ASTRAZENECA PLC
Form 6-K
October 23, 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-_____

23 October 2017 07:00 BST

ASTRAZENECA AND MSD RAPIDLY ADVANCE LYNPARZA
IN JAPAN WITH A SECOND REGULATORY SUBMISSION

Potential to offer a new treatment option for patients with
germline BRCA-mutated, HER2-negative metastatic breast cancer

AstraZeneca and Merck & Co., Inc., Kenilworth, NJ, US (known as MSD outside the US and Canada) today announced that they have submitted a new drug application (NDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the use of Lynparza (olaparib) tablets in unresectable or recurrent BRCA-mutated breast cancer, with a decision expected in the second half of 2018.

The Japan NDA is based on the positive results from the Phase III OlympiAD trial published in the New England Journal of Medicine.

This is the second NDA for Lynparza in Japan where the medicine is currently under review for use in ovarian cancer, with a PMDA decision for this indication anticipated in the first half of 2018.

Lynparza tablets are currently being tested in a range of tumour types in addition to ovarian and breast, including 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 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 the foundation of AstraZeneca's industry-leading portfolio of potential new medicines targeting DDR mechanisms in cancer cells.

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.1

About Breast Cancer in Japan
In Japan, breast cancer is the fifth leading cause of death among women.2 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 age3-5. 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. In Japan, 5- and 10-year relative survival rates for patients with Stage IV breast cancer are as low as 32.6% and 15.6%, respectively.6 Therefore, the primary aim of treatment is to slow progression of the disease for as long as possible and improving or maintaining a patient's quality of life.7

About the AstraZeneca and MSD Strategic Oncology Collaboration
On 27 July 2017, AstraZeneca and Merck & Co., Inc., Kenilworth, NJ, US 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 PD-L1/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

1 National Cancer Institute. BRCA1 and BRCA2: Cancer Risk and Genetic Testing. Available Online. Accessed October 2017.
2 .National Cancer Institute: Cancer Information Services: Cancer death data calculated by demographic statistics (1985~2015) http://ganjoho.jp/data/professional/statistics/odjrh3000000hwsa-att/cancer_mortality(1958-2015).xls.
3.Toi M, Ohashi Y, Seow A, Moriya T, Tse G, Sasano H, Park BW, Chow LW, Laudico AV, Yip CH, Ueno E, Ishiguro H, Bando H. The Breast Cancer Working Group presentation was divided into three sections: the epidemiology, pathology and treatment of breast cancer. Jpn J Clin Oncol. 2010;40(Suppl 1):i13-8.
4. Iwasaki M, Tsugane S. Risk factors for breast cancer: epidemiological evidence from Japanese studies. Cancer Sci. 2011;102:1607-14.
5. Matsuda A, Matsuda T, Shibata A, Katanoda K, Sobue T, Nishimoto H, Japan Cancer Surveillance Research Group. Cancer incidence and incidence rates in Japan in 2007: a study of 21 population-based cancer registries for the Monitoring of Cancer Incidence in Japan (MCIJ) project. Jpn J Clin Oncol. 2013;43:328-36.
6. Ministry of Health, Labor and Welfare of Japan (2007) Survival rate surveillance (in Japanese). http://www.gunma-cc.jp/sarukihan/seizonritu/seizonritu2007.html. Accessed October 2017
7. O'Shaughnessy J. Extending Survival with Chemotherapy in Metastatic Breast Cancer. The Oncologist 2005;10(3):20-29.

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: 23 October 2017

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