ASTRAZENECA PLC
Form 6-K
October 16, 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 October 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-_____

AstraZeneca PLC

INDEX TO EXHIBITS

1.
FDA Orphan Drug for Lynparza in pancreatic cancer

16 October 2018 07:00 BST

US FDA grants Lynparza Orphan Drug Designation for pancreatic cancer

Fourth Orphan Drug Designation in the US 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 they were granted orphan drug designation (ODD) by the US Food and Drug Administration (FDA) for Lynparza (olaparib) for the treatment of pancreatic cancer.

Pancreatic cancer is a rare, life-threatening disease that accounts for about 3% of all cancers in the US.i Due to the late onset of symptoms, patients are often diagnosed after the cancer has progressed to locally advanced or metastatic stages of the disease.ii Five-year survival rates remain low in the US at 8.5%.iii

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer said: "Pancreatic cancer is an area of significant unmet medical need. This is especially true for patients with metastatic disease where the benefits of current treatment options are very limited."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, at MSD Research Laboratories, said: "Pancreatic cancer is a relatively less common, but life-threatening, form of cancer. The FDA granting Orphan Drug Designation is a positive step for patients with pancreatic cancer and continues to reinforce the importance of our collaboration in bringing Lynparza to more patients in need."

ODD status was granted for the treatment of ovarian cancer in October 2013. Earlier this year an amended ODD status was granted to include both fallopian tube and primary peritoneal cancers following the expanded US approval of Lynparza in August 2017 for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. The FDA grants ODD status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US.

The use of Lynparza in pancreatic cancer is being assessed in the ongoing Phase III POLO trial, which is testing Lynparza as maintenance monotherapy vs placebo in patients with germline BRCA-mutated metastatic pancreatic cancer whose disease has not progressed following 1st-line platinum-based chemotherapy. Results from the POLO trial are expected in the first half of 2019.

About the POLO Phase III trial
POLO is a Phase III, randomised, double-blinded, placebo-controlled trial to evaluate the efficacy and safety of Lynparza tablets (300 mg twice daily) as maintenance monotherapy compared with placebo, in patients with germline BRCA-mutated metastatic pancreatic cancer whose disease has not progressed following 1st-line platinum-based chemotherapy. The trial randomised 145 patients to receive Lynparza or placebo (3:2). The primary endpoint is progression-free survival.

About Lynparza
Lynparza (olaparib) 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 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, 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. 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 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. 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 American Cancer Society. Key statistics for pancreatic cancer. Available at: https://www.cancer.org/cancer/pancreatic-cancer/about/key-statistics.html. Accessed October 2018.
ii Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER website, April 2018.
iii Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER website, April 2018.

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: 16 October 2018

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