ASTRAZENECA PLC
Form 6-K
October 10, 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 October 2017

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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-_____

9 October 2017 07:00 BST

TAGRISSO GRANTED BREAKTHROUGH THERAPY DESIGNATION BY US FDA FOR THE 1ST-LINE TREATMENT OF PATIENTS WITH EGFR MUTATION-POSITIVE NON-SMALL CELL LUNG CANCER

Designation based on positive Phase III FLAURA trial results

Sixth Breakthrough Therapy Designation for an AstraZeneca New Oncology medicine

AstraZeneca today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for Tagrisso (osimertinib) for the 1st-line treatment of patients with metastatic epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC).

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The Breakthrough Therapy Designation acknowledges not only Tagrisso's potential as a 1st-line standard of care in advanced EGFR mutation-positive NSCLC, but also the significant need for improved clinical outcomes in this disease. The results of the FLAURA trial have the potential to redefine clinical expectations and offer new hope for patients who currently have a poor prognosis."

The FDA granted the BTD based on data from the Phase III FLAURA trial of Tagrisso versus standard-of-care EGFR tyrosine kinase inhibitor (TKI) therapy in previously-untreated patients with locally-advanced or metastatic EGFR mutation-positive NSCLC. In the trial, median progression-free survival was nearly double at 18.9 months for Tagrisso compared with 10.2 months for current 1st-line EGFR TKIs (erlotinib or gefitinib). Improvements were seen in all pre-specified subgroups, including patients with and without brain metastases. Tagrisso was well tolerated with a safety profile consistent with previous experience.

On 28 September 2017, the US National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology were updated to include the use of Tagrisso in the 1st-line treatment of patients with locally-advanced or metastatic EGFR mutation-positive NSCLC. The use of Tagrisso for the 1st-line treatment of patients with locally-advanced or metastatic EGFR mutation-positive NSCLC is not yet FDA approved. However, Tagrisso is currently approved in more than 50 countries, including the US, EU, Japan and China, as 2nd-line treatment for patients with advanced NSCLC who progress following treatment with an EGFR TKI due to the EGFR T790M resistance mutation.

This is the sixth BTD that AstraZeneca has received from the FDA for an oncology medicine since 2014. BTD is designed to expedite the development and regulatory review of new medicines that are intended to treat a serious condition and that have shown encouraging early clinical results, which demonstrate substantial improvement on a clinically-significant endpoint over available medicines and when there is significant unmet medical need.

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 EGFR-mutated 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 central nervous system (CNS) metastases. Tagrisso 40mg and 80mg once-daily oral tablets have been approved in more than 50 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 FLAURA
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 study, with 556 patients across 30 countries.

The primary endpoint of the trial was progression-free survival (PFS), and secondary endpoints included overall survival (OS), objective response rate (ORR), duration of response (DOR), disease control rate (DCR), safety, and measures of health-related quality of life (HRQoL).

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 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.

Media Relations		
Esra Erkal-Paler	UK/Global	+44 203 749 5638
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Gonzalo Viña	UK/Global	+44 203 749 5916
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations	
Thomas Kudsk Larsen	+44 203 749 5712

Craig Marks	Finance, Fixed Income, M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology	+1 240 477 3771
Christer Gruvris	Diabetes; Autoimmunity, Neuroscience & Infection	+44 203 749 5711
Nick Stone	Respiratory; Brilinta	+44 203 749 5716
US toll free		+1 866 381 7277

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: 09 October 2017

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