ASTRAZENECA PLC
Form 6-K
July 02, 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 July 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):

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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

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 approved in Japan for BRCAm breast cancer

02 July 2018 07:00BST

Lynparza approved in Japan for BRCA-mutated metastatic breast cancer

Lynparza is the first and only PARP inhibitor approved for use beyond ovarian cancer

Second approval in Japan for AstraZeneca and MSD's Lynparza

AstraZeneca and Merck & Co., Inc., Kenilworth, N.J., US (Merck: known as MSD outside the US and Canada) today announced that Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has approved Lynparza (olaparib) tablets for use in patients with unresectable or recurrent BRCA-mutated (BRCAm), human epidermal growth factor receptor 2 (HER2) negative breast cancer who have received prior chemotherapy. Patients are selected for therapy based on an approved companion diagnostic.

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: "Earlier this year, Lynparza became the first PARP inhibitor available in Japan for advanced ovarian cancer. Now patients in Japan with BRCA-mutated, metastatic breast cancer will also have the opportunity to benefit from Lynparza. This latest approval underlines our ongoing efforts to make Lynparza available across multiple cancers as quickly as possible to patients around the world."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Metastatic breast cancer is a complex disease with remaining unmet medical need. This approval is significant for breast cancer patients as the evaluation of BRCA mutations, in addition to hormone receptor and HER2 status, now becomes an important step in the management of the disease."

The approval is based on data from the randomised, open-label, Phase III OlympiAD trial, which tested Lynparza vs chemotherapy. Patients were selected for therapy based upon a confirmed BRCA mutation. In the trial, Lynparza significantly prolonged progression-free survival (PFS) compared with chemotherapy, reducing the risk of disease progression or death by 42% (HR 0.58; 95% CI 0.43-0.80; p=0.0009, median PFS was 7.0 months with Lynparza vs 4.2 months with chemotherapy).

Lynparza was generally well tolerated with the majority of adverse events (AEs) reported as mild to moderate with a lower rate of Grade 3 or higher AEs compared with chemotherapy (36.6% vs 50.5%). The most common AEs were nausea (50.2%), anaemia (32.2%) and fatigue (22.4%).

Lynparza is also approved in Japan as maintenance treatment for women with platinum-sensitive relapsed ovarian cancer, regardless of BRCA mutation status. In Japan, the co-promotion of Lynparza by both companies will begin on 1 July 2018.

About OlympiAD
OlympiAD was a randomised, open-label, multicentre Phase III trial assessing the efficacy and safety of Lynparza tablets (300 mg twice daily) compared to physician's choice of chemotherapy (capecitabine, eribulin, or vinorelbine) in 302 patients with HER2-negative metastatic breast cancer with germline BRCA1 or BRCA2 mutations, which are confirmed or suspected to be deleterious. The international trial was conducted in 19 countries across Europe, Asia,

North America and South America.

Patients in the OlympiAD trial had HER2-negative gBRCA1- or gBRCA2-mutated breast cancer, which was hormone-receptor positive (HR+) or triple negative, and received Lynparza for metastatic disease. Approximately half of the patients in the Lynparza and chemotherapy arm of the trial were HR+ (n=152), and approximately half were triple negative (n=150). Among the 205 patients treated with Lynparza, the median age was 44 years (range: 22 to 76). Before enrolment, patients had prior treatment with an anthracycline (unless contraindicated) and a taxane chemotherapy either in the neoadjuvant, adjuvant or metastatic setting and no more than two prior lines of chemotherapy for metastatic disease. HR+ patients had received at least one endocrine medicine or were not eligible for endocrine medicines. Prior treatments with endocrine medicines were not counted as prior lines of chemotherapy.

The primary endpoint of the trial was PFS as measured by a Blinded Independent Central Review. Secondary endpoints included overall survival, time to second progression or death, objective response rate, and effect on health-related quality of life.

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 breast cancer in Japan
In Japan, breast cancer is the fifth leading cause of death among women.[1] In Japanese women, breast cancer incidence peaks in the late forties, whereas in the US and Europe the peak incidence is in women over 60 years of age.[2] Despite more treatment options becoming available during the past three decades, there is currently no cure for patients diagnosed with metastatic (Stage IV) breast cancer.[3] In Japan, 5-year and 10-year relative survival rates for patients with Stage IV breast cancer are as low as 32.6% and 15.6%, respectively.[4] Therefore, the primary aim of treatment is to slow progression of the disease for as long as possible and improve or maintain a patient's quality of life.5

About Lynparza
Lynparza (olaparib) is the 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. Specifically, in vitro studies have shown that Lynparza-induced cytotoxicity may involve inhibition of PARP-enzymatic activity and increased formation of PARP-DNA complexes, resulting in DNA damage and cancer cell death. Lynparza is being tested in a range of DDR-deficient tumour types.

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. Lynparza has the broadest and most advanced clinical trial development programme of any PARP inhibitor and AstraZeneca and MSD are working together to deliver it as quickly as possible to more patients 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 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. 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

[1] IARC, Globocan population fact sheets, Japan. Accessed June 2018 from http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

[2] Kunichika M et al Cost of illness of breast cancer in Japan: trends and future projections. BMC Research Notes, 2015; 8: 539
[3] O'Shaughnessy J. Extending Survival with Chemotherapy in Metastatic Breast Cancer. The Oncologist 2005;10(3):20-29.
[4] Maeda S et al Efficacy and safety of eribulin as first to third line treatment in patients with advanced or metastatic breast cancer previously treated with anthracyclines and taxanes. The Breast, Vol 32, April 2017, Pg 66-72

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: 02 July 2018

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