ASTRAZENECA PLC
Form 6-K
July 18, 2016

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 July 2016

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-_____

This announcement contains inside information

TAGRISSO MET PRIMARY ENDPOINT IN PHASE III 2ND-LINE LUNG CANCER TRIAL

Tagrisso demonstrated superior progression-free survival compared to standard platinum-based chemotherapy, with a safety profile consistent with previous trials

First randomised trial to evaluate the clinical benefit of an EGFR T790M
medicine, and data are consistent with those supporting Tagrisso approvals

AstraZeneca today announced that the Phase III AURA3 trial met its primary end point, demonstrating superior progression-free survival (PFS) compared to standard platinum-based doublet chemotherapy. The AURA3 randomised trial assessed the efficacy and safety of Tagrisso as a 2nd-line treatment in more than 400 patients with EGFR T790M mutation-positive, locally-advanced or metastatic NSCLC, whose disease had progressed following 1st-line EGFR tyrosine kinase inhibitor (TKI) therapy. Tagrisso also demonstrated a safety profile consistent with previous trials.
In addition to PFS, the objective response rate (ORR), disease control rate (DCR) and duration of response (DoR) also achieved clinically meaningful improvement versus chemotherapy. A full evaluation of AURA3 data, including an analysis of overall survival (OS), is ongoing, and results will be presented at an upcoming medical meeting.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "These results confirm Tagrisso
as a meaningful alternative to benefit EGFR T790M lung cancer patients. The AURA3 results demonstrate the benefits of our science-led approach that enabled the rapid development of Tagrisso as a targeted treatment to address the most common cause of resistance to a first-generation EGFR-TKI for patients with metastatic EGFR-mutant lung cancer. We remain committed to exploring the potential of Tagrisso to further extend its reach and help meet patient need."

Tagrisso is one of the fastest development programmes ever, from start of clinical trials to approval in just over two and a half years . It was approved in the US, EU, Japan, Canada, Switzerland, Israel and Mexico as the first treatment for patients with EGFR T790M mutation-positive advanced NSCLC. Tagrisso is also approved in South Korea in the same indication. Eligibility for treatment with Tagrisso
is dependent on confirmation that the EGFR T790M mutation is present in the tumour .

AstraZeneca is committed to exploring the full potential of Tagrisso as monotherapy and in combination, for patients with lung cancer, including in adjuvant and locally-advanced/ metastatic 1st-line EGFRm settings .In addition, AstraZeneca is exploring
Tagrisso in NSCLC patients with and without brain metastases, and has presented encouraging data in a small cohort of patients with leptomeningeal disease.

About Non-Small Cell Lung Cancer (NSCLC)
Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths and more than breast, prostate and colorectal cancers combined. Patients who have the EGFRm form of NSCLC, which occurs in 10-15% of NSCLC patients in the US and Europe and 30-40% of NSCLC patients in Asia, 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 treatment, leading to disease progression. In approximately two-thirds of patients treated with approved EGFR-TKIs such as gefitinib and erlotinib, this resistance is caused by the secondary mutation, T790M.

About Tagrisso
Tagrisso (osimertinib, AZD9291) 80mg once-daily tablet is the first medicine indicated for the treatment of adult patients with locally-advanced or metastatic EGFR T790M mutation-positive NSCLC. Tagrisso is as an irreversible

EGFR inhibitor, born out of scientific exploration and engineered to combat the mechanism of resistance by targeting the T790M resistance mutation. Tagrisso is also being investigated in the adjuvant and metastatic 1st-line settings, including in patients with and without brain metastases, in leptomeningeal disease, and in combination with other treatments.

About AURA3

AURA3 compared the efficacy and safety of Tagrisso 80mg once daily and platinum-based doublet chemotherapy in 419 patients with EGFR T790M mutation-positive, locally-advanced or metastatic NSCLC whose disease had progressed on or after treatment with a previous EGFR-TKI. The trial was carried out in more than 130 locations worldwide, including the USA, Canada, Europe, China, Japan, Korea, Taiwan and Australia.

The primary endpoint of the trial was PFS, and secondary endpoints included OS, ORR, DoR, DCR, safety and measures of health-related quality of life (HRQoL).

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 6 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 six 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, the genetic drivers of cancer 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 - Respiratory and Autoimmunity, Cardiovascular and Metabolic Diseases, and Oncology. The Company is also active in inflammation, infection and neuroscience through numerous collaborations. 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

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Adrian Kemp
Company Secretary
AstraZeneca PLC

-ENDS-

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: 18 July 2016

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