ASTRAZENECA PLC
Form 6-K
January 19, 2018

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 January 2018

Commission File Number: 001-11960

AstraZeneca PLC

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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):

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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 PLC

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LYNPARZA APPROVED IN JAPAN FOR OVARIAN CANCER

19 January 2018 07:00 GMT

LYNPARZA RECEIVES APPROVAL IN JAPAN FOR THE TREATMENT OF ADVANCED OVARIAN CANCER

Lynparza is the first PARP inhibitor approved in Japan

Lynparza tablets approved as maintenance treatment for women with platinum-sensitive relapsed ovarian cancer regardless of BRCA mutation status

AstraZeneca and Merck & Co., Inc., Kenilworth, NJ, US (known as MSD outside the US and Canada) today announced that the Japanese Ministry of Health, Labour and Welfare has approved Lynparza (olaparib) tablets (300mg twice daily) for use as a maintenance therapy for patients with platinum-sensitive relapsed ovarian cancer, regardless of their BRCA mutation status, who responded to their last platinum-based chemotherapy. Lynparza is the first poly ADP-ribose polymerase (PARP) inhibitor to be approved in Japan.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: "We are proud to bring this important first-in-class treatment to women with platinum-sensitive relapsed ovarian cancer in Japan who currently have very few treatment options. The trials show that with Lynparza maintenance therapy, women with ovarian cancer can live longer without their disease worsening and Lynparza is well tolerated."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Today's decision is significant for Lynparza and, more importantly, for Japanese patients living with advanced ovarian cancer. Our global collaboration with AstraZeneca reinforces how our joint efforts can advance science for patients, and we look forward to working together to explore the potential of Lynparza across multiple tumour types."

The approval was granted on the basis of two randomised trials of Lynparza maintenance therapy for platinum-sensitive relapsed ovarian cancer, SOLO-2 and Study 19.

Table 1. Summary of key efficacy results from randomised trials:

Analysis		Reduction in the risk of disease progression or death (PFS)	Reduction in the risk of death (OS)
SOLO-2 [gBRCAm] n=295	Lynparza Placebo	70% (HR 0.30 [95% CI, 0.22-0.41], P<0.0001; median 19.1 vs 5.5 months by investigator-assessed analysis)	Data not yet mature
Study 19 [PSR OC*] n=265	Lynparza Placebo	65% (HR 0.35 [95% CI, 0.25-0.49], P<0.0001; median 8.4 vs 4.8 months)	27% (HR 0.73 [95% CI, 0.55-0.95]; median 29.8 vs 27.8 months)

*PSR = Platinum-sensitive recurrent ovarian cancer

In SOLO-2, the most common adverse drug reactions (≥20%) of any grade reported in patients in the Lynparza arm were nausea (66.7%), anaemia (39.0%), fatigue (29.7%), vomiting (25.6%), asthenia (24.1%) and dysgeusia (23.1%).

In Study 19, the most common adverse drug reactions (≥20%) of any grade reported in patients in the Lynparza arm were nausea (64.0%), fatigue (43.4%) and vomiting (21.3%).

Lynparza is also currently under review for use in unresectable or recurrent BRCA-mutated, HER2-negative breast cancer in Japan, with a decision expected in the second half of 2018 based upon a priority review.

About Ovarian Cancer in Japan
Worldwide, ovarian cancer is the seventh most-commonly diagnosed cancer and the eighth most-common cause of cancer deaths in women. In Japan, more than 9,000 women are diagnosed with ovarian cancer every year and the five-year survival rate is 58%, the lowest among all gynaecological cancers. In 2012, 4,758 women with ovarian cancer died, which represents one out of every two patients. As there is no cure for relapsed ovarian cancer, the primary aim of treatment is to slow progression of the disease for as long as possible and improving or maintaining a patient's quality of life.

About SOLO-2
SOLO-2 was a Phase III, randomised, double-blinded, multicentre trial designed to determine the efficacy of Lynparza tablets as a maintenance monotherapy compared with placebo, in patients with platinum-sensitive, relapsed or recurrent gBRCA-mutated ovarian, fallopian tube and primary peritoneal cancer. The trial, conducted in collaboration with the European Network for Gynaecological Oncological Trial Groups (ENGOT) and Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein (GINECO), randomised 295 patients with documented germline BRCA1 or BRCA2 mutations who had received at least two prior lines of platinum-based chemotherapy and were in complete or partial response. Eligible patients were randomised to receive 300mg Lynparza tablets twice daily or placebo tablets twice daily.

About Study 19
Study 19 was a Phase II, randomised, double-blinded, placebo-controlled, multicentre trial, which evaluated the efficacy and safety of Lynparza compared with placebo in relapsed, high-grade serous ovarian cancer patients. The trial randomised 265 patients regardless of BRCA mutation status and who had completed at least two courses of platinum-based chemotherapy and their most recent treatment regimen. Eligible patients were randomised to receive Lynparza maintenance monotherapy at a dose of 400mg per day or matching placebo.

About Lynparza (olaparib)
Lynparza is a first-in-class poly ADP-ribose polymerase (PARP) inhibitor and the first targeted treatment to potentially exploit tumour DNA damage response (DDR)-pathway deficiencies to preferentially kill cancer cells. Specifically, in vitro studies have shown that Lynparza-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes, resulting in DNA damage and cancer cell death.

Lynparza is being investigated in a range of DDR-deficient tumour types and is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DDR mechanisms in cancer cells.

About the AstraZeneca and MSD Strategic Oncology Collaboration
In July 2017, AstraZeneca and Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the United States and Canada, announced a global strategic oncology collaboration to co-develop and co-commercialise Lynparza, the world's first PARP inhibitor, and potential new medicine selumetinib, a MEK inhibitor, for multiple cancer types. The

collaboration is based on increasing evidence that PARP and MEK inhibitors can be combined with PD-L1/PD-1 inhibitors for a range of tumour types. Working together, the companies will develop Lynparza and selumetinib in combination with other potential new medicines and as a monotherapy. Independently, the companies will develop Lynparza and selumetinib in combination with their respective PD-L1 and PD-1 medicines.

About AstraZeneca in Oncology
AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly-growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020, and a broad pipeline of small molecules and biologics in development, we are committed to advance New Oncology as one of AstraZeneca's five Growth Platforms focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms - Immuno-Oncology, Tumour Drivers and Resistance, DNA Damage Response and Antibody-Drug Conjugates - and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

About AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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 and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

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: 19 January 2018

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