ASTRAZENECA PLC
Form 6-K
October 18, 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 October 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):

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-_____

18 October 2017 07:00 BST

US FDA ACCEPTS REGULATORY SUBMISSION FOR
LYNPARZA IN METASTATIC BREAST CANCER AND

GRANTS PRIORITY REVIEW

Lynparza has the potential to offer a new treatment option for patients with germline BRCA-mutated, HER2-negative metastatic breast cancer

Regulatory submission acceptance is first for a PARP inhibitor beyond ovarian cancer

AstraZeneca and Merck & Co., Inc., (Merck: known as MSD outside the US and Canada) today announced that the US Food and Drug Administration (FDA) has accepted and granted priority review for a supplemental New Drug Application (sNDA) for the use of Lynparza (olaparib) tablets in patients with germline BRCA-mutated (gBRCAm), HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic settings. A Prescription Drug User Fee Act date is set for the first quarter of 2018.

This is the first submission for a poly ADP-ribose polymerase (PARP) inhibitor outside ovarian cancer and the third indication submission for Lynparza in the US. The sNDA is based on the positive results from the Phase III OlympiAD trial published in the New England Journal of Medicine.

Lynparza was first approved in December 2014 as a capsule formulation, making it the first ever PARP inhibitor to be approved. Since then, Lynparza has been used to treat more than 3,000 advanced ovarian cancer patients. Lynparza tablets are currently being tested in a range of tumour types including breast, prostate and pancreatic cancers.

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

About Lynparza (olaparib)

Lynparza was the first FDA-approved oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour DNA damage response (DDR) pathway deficiencies to potentially kill cancer cells. Specifically, in vitro studies have shown that olaparib-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 the foundation of AstraZeneca's industry-leading portfolio of potential new medicines targeting DDR mechanisms in cancer cells.

About Metastatic Breast Cancer
Approximately one in eight women will be diagnosed with breast cancer in the US, based on 2012 - 2014 data.[[i]] In 2017 this would amount to more than 250,000 women who will be diagnosed with breast cancer.[i] Despite treatment options increasing during the past three decades, there is currently no cure for patients diagnosed with metastatic breast cancer and the 5-year relative survival rate for this patient population is currently 26.9%.[i,[ii],[iii]] 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.[ii]

About Germline 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 is either not made or is faulty, DNA damage may not be repaired properly. As a result, cells are more likely to develop additional genetic alterations that can lead to cancer.[[iv]]

About the AstraZeneca and Merck Strategic Oncology Collaboration
On 27 July 2017, AstraZeneca and Merck & Co., Inc., announced a global strategic oncology collaboration to jointly develop and 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 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 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

[i] National Cancer Institute. Cancer Fact Sheet: Female Breast Cancer. Available at https://seer.cancer.gov/statfacts/html/breast.html Last accessed October 2017
[ii] American Cancer Society. Breast Cancer Facts & Figures 2015-2016. Available Online. Accessed October 2017.
[iii] American Cancer Society. Managing Cancer as a Chronic Illness. Available Online. Accessed October 2017.
[iv] National Cancer Institute. BRCA1 and BRCA2: Cancer Risk and Genetic Testing. Available Online. Accessed October 2017.

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: 18 October 2017

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