ASTRAZENECA PLC
Form 6-K
October 22, 2013

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 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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 INITIATES PHASE III CLINICAL PROGRAMME FOR SELUMETINIB, A TREATMENT IN DEVELOPMENT FOR PATIENTS WITH ADVANCED OR METASTATIC NON-SMALL-CELL LUNG CANCER

AstraZeneca today announced the first patient randomised in the Phase III clinical programme for selumetinib, an oral, potent, selective MEK inhibitor, being investigated as second-line therapy in patients with advanced or metastatic non-small-cell lung cancer (NSCLC) whose tumours are KRAS mutation-positive.

The SELumetinib Evaluation as Combination Therapy-1 (SELECT-1) study is a randomised, double-blind, placebo-controlled study that will evaluate the safety and efficacy of selumetinib plus docetaxel as a second line therapy in locally advanced or metastatic KRAS mutation-positive NSCLC. The study is designed to evaluate Progression Free Survival (PFS) and Overall Survival (OS). SELECT-1 will be the largest prospective study ever conducted in this patient population, a genetic sub-type of lung cancer associated with poor prognosis and limited treatment options.

The decision to progress selumetinib to Phase III studies in NSCLC followed the results from Study 16, a randomised Phase II study evaluating the combination of selumetinib with standard of care docetaxel against docetaxel alone in KRAS-mutation positive NSCLC. Study 16 demonstrated a high and durable response rate of 37.2% vs 0% ($p<0.0001$), translating into a statistically significant improvement in progression free survival (PFS) of 5.3 vs 2.1 months (HR 0.58, $p<0.014$).

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

Antoine Yver, Vice President and Head of Oncology in AstraZeneca's Global Medicines Development unit said: "To our knowledge, SELECT-1 will be the first Phase III study to investigate whether a MEK inhibitor in combination with chemotherapy is superior to chemotherapy alone in KRAS mutation positive advanced or metastatic non-small cell lung cancer. This is an area of pressing clinical need, and our decision to progress selumetinib was based on Phase II results, which showed promising clinical activity in this group of patients."

NOTES TO EDITORS

About the SELECT-1 clinical programme
The SELECT-1 trial will include 220 centres globally and enroll 634 patients, who will be randomized in a ratio of 1:1 to receive either selumetinib (75mg, orally, twice daily) or matching placebo in combination with docetaxel (intravenously, 75mg / m2, on day one of every 21 day cycle).

About selumetinib
Selumetinib is an oral, potent, selective MEK inhibitor, which has been shown to be effective as monotherapy and in combination with standard chemotherapy regimens in Phase I and Phase II clinical studies across a range of solid tumours, which support the development of selumetinib in patients with MEK-dependent cancers.

MEK is part of the MAPK pathway which is frequently activated in cancer, and is elevated in many different solid tumour types, including those featuring the KRAS mutation, which is present in 20% of human cancers and 20-30% of NSCLC tumours.

AstraZeneca is also investigating the potential for selumetinib in several types of MEK-dependent cancers. A Phase II study assessing the efficacy and tolerability of selumetinib combined with radioactive iodine (RAI) as adjuvant therapy in patients with differentiated thyroid cancer with high risk of recurrence started in August 2013, and a further Phase II study assessing the clinical efficacy and tolerability in combination with dacarbazine in patients with metastatic uveal melanoma is planned to start in late 2013.

About Array BioPharma
Array BioPharma Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer. Array is evolving into a late-stage development company and currently expects significant progress toward generating data to support our upcoming Phase 3 / pivotal trial decisions. Novartis began Phase 3 trials evaluating Array-invented MEK162 in patients with NRAS-mutant melanoma in July 2013 and in patients with BRAF-mutant melanoma in October 2013. In addition, Array began a Phase 3 trial evaluating MEK162 in patients with low-grade serous ovarian cancer under the license agreement with Novartis in June 2013. AstraZeneca began a pivotal trial with Array-invented selumetinib in patients with thyroid cancer in May 2013 and began a Phase 3 trial in patients with non-small cell lung cancer in October 2013. Two other wholly-owned drugs, ARRY-520 and ARRY-614, are also approaching Phase 3 or pivotal trial decisions which are expected by the end of 2013. For more information on Array, please go to www.arraybiopharma.com.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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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22 October 2013

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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: 22 October 2013

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