ASTRAZENECA PLC
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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 August 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.

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):

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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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This announcement contains inside information

17 August 2017 20:05 BST

LYNPARZA RECEIVES ADDITIONAL AND BROAD
APPROVAL IN THE US FOR OVARIAN CANCER

Lynparza's new tablet formulation approved as maintenance treatment for women
with platinum-sensitive recurrent ovarian cancer regardless of BRCA-mutation status

Lynparza tablets also indicated in BRCA-mutated ovarian cancer beyond the third-line setting

Newly-approved tablet formulation means improved patient convenience

AstraZeneca and Merck & Co., Inc., (Merck: known as MSD outside the U.S. and Canada) today announced that the US Food and Drug Administration (FDA) has granted approval for the PARP inhibitor, Lynparza (olaparib), as follows:

New use of Lynparza as a maintenance treatment for recurrent, epithelial ovarian, fallopian tube or primary peritoneal adult cancer who are in response to platinum-based chemotherapy, regardless of BRCA status;

New use of Lynparza tablets (2 tablets twice daily) as opposed to capsules (8 capsules twice daily);

Lynparza tablets also now indicated (conversion from the current accelerated approval) for the use in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, AstraZeneca, said: "Physicians have almost three years of clinical experience with Lynparza on the market and we are now pleased to bring this important medicine, in a new tablet formulation, to a broader group of women. Today's approvals validate more than 10 years of dedicated research behind Lynparza, the world's first PARP inhibitor, which now provides oncologists with the greater flexibility for use in terms of treatment settings. It builds on our recently-announced collaboration with Merck, which aims to further increase the number of treatment options available to patients."

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 the SOLO-2 trial, one of the trials supporting the approval, said: "Today's approval is welcome news for US patients with ovarian cancer, who are now able to benefit from treatment with olaparib irrespective of their BRCA-mutation status. This latest regulatory milestone underscores the breadth and depth of clinical data on olaparib, and not only demonstrates its efficacy as maintenance therapy, but adds to the data presented earlier this year showing sustained quality of life for patients undergoing treatment for this serious disease."

Roger M. Perlmutter, President of Merck Research Laboratories, said: “We congratulate AstraZeneca on the approval of these new indications and the new dosage form and schedule for Lynparza, an important therapeutic advance for many patients with ovarian cancer. This is a significant first regulatory event in our collaboration with AstraZeneca. We look forward to working with AstraZeneca in our global collaboration to bring this medicine with its new indications to patients.”

Two randomised trials supported the new approvals and the conversion of accelerated approval to full approval which was originally based on a single-arm trial:

SOLO-2 (n=295) confirmed the benefit of Lynparza in germline BRCA-mutated (gBRCAm) patients, demonstrating a 70% reduced risk of disease progression or death (HR 0.30 [95% CI, 0.22-0.41], P<0.0001) and improved progression-free survival (PFS) to 19.1 vs 5.5 months for placebo by investigator-assessed analysis.

Study 19 (n=265) showed that Lynparza reduced the risk of disease progression or death by 65% and improved PFS compared with placebo in patients of any BRCA status (HR 0.35 [95% CI, 0.25-0.49], P<0.0001; median PFS of 8.4 months vs 4.8 months for placebo). Additionally, patients in Study 19, treated with Lynparza as a maintenance therapy, had a median overall survival (OS) of 29.8 months vs 27.8 months for placebo (HR 0.73 [95% CI, 0.55-0.95]).

Table 1. Summary of key efficacy results from randomised trials:

Analysis		Reduction in the risk of disease progression or death (PFS)	Reduction in the risk of death (OS)
SOLO-2 [gBRCAm]	Lynparza Placebo	70% (HR 0.30 [95% CI, 0.22-0.41], P<0.0001)	Data not yet mature
Study 19 [PSR OC*]	Lynparza Placebo	65% (HR 0.35 [95% CI, 0.25-0.49], P<0.0001)	27% (HR 0.73 [95% CI, 0.55-0.95]

*PSR = Platinum-sensitive recurrent ovarian cancer

The most-common adverse events reported in 20% or more of patients across the SOLO-2 trial in the Lynparza arm were anaemia (44%), nausea (76%), vomiting (37%), diarrhoea (33%), fatigue/asthenia (66%), decreased appetite (22%), headache (25%), and dysgeusia (27%). The most-common Grade 3 or 4 adverse events were anaemia (20%), nausea (2.6%), vomiting (2.6%), diarrhoea (1.0%), fatigue/asthenia (4.1%), and headache (0.5%). Discontinuation of Lynparza resulting from adverse events was seen in 11% of patients. Dose interruptions of Lynparza due to an adverse reaction of any grade was 45%. Dose reductions of Lynparza due to an adverse reaction was 25%.

The most-common adverse events reported in 20% or more of patients across the Study 19 trial in the Lynparza arm were anaemia (23%), nausea (71%), vomiting (35%), diarrhoea (27%), fatigue (including asthenia) (63%), decreased appetite (21%), and headache (21%). The most-common Grade 3 or 4 adverse events were anaemia (7.4%), nausea (2.2%), vomiting (2.2%), diarrhoea (2.2%), and fatigue (including asthenia) (8.8%). Discontinuation of Lynparza resulting from adverse events was seen in 4% of patients. Dose interruptions of Lynparza due to an adverse reaction of any grade was 25%. Dose reductions of Lynparza due to an adverse reaction was 15%.

The full data from the SOLO-2 trial can be found in the 25 July 2017 publication of The Lancet Oncology.

Lynparza was first approved under the FDA’s Accelerated Approval programme in December 2014, as a capsule formulation, making it the first poly ADP-ribose polymerase (PARP) inhibitor approved. Since then, more than 3,000 advanced ovarian cancer patients have been treated with Lynparza capsules in its approved indication.

About SOLO-2

SOLO-2 was a Phase III, randomised, double-blinded, 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 ovarian, fallopian tube and primary peritoneal 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 Study 19
Study 19 was a Phase II, randomised, double-blinded, placebo-controlled, multicentre trial, which evaluated the efficacy and safety of Lynparza compared with placebo in relapsed, high-grade serous ovarian cancer patients, involving 82 sites across 16 countries. Patients received Lynparza maintenance monotherapy, at a dose of 400mg per day or matching placebo. Treatment continued until disease progression if toxicities were manageable.

About Lynparza
Lynparza 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 potential new medicines targeting DDR mechanisms in cancer cells. Lynparza tablets are currently being tested in combinations in a range of tumour types including breast, prostate, and pancreatic cancers.

About the AstraZeneca and Merck Strategic Oncology Collaboration
On 27 July 2017, AstraZeneca and Merck & Co., Inc., announced a global strategic oncology collaboration to co-develop and co-commercialise AstraZeneca's Lynparza, the world's first and leading PARP inhibitor, and potential new medicine selumetinib, a MEK inhibitor, for multiple cancer types. The collaboration is based on increasing evidence that PARP and MEK inhibitors can be combined with PDL-1/PD-1 inhibitors for a range of tumour types and is aimed at maximising the potential of Lynparza to become the preferred backbone of combination therapies. Working together, the companies will jointly develop Lynparza and selumetinib in combination with other potential new medicines and as a monotherapy. Independently, the companies will develop Lynparza and selumetinib in combination with their respective PD-L1 and PD-1 medicines.

About AstraZeneca in Ovarian Cancer
Worldwide, ovarian cancer is the 7th most-commonly diagnosed cancer and the 8th most-common cause of cancer death in women. 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 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 New Oncology as one of AstraZeneca's five 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 majority 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 & Metabolic 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

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: 17 August 2017

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