ASTRAZENECA PLC
Form 6-K
February 26, 2019

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 February 2019

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): _____

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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 significantly delayed disease progression

26 February 2019 07:00 GMT

Lynparza significantly delayed disease progression as 1st-line maintenance treatment in germline BRCA-mutated metastatic pancreatic cancer

Phase III POLO trial met its primary endpoint of progression-free survival

AstraZeneca and MSD's Lynparza is the first PARP inhibitor to demonstrate
benefit in gBRCAm metastatic pancreatic cancer in a Phase III trial

AstraZeneca and MSD Inc., Kenilworth, N.J., US (MSD: known as Merck & Co., Inc. inside the US and Canada) today announced positive results from the Phase III POLO trial.

Results from the trial showed a statistically-significant and clinically-meaningful improvement in progression-free survival (PFS) with Lynparza (olaparib) vs. placebo. The safety and tolerability profile of Lynparza was consistent with previous trials.

POLO is a randomised, double-blinded, placebo-controlled trial exploring the efficacy of Lynparzatablets as 1st-line maintenance monotherapy in patients with germline BRCA-mutated (gBRCAm) metastatic adenocarcinoma of the pancreas (pancreatic cancer) whose disease has not progressed on platinum-based chemotherapy.

Jose Baselga, Executive Vice President, Research and Development, Oncology, said: "This is the first positive Phase III trial of any PARP inhibitor in germline BRCA-mutated metastatic pancreatic cancer, a devastating disease with critical unmet need. The results of POLO provide further evidence of the clinical benefit of Lynparza across a variety of BRCA-mutated tumour types. We will discuss these results with global health authorities as soon as possible."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Trials like POLO demonstrate the shared commitment of MSD and AstraZeneca to assess treatments for difficult-to-treat cancers. The clinically-meaningful results of this trial potentially support the value of testing for germline BRCA mutations in patients with metastatic pancreatic cancer."

AstraZeneca and MSD plan to present the full data from the trial at a forthcoming medical meeting.

About POLO
POLO is a Phase III randomised, double-blinded, placebo-controlled, multicentre trial of Lynparzatablets (300mg twice daily) as maintenance monotherapy vs. placebo. The trial randomised 154 patients with gBRCAm metastatic pancreatic cancer whose disease had not progressed on 1st-line platinum-based chemotherapy. Patients were

randomised (3:2) to receive Lynparza or placebo until disease progression. The primary endpoint was PFS and key secondary endpoints included overall survival, time to second disease progression, overall response rate, disease control rate and health-related quality of life.

About Lynparza
Lynparza (olaparib) is a first-in-class PARP inhibitor and the first targeted treatment to block DNA damage response in cells/tumours harbouring a deficiency in homologous recombination repair (HRR), such as mutations in BRCA1 and/or BRCA2. Inhibition of PARP with Lynparza leads to the trapping of PARP bound to DNA single-strand breaks, stalling of replication forks, their collapse and the generation of DNA double-strand breaks and cancer cell death. Lynparza is being tested in a range of PARP-dependent tumour types with defects and dependencies in the DDR.

Lynparza, which is being jointly developed and commercialised by AstraZeneca and MSD, is approved for multiple indications in advanced ovarian cancer and metastatic breast cancer and has been used in over 20,000 patients worldwide. Lynparza has the broadest and most advanced clinical trial development programme of any PARP inhibitor, and AstraZeneca and MSD are working together to understand how it may affect multiple PARP-dependent tumours as a monotherapy and in combination 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 pancreatic cancer
Pancreatic cancer is the 12th most common cancer worldwide,1 with 466,000 new cases in 2018 alone.1 Germline BRCA-mutated pancreatic cancer accounts for five to seven percent of all cases globally.2 With the worst survival rate of the most common cancers,3 it is the 4th leading cause of cancer death,4 and less than seven percent of patients survive more than five years after diagnosis.3 Early diagnosis of pancreatic cancer is difficult, as often there are no symptoms until it is too late.5 Around 80% of patients are diagnosed at the metastatic stage.6

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 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. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter@AstraZeneca.


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Adrian Kemp
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AstraZeneca PLC


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2. Holter S et al. Journal of Clinical Oncology. 2015; 33; 3124-3129
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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: 26 February 2019

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