ASTRAZENECA PLC
Form 6-K
June 26, 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 June 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-_____

FDA ADVISORY COMMITTEE VOTES ON ACCELERATED APPROVAL FOR INVESTIGATIONAL MEDICINE OLAPARIB

AstraZeneca today announced that the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 11 to 2 that current evidence from clinical studies does not support an accelerated approval for use of olaparib as a maintenance treatment for women with platinum-sensitive relapsed ovarian cancer who have the germline BRCA (gBRCA) mutation, and who are in complete or partial response to platinum-based chemotherapy.

The ODAC provides the FDA with independent, expert advice and recommendations, however the final decision regarding approval is made by the FDA.

AstraZeneca filed the US regulatory submission for olaparib in February 2014. The FDA granted priority review status for the NDA in April and set a Prescription Drug User Fee Act (PDUFA) action date of 3 October 2014.

Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca said: "Patients with germline BRCA-mutated serous ovarian cancer have few options available to treat this disease. We are disappointed with today's recommendation, and strongly believe that olaparib has the potential to provide patients with relapsed BRCA-mutated ovarian cancer and their doctors with a much-needed treatment option. We look forward to continuing to work with the FDA as it evaluates the Advisory Committee recommendation and completes its review of the application. In the meantime, we are continuing with our Phase III clinical programme to evaluate the benefit of olaparib for this patient population. We aim to have completed this study by the end of 2015."

The NDA filing was based on a subgroup analysis of Phase II data recently published in Lancet Oncology1. The Phase II study was a randomised, double-blind, placebo-controlled trial which evaluated olaparib versus placebo as maintenance treatment in platinum-sensitive relapsed serous ovarian cancer patients who had received previous treatment with at least two platinum regimens and were in a maintained partial or complete response following their last platinum regimen. The study met its primary endpoint of progression-free survival by Response Evaluation Criteria in Solid Tumours guidelines. A pre-defined subgroup analysis was conducted in patients who have germline BRCA mutations.

In addition, as part of its commitment to bring the potential benefits of olaparib to ovarian cancer patients, AstraZeneca has initiated and is committed to complete the Phase III SOLO programme, designed to evaluate the efficacy and safety of olaparib as a maintenance monotherapy in ovarian cancer patients who have a BRCA mutation who are in complete or partial response following platinum-based chemotherapy in the relapsed setting.

1 Ledermann JA, 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 study. The Lancet Oncology 2014. http://dx.doi.org/10.1016/S1470-2045(14)70228-1.

About olaparib
Olaparib is an innovative, investigational, potential first-in-class oral poly ADP ribose polymerase (PARP) inhibitor that exploits tumour DNA repair pathway 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.

PARP is a key enzyme in one of the DNA repair pathways in human cells. Inhibition of PARP results in a build-up of DNA damage in the cell, requiring repair via an alternative pathway called Homologous Recombination repair (HR). Cancer cells that already have a HR pathway deficiency (HRD) are limited in their ability to repair their DNA, overloading them with DNA damage and causing them to die. A number of abnormalities can cause HRD in cancer cells including BRCA gene mutations. HRD is associated with a range of tumor types, in particular with breast and

ovarian cancers.

In addition to ovarian cancer, olaparib is being investigated in combination with chemotherapy in second-line gastric cancer in the GOLD study, while Phase III studies evaluating olaparib in adjuvant and metastatic breast cancer with BRCA mutations have recently been initiated.

About ovarian cancer
Ovarian cancer is the eighth most commonly diagnosed cancer in women and the seventh leading cause of cancer death among women worldwide, mainly because it is often diagnosed late and has an extremely poor prognosis. For the 75% of ovarian cancer patients whose cancer has spread by the time of diagnosis, the five-year survival rate is less than 50%, so there is a real need for additional therapies beyond current standard of care, which is platinum-based chemotherapy.

Women with BRCA1 or BRCA2 mutations have an increased risk of developing ovarian cancer, and the course of their disease is similar to that of the overall patient population. Up to 40% of patients with platinum-sensitive relapsed ovarian cancer harbour a BRCA mutation, which is the most common cause of HRD.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization 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

CONTACTS

Media Enquiries
Esra Erkal-Paler +44 20 7604 8030 (UK/Global)
Vanessa Rhodes +44 20 7604 8037 (UK/Global)
Ayesha Bharmal +44 20 7604 8034 (UK/Global)
Michele Meixell +1 302 885 2677 (US)
Jacob Lund +46 8 553 260 20 (Sweden)

Investor Enquiries
Karl Hård +44 20 7604 8123 mob: +44 7789 654364
Colleen Proctor + 1 302 886 1842 mob: +1 302 357 4882
Anthony Brown +44 20 7604 8067 mob: +44 7585 404943
Jens Lindberg +44 20 7604 8414 mob: +44 7557 319729

26 June 2014

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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: 26 June 2014

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