ASTRAZENECA PLC
Form 6-K
November 13, 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 November 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):

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 PLC

INDEX TO EXHIBITS

1.
US FDA accepts regulatory submission for Lynparza

12 November 2018 07:05 GMT

US FDA accepts regulatory submission for Lynparza maintenance therapy in newly-diagnosed, BRCA-mutated advanced ovarian cancer
and grants Priority Review

Approval would expand use of AstraZeneca and MSD's Lynparza to
patients in the 1st-line setting following platinum-based chemotherapy

First US regulatory submission acceptance for a PARP inhibitor
as a 1st-line maintenance treatment for advanced ovarian cancer

AstraZeneca and Merck & Co., Inc., Kenilworth, N.J., US (Merck: known as MSD outside the US and Canada) today announced that the US Food and Drug Administration (FDA) has accepted a supplemental New Drug Application (sNDA) for Priority Review for the use of Lynparza (olaparib) tablets as a maintenance treatment in patients with newly-diagnosed, BRCA-mutated (BRCAm) advanced ovarian cancer who were in complete or partial response following 1st-line standard platinum-based chemotherapy. A Prescription Drug User Fee Act (PDUFA) date is set for the first quarter of 2019.

This is the first US regulatory submission acceptance for a poly ADP-ribose polymerase (PARP) inhibitor in the 1st-line maintenance setting for advanced ovarian cancer, and if approved will be the fourth indication for Lynparza in the US.

This submission was based on positive results from the pivotal Phase III SOLO-1 trial. The trial showed a statistically-significant and clinically-meaningful improvement in progression-free survival (PFS) for Lynparza compared to placebo, reducing the risk of disease progression or death by 70% in patients with newly-diagnosed, BRCAm advanced ovarian cancer who were in complete or partial response to platinum-based chemotherapy (HR 0.30 [95% CI 0.23-0.41], p<0.001). Of those receiving Lynparza, 60% remained progression-free at 36 months compared to 27% of women in the placebo arm. These data were recently presented for the first time at the ESMO 2018 Congress (European Society for Medical Oncology) and published online in the New England Journal of Medicine.

Lynparza is currently approved in over 60 countries for the treatment of platinum-sensitive relapsed ovarian cancer regardless of BRCA status. It is also approved in several countries, including the US and Japan, for germline BRCAm HER2-negative metastatic breast cancer - regulatory reviews are underway in the EU, Japan and other markets.

About SOLO-1

SOLO-1 is a Phase III randomised, double-blinded, placebo-controlled, multicentre trial to evaluate the efficacy and safety of Lynparza tablets (300mg twice daily) as maintenance monotherapy compared with placebo, in newly-diagnosed patients with BRCAm advanced ovarian cancer following platinum-based chemotherapy. The trial randomised 391 patients with a deleterious or suspected deleterious BRCA1 or BRCA2 mutation who were in clinical complete or partial response following platinum-based chemotherapy. Patients were randomised (2:1) to receive Lynparza or placebo for up to two years or until disease progression (at the investigator's discretion). The primary endpoint was PFS and key secondary endpoints included time to second disease progression or death, time to first subsequent treatment and overall survival.

About Lynparza
Lynparza (olaparib) is a first-in-class PARP inhibitor and the first targeted treatment to potentially exploit DNA damage response (DDR) pathway deficiencies, such as BRCA mutations, 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 tested in a range of DDR-deficient tumour types.

Lynparza, which is being jointly developed and commercialised by AstraZeneca and MSD, is approved for advanced ovarian cancer and metastatic breast cancer and has been used in over 20,000 patients worldwide. Lynparza has the broadest and most advanced clinical trial development programme of any PARP inhibitor and AstraZeneca and MSD are working together to understand how it may affect multiple PARP-dependent tumours as a monotherapy and in combination across multiple cancer types. Lynparza is the foundation of AstraZeneca's industry-leading portfolio of potential new medicines targeting DDR mechanisms in cancer cells.

About ovarian cancer
Ovarian cancer is a leading cause of cancer death in women worldwide, with a five-year survival rate of 19%.[i] In 2018, there were over 295,000 new cases diagnosed and around 185,000 deaths.[ii] For newly-diagnosed advanced ovarian cancer, the primary aim of treatment is to delay progression of the disease for as long as possible and maintain the patient's quality of life with the intent of achieving complete remission or cure.[iii],[iv],[v],[vi]

About BRCA mutations
BRCA1 and BRCA2 are human genes that produce proteins responsible for repairing damaged DNA and play an important role in maintaining the genetic stability of cells. When either of these genes is mutated, or altered, such that its protein product either is not made or does not function correctly, DNA damage may not be repaired properly, and cells become unstable. As a result, cells are more likely to develop additional genetic alterations that can lead to cancer.

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. Working together, the companies will develop Lynparza and selumetinib in combination with other potential new medicines and as monotherapies. 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 Oncology as a key growth driver for AstraZeneca 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, Renal & Metabolism and Respiratory. 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

[i] American Cancer Society. Survival Rates for Ovarian Cancer, by Stage. Available at: https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html. Accessed: October 2018
[ii] Globocan 2018 http://gco.iarc.fr/
[iii] Moore K et al. Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. Presented at ESMO October 2018
[iv] Raja, F. A., Chopra, N. & Ledermann, J. A. Optimal first-line treatment in ovarian cancer. Ann. Oncol. Off. J. Eur. Soc. Med. Oncol. 23 Suppl 10, x118-127 (2012
[v] NHS Choices, Ovarian Cancer Accessed https://www.nhs.uk/conditions/ovarian-cancer/treatment/ in September 2018
[vi] Ledermann.et al. 2013. Newly diagnosed and relapsed epithelial ovarian carcinoma: ESMO Clinical Practice.

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: 12 November 2018

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