ASTRAZENECA PLC
Form 6-K
September 04, 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 September 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 OLAPARIB, A TREATMENT IN DEVELOPMENT FOR PATIENTS WITH BRCA MUTATED OVARIAN CANCER

As a result of the initiation of this programme, a pre-tax impairment charge of $285 million will be reversed and the asset restored to our balance sheet in the third quarter of 2013. The reversal of this impairment charge will be excluded from core earnings

4 September 2013

AstraZeneca today announced enrollment of the first patient in the Phase III clinical programme for olaparib, an innovative oral poly ADP ribose polymerase (PARP) inhibitor being investigated for the treatment of BRCA mutated ovarian cancer. The Phase III SOLO (Study of OLaparib in Ovarian cancer) programme is designed to determine the benefit, by progression free survival, of olaparib as a maintenance monotherapy in BRCA mutated ovarian cancer patients who are in complete or partial response following platinum-based chemotherapy in the first line setting (SOLO 1), and in the relapsed setting (SOLO 2).

The SOLO 1 study is being conducted in collaboration with the Gynecologic Oncology Group and the SOLO 2 study with the European Network of Gynaecological Oncological Trial Groups. Both trials are randomised, double blind, placebo controlled studies that utilise the tablet formulation of olaparib at a dose of 300mg twice daily.

The initiation of these studies is based on the subgroup analysis by BRCA mutation status of the Phase II maintenance study in relapsed ovarian cancer, announced at the American Society of Clinical Oncology (ASCO) 2013 Congress, which demonstrated olaparib's potential as a maintenance treatment for platinum-sensitive relapsed patients with BRCA mutated ovarian cancer.

As a result of the initiation of this programme, the pre-tax impairment charge of $285 million, which was incurred in December 2011 following the decision not to progress olaparib into phase III development, will be reversed in the third quarter of 2013. The reversal of this impairment charge will be excluded from Core earnings per share.

Antoine Yver, Vice President and Head of Oncology in AstraZeneca's Global Medicines Development unit said: "This is a significant milestone for olaparib, and further evidence of AstraZeneca's commitment to invest in distinctive science in our core therapy areas, with a particular focus on high unmet need. We feel olaparib has real potential to significantly improve treatment decisions for this group of patients who currently have limited options, and to become the next important product in our growing oncology portfolio."

BRCA1 and BRCA2 are human genes that belong to a type of genes known as tumour suppressors. Mutation of these genes has been linked to hereditary breast and ovarian cancer and a woman's risk of developing breast and/or ovarian cancer is greatly increased if she inherits a BRCA1 or BRCA2 mutation. Only 15 per cent of ovarian cancers are found before the cancer has spread outside the ovary. Despite advances in treatment and diagnosis, for patients with ovarian cancer that has spread beyond the ovary the five-year survival rate is well below 50 per cent.

About the SOLO 1 trial

The SOLO 1 trial looks at olaparib as a maintenance monotherapy in patients with BRCA mutated ovarian cancer following first line platinum based chemotherapy. The aim of the trial is t o determine the benefit of olaparib maintenance monotherapy (compared to placebo) in patients with BRCA mutated high risk ovarian cancer who are in clinical complete response or partial response following first line platinum based chemotherapy, by assessment of progression free survival. Patients must have completed first line platinum based chemotherapy to qualify for the trial. SOLO 1 (GOG-3004) is in collaboration with the Gynecologic Oncology Group. More details can be found at ClinicalTrials.gov (identifier: NCT01844986) .

About the SOLO 2 trial
The SOLO 2 trial looks at olaparib as a maintenance monotherapy in patients with BRCA mutated platinum sensitive relapsed ovarian cancer. The aim of the trial is to determine the benefit of olaparib maintenance monotherapy (compared to placebo) in patients with BRCA mutated relapsed ovarian cancer that are in complete or partial response following platinum based chemotherapy, by assessment of progression free survival. Patients must have completed at least two lines of platinum based chemotherapy to qualify for the trail. SOLO 2 (ENGOT-Ov21) is in collaboration with the European Network of Gynaecological Oncological Trial Groups. More details can be found at ClinicalTrials.gov (identifier: NCT01874353).

About olaparib
Olaparib is an innovative, potential first-in-class oral poly ADP ribose polymerase (PARP) inhibitor that has been shown in pre-clinical models to exploit DNA repair pathway deficiencies to preferentially kill cancer cells. This mode of action gives olaparib the potential for activity in a range of tumour types with DNA repair deficiencies. PARP is associated with a range of tumour types, in particular with breast and ovarian cancers.

The Phase III SOLO studies follow the announcement at the American Society of Clinical Oncology (ASCO) 2013 Congress of the subgroup analysis of the Phase II study of olaparib maintenance treatment in platinum-sensitive relapsed ovarian cancer patients, which identified patients with BRCA mutated ovarian cancer as the population receiving the greatest treatment benefit from olaparib maintenance therapy, significantly prolonging progression free survival compared with placebo (progression free survival HR 0.18; 95% CI 0.11-0.31; p<0.00001, median progression free survival 11.2 vs 4.3 months in favour of the group of patients with BRCAm disease).

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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4 September 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: 04 September 2013 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary