ASTRAZENECA PLC
Form 6-K
April 03, 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 April 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-_____

INDEX TO EXHIBITS

1.
AZ AND MSD SUBMIT LYNPARZA FOR BREAST CANCER IN EU

3 April 2018 07:00 GMT

THE EUROPEAN MEDICINES AGENCY ACCEPTS REGULATORY SUBMISSION FOR LYNPARZA IN BRCA-MUTATED, HER2-NEGATIVE METASTATIC
BREAST CANCER

If approved, AstraZeneca and MSD's Lynparza would be the first PARP inhibitor to treat patients with breast cancer in Europe

AstraZeneca and Merck & Co., Inc., Kenilworth, N.J., US (Merck: known as MSD outside the US and Canada) today announced that the European Medicines Agency has validated for review the Marketing Authorisation Application (MAA) for Lynparza (olaparib) for use in patients with deleterious or suspected deleterious BRCA-mutated, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

This is the first regulatory submission for a poly ADP-ribose polymerase (PARP) inhibitor in breast cancer in Europe. If approved, the identification of a patient's BRCA status could become a critical step in the management of their disease alongside current consideration of their hormone receptor and HER2 status. The MAA includes data from the randomised, open-label, Phase III OlympiAD trial, which investigated Lynparza versus chemotherapy (physician's choice of capecitabine, eribulin or vinorelbine). In the trial, Lynparza significantly prolonged progression-free survival compared with chemotherapy and reduced the risk of disease progression or death by 42% (HR 0.58; 95% CI 0.43-0.80; P=0.0009 median 7.0 vs. 4.2 months).

In January 2018, Lynparza was approved by the US Food and Drug Administration for use in the treatment of BRCA-mutated HER2-negative metastatic breast cancer, becoming the first PARP inhibitor to be approved beyond ovarian cancer. Lynparza is available in nearly 60 countries and has been used to treat more than 20,000 patients. AstraZeneca and MSD are working together to bring Lynparza to more patients across multiple cancers.

About OlympiAD
OlympiAD is a global, randomised, open-label, multi-centre Phase III trial of 302 patients, assessing the efficacy and safety of Lynparza tablets (300 mg twice daily) compared to physician's choice of chemotherapy. 205 patients were randomised to receive Lynparza and 97 patients were randomised to receive chemotherapy.

Patients in the OlympiAD trial had germline BRCA-mutated, HER2-negative (hormone receptor-positive or triple negative) breast cancer and received Lynparza for treatment in the metastatic setting. Prior to enrolment, 71% of patients had received no more than two previous chemotherapy treatments for metastasised breast cancer and 28% of patients had received prior platinum-based chemotherapy. Also enrolled were patients with HR+ breast cancer who had received at least one endocrine therapy (adjuvant therapy or therapy for metastatic disease) and had disease progression during therapy unless they had disease for which the endocrine therapy was considered inappropriate.

About Metastatic Breast Cancer
Progesterone receptors (PR), estrogen receptors (ER) and HER2 receptors may be expressed on breast cancer cells. A patient's breast cancer will test either negative or positive for these three receptors. If a tumour tests positive for PR and/or ER, it is considered HR+. If a tumour tests negative for all three receptors, it is considered triple negative.

These receptors indicate which hormones or other proteins may be promoting growth of the cancer.

Metastatic Breast Cancer (MBC) is the most advanced stage of breast cancer (Stage IV), and occurs when cancer cells have spread beyond the initial tumour site to other parts of the body, outside of the breast and nearby lymph nodes.

Despite the increase in treatment options during the past three decades, there is currently no cure for patients diagnosed with MBC and only 26.9% of patients survive for five years after diagnosis. Thus, the primary aim of treatment is to slow progression of the disease for as long as possible, improving, or at least maintaining, a patient's quality of life.

Breast cancer is the most common cancer in women, with an estimated 1.67 million new cases diagnosed worldwide in 2012 alone - one in four of all cancer cases. Approximately 30% of women who are diagnosed with early breast cancer will go on to develop advanced disease.

About BRCA Mutations
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 was 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 trials 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, which has the broadest clinical development programme of any PARP inhibitor, is being investigated in a range of DDR-deficient tumour types, and is the foundation of AstraZeneca's industry-leading portfolio of compounds 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. The collaboration is based on increasing evidence that PARP and MEK inhibitors can be combined with PD-L1/PD-1 inhibitors for a range of tumour types. Working together, the companies will 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 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 personalized 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

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: 03 April 2018

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