ASTRAZENECA PLC
Form 6-K
December 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 December 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.
FDA approves Lynparza as 1L maintenance therapy

19 December 2018 18:30 GMT

Lynparza approved by US FDA for 1st-line maintenance therapy in BRCA-mutated advanced ovarian cancer

AstraZeneca and MSD's Lynparza reduced the risk of disease progression or death by 70% compared to placebo following response to platinum-based chemotherapy

First PARP inhibitor approved in 1st-line maintenance for BRCAm 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 approved Lynparza for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy, as detected by an FDA-approved companion diagnostic test.

This is the first regulatory approval for a PARP inhibitor in the 1st-line maintenance setting for BRCAm advanced ovarian cancer. The approval was based on positive results from the pivotal Phase III SOLO-1 trial in which Lynparza reduced the risk of disease progression or death by 70percent in patients with 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<0.0001) compared to placebo following platinum-based chemotherapy. The safety profile of Lynparza was consistent with previous trials.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit, AstraZeneca, said: "Women with ovarian cancer are often first diagnosed with advanced disease, which is associated with poor outcomes. In SOLO-1, Lynparza in the first-line maintenance setting reduced the risk of disease progression or death by 70 percent for patients with BRCAm advanced ovarian cancer. Today's approval is a critical advancement and brings us closer to our goal of helping these patients achieve long-term remission."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "The expanded approval of Lynparza based upon the SOLO-1 trial has the potential to change medical practice and reinforces the importance of knowing a woman's BRCA status at diagnosis. We continue to work in collaboration with AstraZeneca on our overall goal of improving outcomes for patients."

In the SOLO-1 trial, with median 41 months of follow-up, the median progression-free survival (PFS) for patients treated with Lynparza was not reached compared to 13.8 months for patients treated with placebo. Sixty percent of patients receiving Lynparza remained progression-free at three years compared to 27 percent of patients receiving

placebo. The data from the SOLO-1 trial can be found in the 21 October 2018 online issue of the New England Journal of Medicine.

Kathleen Moore, co-principal investigator of the SOLO-1 trial and Associate Director for Clinical Research, Stephenson Cancer Center at The University of Oklahoma, Oklahoma City, Oklahoma, said: "SOLO-1 is truly a landmark trial in gynecologic cancer. This approval will likely change the way we treat women with BRCA-mutated advanced ovarian cancer. The ability to offer this important first-line maintenance treatment option to eligible patients may slow down or even stop the natural course of disease progression."

AstraZeneca and MSD are exploring additional trials in advanced ovarian cancer, including the ongoing GINECO/ENGOTov25 Phase III trial, PAOLA-1. This trial is testing the effect of Lynparzain combination with bevacizumab as a maintenance treatment for patients with newly-diagnosed advanced ovarian cancer, regardless of their BRCA status. Results are expected during the second half of 2019.

Financial considerations
Under the oncology collaboration with MSD and following this new approval for Lynparza, AstraZeneca will receive $70 million as Ongoing Externalisation Revenue.

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 patients with BRCAm advanced ovarian cancer following 1st-line platinum-based chemotherapy. The trial randomised 391 patients with a deleterious or suspected deleterious germline or somatic BRCA1 or BRCA2 mutation who were in clinical complete or partial response following platinum-based chemotherapy. Patients were randomized (2:1) to receive Lynparza or placebo for up to two years or until disease progression. Patients who had a partial response at two years were permitted to stay on therapy 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 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. Inhibition of PARP with Lynparza leads to the trapping of PARP bound to DNA single-strand breaks, stalling of replication forks, their collapse and the generation of DNA double-strand breaks and cancer cell death. Lynparza is being tested in a range of tumour types with defects and dependencies in the DDR.

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: 19 December 2018

By: /s/ Adrian Kemp

Name: Adrian Kemp
Title: Company Secretary