ASTRAZENECA PLC
Form 6-K
December 18, 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 December 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™ APPROVED IN THE EUROPEAN UNION AS FIRST-IN-CLASS TREATMENT FOR ADVANCED BRCA-MUTATED OVARIAN CANCER

AstraZeneca today announced that the European Commission (EC) has granted Marketing Authorisation for Lynparza™ (olaparib) capsules (400mg twice daily) as the first therapy 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 complete response or partial response 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. It is the first PARP inhibitor to be approved for patients with platinum-sensitive relapsed BRCA-mutated ovarian cancer. Patients will be identified through a validated diagnostic test.

"We are delighted to be able to bring this much needed treatment to patients with BRCA-mutated ovarian cancer whose options are currently very limited. Today's approval marks a significant milestone in the development of the next generation of targeted medicines," said Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca. "We are committed to bringing new treatments to the patients who need them most and today's news marks only the first of what we hope will be a number of indications in which Lynparza has the potential to transform the lives of cancer patients, including those with breast, pancreatic and gastric cancers."

The EC decision is applicable to all 28 EU member states as well as Norway, Iceland and Liechtenstein. The approval of olaparib was based on data from Study 191, a Phase II clinical trial that evaluated its efficacy and safety 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 Hazard Ratio = 0.18; 95% Confidence Interval 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.

Professor Steve Jackson, scientist at the University of Cambridge, whose research established the basis for olaparib and its clinical potential said: "It is wonderful to learn that olaparib is set to become a licensed drug and will therefore soon become available to advanced ovarian cancer sufferers. I also look forward to learning the results of ongoing trials exploring olaparib's potential for the treatment of other cancers. Today's announcement highlights how, by collaborating with a partner such as AstraZeneca, basic academic research, such as that carried out by the research team at the University of Cambridge, can lead to major medical developments."

"It is fantastic news that Lynparza will now be available for women with advanced relapsed BRCA-mutated ovarian cancer," said Dr John Green, Senior Lecturer, Institute of Translational Medicine, University of Liverpool and Chair, European Network of Gynaecological Cancer Advocacy Groups (ENGAGe). "This is a devastating disease which has a profound impact on patients and their families. Women with a BRCAmutation are especially at risk and there has been a significant need for new treatment options with novel modes of action. The development of a targeted treatment like Lynparza is an excellent example of pioneering research being translated into a treatment that has the potential to transform the lives of patients."

1Ledermann 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 2 trial. Lancet Oncology. 2014. 15:852-861.

Additional commentary
Harpal Kumar, chief executive of Cancer Research UK, said: "It's great news that the European Commission has approved the use of olaparib within the European Union, especially when Cancer Research UK scientists played a crucial role in discovering and developing this new generation of cancer drugs. This drug offers new hope to women with advanced ovarian cancer by targeting the weaknesses cancer cells have in repairing damaged DNA. With clinical trial results showing this treatment has potential in other types of cancer, we hope there will be more good news in the

future. Our partnerships with AstraZeneca are helping us to bring more new treatments to patients, accelerating our efforts to beat cancer sooner."

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

In addition to ovarian cancer, AstraZeneca will investigate the full potential of olaparib in multiple tumour types, with Phase III studies in second line gastric cancer, BRCA-mutated pancreatic cancer and adjuvant and metastatic BRCA-mutated breast cancers underway.

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 by which time the patient has an extremely poor prognosis. For the 61% of ovarian cancer patients whose cancer has metastasised by the time of diagnosis, the five-year survival rate is only 27%.

Up to 15% of women with ovarian cancer have a BRCAmutation, which is the most common cause of homologous repair deficiency. In BRCA-mutated tumour cells, homologous recombination is defective and DNA double-strand break repair is forced to occur via error-prone pathways, which can lead to genomic instability and cell death.

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

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)
Jacob Lund	+46 8 553 260 20 (Sweden)

Investor Enquiries

Thomas Kudsk Larsen	+44 20 7604 8199	mob: +44 7818 524185
Karl Hård	+44 20 7604 8123	mob: +44 7789 654364
Eugenia Litz	+44 20 7604 8233	mob: +44 7884 735627
Christer Gruvris	+44 20 7604 8126	mob: +44 7827 836825

18 December 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: 18 December 2014

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