-TKIs such as gefitinib and erlotinib due to the resistance mutation, EGFR T790M.Tagrisso also targets this secondary mutation that leads to disease progression. There is also a need for medicines with improved CNS efficacy, since approximately 25% of patients with EGFR-mutated 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 more than 60 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 EGFR-mutated NSCLC. The trial was a double-blinded, randomised trial, 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 two 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 New Oncology as one of AstraZeneca's five 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 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: 28 November 2017
By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary