ASTRAZENECA PLC
Form 6-K
April 29, 2019

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 April

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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 receives positive EU CHMP opinion for 1st

29 April 2019 07:00 BST

Lynparza receives positive EU CHMP opinion for 1st-line
maintenance treatment of BRCA-mutated advanced ovarian cancer

AstraZeneca and MSD's Lynparza is the only PARP inhibitor to demonstrate
an improvement in progression-free survival for patients in this setting

AstraZeneca and MSD Inc., Kenilworth, N.J., US (MSD: known as Merck & Co., Inc. inside the US and Canada) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion, recommending Lynparza(olaparib) as a 1st-line maintenance treatment of BRCA-mutated advanced ovarian cancer.

The recommendation is for the use of Lynparza tablets as a maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Dave Fredrickson, Executive Vice President, Oncology, said: "There remains a significant unmet need in the treatment of advanced ovarian cancer as 70% of women globally relapse within the first three years after their initial treatment. The results of SOLO-1 demonstrate the potential of using Lynparza earlier in the treatment pathway as a maintenance therapy, and reinforce the importance of identifying a patient's BRCA mutation status as soon as they are diagnosed."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Women with advanced ovarian cancer need and deserve new treatment options. In the SOLO-1 trial, Lynparza demonstrated a significant progression-free survival benefit as maintenance treatment for patients with advanced BRCA-mutated ovarian cancer following response to first-line platinum-based chemotherapy. If approved, this expanded indication could change the way women in Europe with BRCA-mutated advanced ovarian cancer are treated."

The positive opinion is based on data from the pivotal Phase III SOLO-1 trial which showed that Lynparza reduced the risk of disease progression or death by 70% vs. placebo following response to platinum-based chemotherapy (HR 0.30 [95% CI 0.23-0.41], p<0.001). Of those patients receiving Lynparza, 60.4% remained progression-free at 36 months vs. 26.9% of women in the placebo arm.

Lynparza is currently approved in 64 countries, including those in the EU, for the maintenance treatment of platinum-sensitive relapsed ovarian cancer regardless of BRCA status. It is approved in the US as 1st-line

maintenance treatment of BRCAm advanced ovarian cancer following response to platinum-based chemotherapy. It is also approved in 38 countries, including the US, countries in the EU and Japan, for germline BRCAm HER2-negative metastatic breast cancer previously treated with chemotherapy; in the EU this includes locally advanced breast cancer. Regulatory reviews are underway in other jurisdictions for both ovarian cancer and breast cancer.

About SOLO-1
SOLO-1 was 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 complete or partial clinical response following platinum-based chemotherapy.

Patients were randomised (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 progression-free survival (PFS) and key secondary endpoints included time to second disease progression or death, time to first subsequent treatment and overall survival.

The data were presented on 21 October 2018 at the Presidential Symposium of the ESMO 2018 Congress in Munich, Germany and published simultaneously online in the New England Journal of Medicine.

Summary of PFSi,ii

	Lynparza (n=260)	Placebo (n=131)
Number of patients with event (%)iii	102 (39)	96 (73)
Median PFS (in months)	Not reached	13.8
Hazard ratio (95% CI)	0.30 (0.23-0.41)	
P-value	p<0.001	

i Investigator-assessed
ii Median (interquartile range) duration of follow-up 40.7 months (34.9-42.9) for Lynparza and 41.2 months (32.2-41.6) for placebo
iii Analysis was done at 50.6% maturity

The SOLO-1 safety profile was in line with that observed in prior clinical trials. The most common adverse events (AEs) ≥ 20% were nausea (77%), fatigue (63%), vomiting (40%), anaemia (39%) and diarrhoea (34%). The most common ≥ Grade 3 AEs were anaemia (22%) and neutropenia (9%). Some 71% of patients on Lynparza remained on the recommended starting dose. Additionally, 88% of patients on Lynparza continued treatment without an AE-related discontinuation.

About ovarian cancer
Ovarian cancer is a leading cause of cancer death in women worldwide, with a five-year survival rate of 19%.1 In 2018, there were over 295,000 new cases diagnosed and around 185,000 deaths.2 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.3,4,5,6

About BRCA mutations
Breast cancer susceptibility genes 1/2 (BRCA1 and BRCA2) are human genes that produce proteins responsible for repairing damaged DNA and play an important role 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 Lynparza
Lynparza (olaparib) is a first-in-class PARP inhibitor and the first targeted treatment to block DNA damage response (DDR) in cells/tumours harbouring a deficiency in homologous recombination repair (HRR), such as mutations in BRCA1 and/or BRCA2. 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. On 26 February 2019, AstraZeneca and MSD announced that Lynparza became the first PARP inhibitor to demonstrate benefit in germline BRCAm metastatic pancreatic cancer in the Phase III POLO trial.

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 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 one of AstraZeneca's four 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, 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 astrazeneca.com and follow us on Twitter@AstraZeneca.

Media Relations		
Gonzalo Viña		+44 203 749 5916
Rob Skelding	Oncology	+44 203 749 5821
Rebecca Einhorn	Oncology	+1 301 518 4122

Matt Kent	BioPharma	+44 203 749 5906
Jennifer Hursit	Other	+44 203 749 5762
Christina Malmberg Hägerstrand	Sweden	+46 8 552 53 106
Michele Meixell	US	+1 302 885 2677
Investor Relations		
Thomas Kudsk Larsen		+44 203 749 5712
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	BioPharma (cardiovascular, metabolism)	+44 203 749 5711
Nick Stone	BioPharma (respiratory, renal)	+44 203 749 5716
Josie Afolabi	Other medicines	+44 203 749 5631
Craig Marks	Finance, fixed income	+44 7881 615 764
Jennifer Kretzmann	Corporate access, retail investors	+44 203 749 5824
US toll-free		+1 866 381 72 77

Adrian Kemp
Company Secretary
AstraZeneca PLC

References

1. 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: March 2019
2. Globocan 2018 http://gco.iarc.fr/
3. Moore K et al. Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. Presented at ESMO October 2018
4. 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)
5. NHS Choices, Ovarian Cancer Accessed https://www.nhs.uk/conditions/ovarian-cancer/treatment/ in September 2018
6. 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: 29 April 2019

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