ASTRAZENECA PLC
Form 6-K
March 15, 2017

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 March 2017

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.

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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

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15 March 2017 07:00GMT

LYNPARZA PHASE III SOLO-2 DATA DEMONSTRATE PROGRESSION-FREE SURVIVAL BENEFIT IN BRCA-MUTATED OVARIAN CANCER AS MAINTENANCE THERAPY

Lynparza reduced risk of disease progression by 70% with an investigator-assessed progression-free survival of 19.1 months vs 5.5 months with placebo

Blinded independent central review showed impressive progression-free survival of 30.2 months vs 5.5 months with placebo

Lynparza tablets demonstrated a safety profile generally consistent with previous studies, including a low incidence of haematological toxicity

AstraZeneca today presented results from the Phase III SOLO-2 trial demonstrating a significant improvement in progression-free survival (PFS) in germline BRCA-mutated (gBRCA), platinum-sensitive, relapsed ovarian cancer patients treated with
Lynparza (olaparib) tablets (300mg twice daily) compared with placebo in the maintenance setting. The trial met its primary endpoint of investigator assessed PFS (HR 0.30; 95% CI 0.22 to 0.41; P<0.0001; median 19.1 months vs 5.5 months).

PFS as measured by Blinded Independent Central Review (BICR) evaluation, a pre-specified analysis supporting the primary endpoint, demonstrated a median PFS of 30.2 months vs 5.5 months for placebo, representing an improvement of 24.7 months (HR 0.25; 95% CI 0.18-0.35; P<0.0001).

Additionally, a statistically-significant benefit in time to second progression or death (PFS2) was also seen in patients treated with
Lynparza (HR 0.50; 95% CI 0.34 to 0.72; P=0.0002; median not reached vs 18.4 months) compared with placebo, as well as improvements in other key secondary endpoints.

Progression-Free Survival by investigator and BICR assessment:

Analysis		Median progression-free survival, months	Hazard ratio
Investigator-assessed analysis	Lynparza	19.1	0.30 (95% CI, 0.22-0.41), P<0.0001
	Placebo	5.5	
Blinded Independent Central Review	Lynparza	30.2	0.25 (95% CI, 0.18-0.35), P<0.0001
	Placebo		

5.5

These results, presented at the Society of Gynecologic Oncology Annual Meeting on Women's Cancer in National Harbor, USA, build upon prior data in this setting, demonstrating the benefit of Lynparza as a maintenance therapy in relapsed ovarian cancer.

Eric Pujade-Lauraine, Head of the Women Cancers and Clinical Research Department at Hôpitaux Universitaires Paris Centre, site Hôtel-Dieu, AP-HP and Principal Investigator of SOLO-2, said: "Today's results are very encouraging, as they build upon previous trials examining Lynparza in platinum-sensitive relapsed BRCA-mutated ovarian cancer. Most importantly, patients were able to maintain quality of life while experiencing an impressive delay in disease progression, demonstrating the benefits of Lynparza tablets for these women whose cancer is often difficult to treat."

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We are extremely pleased with the results from SOLO-2, which support the potential benefit of Lynparza tablets as a maintenance therapy for patients with relapsed ovarian cancer. The tablet formulation may offer patients a reduced pill burden for Lynparza and a safety profile that is generally consistent with previous trials. We will work with regulatory authorities to make Lynparza tablets available to patients as quickly as possible."

The safety profile for patients treated with Lynparza tablets during the trial was consistent to those observed with the currently-approved capsule formulation. Any adverse events (AE) Grade ≥3 were reported in 36.9% of patients treated with Lynparza and in 18.2% of patients who received placebo. The most common non-haematological AEs reported at a frequency of ≥20% were nausea (75.9% [grade ≥3, 2.6%]), fatigue/asthenia (65.6% [grade ≥3, 4.1%]), and vomiting (37.4% [≥3, 2.6%]).

The most common haematological AEs reported in the Lynparza arm versus placebo were anaemia (43.6% [grade ≥3, 19.5%]), neutropenia (19.5% [grade ≥3, 5.1%]), and thrombocytopenia (13.8% [grade ≥3, 1.0%]).

The 300mg twice-daily tablet dose reduces the pill burden for patients from sixteen capsules to four tablets per day.

NOTES TO EDITORS

About SOLO-2
SOLO-2 was a Phase III, randomised, double-blind, 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 (BRCAm) ovarian 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 2 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 Lynparza
Lynparza (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour DNA damage response (DDR) pathway deficiencies to preferentially kill cancer cells. It is approved by regulatory authorities in the EU and US for the treatment of women with BRCAm ovarian cancer. Lynparza is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DNA damage response (DDR) mechanisms in cancer cells. In a previous study Lynparza capsules were shown to result in a significant improvement in PFS compared to placebo in platinum-sensitive, relapsed ovarian cancer (PSR OC) patients (HR 0.35; 95% CI 0.25-0.49; p <0.0001) as well as in the subgroup of patients whose tumours harbour BRCA mutations (HR 0.18; 95%

CI 0.10-0.31; p <0.0001).

About ENGOT
ENGOT (European Network for Gynaecological Oncological Trial groups) is a research network of the European Society of Gynaecological Oncology (ESGO) and was founded in 2007. Currently, ENGOT consists of 19 cooperative groups from 15 European countries. ENGOT's ultimate goal is to bring the best treatment to gynaecological cancer patients through the best science, and enabling every patient in every European country to access a clinical trial. ENGOT coordinates and promotes multinational clinical trials within Europe on patients with gynaecological cancer. This coordination is particularly relevant for academic clinical trials, translational research, research on rare diseases, and for clinical trials sponsored by the industry.

About GINECO
GINECO (Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein) is the French Cooperative Group in Oncology labelled by INCA (Institut National du Cancer or French NCI) for developing and conducting gynaecological and advanced breast cancer clinical trials at the national and international level. The network is nationwide with 700 specialized investigators belonging to more than 150 public or private oncology units. The GINECO group was founded in 1993 and is member of international consortia such as ENGOT and GCIG (Gynecologic Cancer InterGroup). GINECO was the ENGOT leading group for SOLO-2 trial.

About AstraZeneca in ovarian cancer
Worldwide, ovarian cancer is the 7th most commonly diagnosed cancer1 and the 8th most common cause of cancer death in women.2 The risk of developing ovarian cancer is increased in women with specific inherited genetic abnormalities, including BRCA mutations. AstraZeneca is committed to the continued development of our R&D portfolio for ovarian cancer, with a focus on improved care for all patients, including the development of targeted therapies for patients with specific gene mutations such as BRCA.

About AstraZeneca in Oncology
AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly growing portfolio of new medicines that have the potential to transform patients' lives and the Company's future. With at least 6 new medicines to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, we are committed to advancing New Oncology as one of AstraZeneca's six 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, the genetic drivers of cancer 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 main therapy areas - Oncology, Cardiovascular & Me
tabolic 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

References

1. Cancer Research UK. Ovarian cancer incidence statistics. Available at: http://www.cancerresearchuk.org/cancer-info/cancerstats/types/ovary/incidence/uk-ovarian-cancer-incidence-statistics. Last accessed June 2016.
2. Cancer Research UK. Ovarian cancer mortality statistics. Available at: http://www.cancerresearchuk.org/cancer-info/cancerstats/types/ovary/mortality/ Last accessed June 2016.

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: 15 March 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary