ASTRAZENECA PLC
Form 6-K
August 09, 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 August 2016

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-_____

This announcement contains inside information

09 August 2016 07:00

ASTRAZENECA PROVIDES UPDATE ON PHASE III TRIAL OF SELUMETINIB IN NON-SMALL CELL LUNG CANCER

Selumetinib did not meet trial endpoint of
progression-free survival in KRASm NSCLC patients

AstraZeneca today announced results from the Phase III SELECT-1 trial of the MEK 1/2 inhibitor, selumetinib, in combination with docetaxel chemotherapy as 2nd-line treatment in patients with KRAS mutation-positive (KRASm) locally-advanced or metastatic non-small cell lung cancer (NSCLC).

The results showed that the trial did not meet its primary endpoint of progression-free survival (PFS), and selumetinib did not have a significant effect on overall survival (OS). The adverse event profiles for selumetinib and docetaxel were consistent with those seen previously.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "A randomised Phase II trial showed promising activity of selumetinib in combination with docetaxel in patients with KRAS mutation-positive lung cancer. It is disappointing for patients that these results have not been confirmed in Phase III. We expect to present data at a forthcoming medical meeting. We remain committed to further developing treatments in the lung cancer setting, such as our immunotherapy combinations and targeted EGFR treatments."

SELECT-1 is an international trial with 510 randomised patients in over 200 centres. Patients received either selumetinib (75mg, orally, twice daily) or placebo in combination with docetaxel (intravenously, 75mg/m2, on day one of every 21-day cycle).

Selumetinib is being explored as a treatment option in registration-enabling studies in patients with differentiated thyroid cancer where the treatment received Orphan Drug Designation, and patients with neurofibromatosis type 1, a genetic disorder that causes tumours to grow along nerve tissue.1

About KRASm non-small cell lung cancer
KRAS is one of the most common genetic mutations in NSCLC, and is found in 30% of patients.2 Adenocarcinomas make up the majority of cases with KRAS mutations, which are less common in squamous cell NSCLC.2,3
KRAS mutations are associated with activation of the RAS-ERK signalling pathway, which drives tumour growth.3

About selumetinib (AZD6244, ARRY-142886)
Selumetinib is an oral, potent and highly selective MEK 1/2 inhibitor. MEK 1/2 are critical components of the RAS-ERK pathway, activation of which is implicated in driving cancer growth and progression, including in patients with KRASm NSCLC.4,5

AstraZeneca acquired exclusive worldwide rights to selumetinib from Array BioPharma Inc. (NASDAQ: ARRY) in 2003.

In May 2016, selumetinib was granted Orphan Drug Designation by the US Food and Drug Administration (FDA) for adjuvant treatment of patients with stage III or IV differentiated thyroid cancer (DTC), and AstraZeneca is committed to exploring its full potential, including in Phase III trials in patients with DTC and in a US National Cancer Institute-sponsored Phase II registration trial in patients with paediatric neurofibromatosis type 1.

About SELECT-1
SELECT-1 (NCT01933932) is a Phase III, double-blind, randomised, placebo-controlled trial. It is designed to assess the efficacy and safety of selumetinib (75 mg twice daily, given orally on a continuous schedule) in combination with

docetaxel (75 mg/m2 intravenously on day 1 of every 21-day cycle), compared with matched placebo in combination with docetaxel (same schedule) in 510 patients receiving 2nd-line treatment for KRASm locally advanced or metastatic NSCLC (stage IIIB-IV), confirmed by central testing of tumour tissue using the cobas® KRAS Mutation Test (Roche Molecular Systems).3
The primary endpoint is PFS, and secondary endpoints include OS, objective response rate (ORR), duration of response (DoR), and safety and tolerability.3

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 main 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.

References

1 U.S. National Library of Medicine. Genetics Home Reference: neurofibromatosis type 1. Published 5 July 2016. Available at https://ghr.nlm.nih.gov/condition/neurofibromatosis-type-1. Accessed 6 July 2016.

2 Dearden S et al. Mutation incidence and coincidence in non small-cell lung cancer: meta-analyses by ethnicity and histology (mutMap). Ann Oncol. 2013 Sep;24(9):2371-6.

3 Jänne PA et al. Study design and rationale for a randomized, placebo-controlled, double-blind study to assess the efficacy and safety of selumetinib in combination with docetaxel as second-line treatment in patients with KRAS-mutant advanced non-small cell lung cancer (SELECT-1). Clin Lung Cancer 2016 Mar;17(2):e1-4

4 Davies BR, et al. AZD6244 (ARRY-142886), a potent inhibitor of mitogen-activated protein kinase/extracellular signal-regulated kinase kinase 1/2 kinases: mechanism of action in vivo, pharmacokinetic/pharmacodynamic relationship, and potential for combination in preclinical models. Mol Cancer Ther 2007;6:2209-19.

5 Roberts PJ, Stinchcombe TE. KRAS Mutation: Should We Test for It, and Does It Matter? J Clin Oncol 2013;31(8):1112-21.

CONTACTS

Media Enquiries

Neil Burrows	UK/Global	+44 203 749 5637
Vanessa Rhodes	UK/Global	+44 203 749 5736
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations
UK
Thomas Kudsk Larsen +44 203 749 5712

Craig Marks	Finance, Fixed Income, M&A	+44 7881 615 764
Nick Stone	Respiratory & Autoimmunity	+44 203 749 5716
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	Infection & Neuroscience	+44 203 749 5711

US

Lindsey Trickett	Cardiovascular & Metabolic Diseases	+1 240 543 7970
Mitchell Chan	Oncology	+1 240 477 3771
Toll free		+1 866 381 7277

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: 09 August 2016

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