ASTRAZENECA PLC
Form 6-K
October 24, 2014

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 2014

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-_____

LYNPARZA™ (OLAPARIB) RECEIVES POSITIVE CHMP OPINION IN THE EU FOR THE MAINTENANCE TREATMENT OF BRCA-MUTATED PLATINUM SENSITIVE RELAPSED OVARIAN CANCER

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the marketing authorisation of Lynparza™ (olaparib) as monotherapy for the maintenance treatment of adult patients with platinum sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Olaparib is a poly ADP-ribose polymerase (PARP) inhibitor that exploits tumour DNA repair pathway deficiencies to preferentially kill cancer cells.

Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We are delighted that the CHMP has recommended Lynparza as a first-in-class treatment option for women with BRCA-mutated ovarian cancer and we look forward to the European Commission's decision once it completes its review. We are committed to investigating the full potential of olaparib and have a number of studies underway in multiple tumour types including breast and gastric cancer."

The positive CHMP opinion was based on the results from Study 191, a Phase II clinical trial that evaluated the efficacy and safety of olaparib compared to placebo in platinum sensitive relapsed high grade serous ovarian cancer patients. The study showed that olaparib maintenance therapy significantly prolonged progression free survival (PFS) compared with placebo in patients with BRCA-mutated ovarian cancer- median PFS 11.2 months vs. 4.3 months (PFS HR=0.18; 95% CI 0.10-0.31; p<0.0001). The most common adverse events associated with olaparib monotherapy to date were generally mild to moderate and included nausea, vomiting, fatigue and anaemia.

Harpal Kumar, Chief Executive, Cancer Research UK, said: "We're delighted that olaparib has received a positive opinion from the CHMP, particularly given the early role Cancer Research UK scientists played in discovering and developing PARP inhibitors as a new generation of drugs that exploit the weaknesses cancer cells have in repairing damaged DNA. If approved, olaparib could offer new hope to women with advanced ovarian cancer and this illustrates how our partnerships with AstraZeneca are helping us to accelerate our efforts to beat cancer through new treatments for patients."

The CHMP's positive opinion on olaparib will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The final decision will be applicable to all 28 European Union member countries plus Iceland, Norway and Liechtenstein. If approved, Lynparza will be the first PARP inhibitor available in these markets for the treatment of platinum sensitive relapsed BRCA-mutated high grade serous ovarian cancer.

1 Ledermann J, et al. Olaparib maintenance therapy in patients with platinum-sensitive relapsed serous ovarian cancer: a preplanned retrospective analysis of outcomes by BRCA status in a randomised Phase II trial. The Lancet Oncology 2014. http://dx.doi.org/10.1016/S1470-2045(14)70228-1

About ovarian cancer
In Europe, ovarian cancer is the fifth most commonly diagnosed cancer in women and the sixth leading cause of cancer death among women, mainly because it is often diagnosed late and has an extremely poor prognosis. Women with BRCA1 or BRCA2 mutations have an increased risk of developing ovarian cancer; the lifetime risk for ovarian cancer is up to 40% in individuals who harbour these mutations.

About olaparib
Olaparib is an innovative, investigational, potential first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that exploits tumour DNA repair pathways deficiencies to selectively induce cancer cell death. This mode of action gives olaparib the potential for activity in a range of tumour types with DNA repair deficiencies.

Study 19, a randomised, double-blinded Phase II clinical trial of 265 patients, evaluated the efficacy and safety of olaparib compared to placebo in PSR high grade serous ovarian cancer patients.

Olaparib is currently being investigated in Phase III trials for the treatment of BRCAm ovarian cancer patients who are in complete or partial response following platinum-based chemotherapy in the relapsed and first-line settings and is one of a number of compounds being investigated by AstraZeneca for ovarian cancer. Phase III studies in gastric cancer and adjuvant and metastatic BRCAm breast cancers are also underway.

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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24 October 2014

-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: 24 October 2014 By: /s/ Adrian Kemp
Name: Adrian Kemp

Title: Company Secretary