ASTRAZENECA PLC
Form 6-K
December 20, 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.
Lynparza meets primary endpoint in SOLO-3 trial

20 December 2018 07:05 GMT

Lynparza meets primary endpoint in Phase III SOLO-3 trial for the treatment of relapsed BRCA-mutated advanced ovarian cancer

AstraZeneca and MSD's Lynparza significantly improved objective response rate compared to chemotherapy in platinum-sensitive relapsed patients who had two or more prior lines of chemotherapy

AstraZeneca and Merck & Co., Inc., Kenilworth, N.J., US (Merck: known as MSD outside the US and Canada) today announced positive results from the randomised, open-label, controlled, Phase III SOLO-3 trial of Lynparza (olaparib) tablets in 266 patients with relapsed ovarian cancer after two or more lines of treatment. The trial was conducted as a post-approval commitment in agreement with the US Food and Drug Administration (FDA). This is the fourth Phase III trial to demonstrate a positive result for Lynparza. AstraZeneca and MSD now plan to discuss these results with the FDA.

Results from the trial showed BRCA-mutated (BRCAm) advanced ovarian cancer patients treated with Lynparza following two or more prior lines of chemotherapy demonstrated a statistically-significant and clinically-meaningful improvement in the primary endpoint of objective response rate (ORR) and the key secondary endpoint of progression-free survival (PFS) compared to chemotherapy. The safety and tolerability profile of Lynparza was consistent with previous trials.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "We are very excited about SOLO-3, which is the first Phase III trial for a PARP inhibitor to demonstrate a positive result versus chemotherapy in advanced ovarian cancer where effective options are needed. We look forward to sharing the full results at a forthcoming medical meeting."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Following on the US approval of Lynparza as first-line maintenance therapy for certain patients with BRCAm advanced ovarian cancer, the results of SOLO-3 further reinforce the efficacy of Lynparza in relapsed patients with gBRCAm advanced ovarian cancer following multiple lines of chemotherapy."

About SOLO-3
SOLO-3 is a Phase III randomised, open-label, controlled, multicentre trial to evaluate the efficacy and safety of Lynparza tablets following two or more prior lines of chemotherapy. The trial randomised 266 patients with a deleterious or suspected deleterious BRCA1 or BRCA2 mutation. Eligible patients were randomised (2:1) to receive Lynparza 300mg tablets twice daily or physician's choice single-agent chemotherapy (paclitaxel, topotecan, pegylated liposomal doxorubicin or gemcitabine). The primary endpoint was ORR by blinded independent central

review and key secondary endpoints included progression-free survival, time to second disease progression or death 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: 20 December 2018

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