

ASTRAZENECA PLC
Form 6-K
June 27, 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 June 2018

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

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 ☒ 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 ☒

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: significant PFS 1st-line ovarian cancer

This announcement contains inside information
27 June 2018 07:00 BST

Lynparza significantly delays disease progression in Phase III
1st-line SOLO-1 trial for ovarian cancer

Lynparza met primary endpoint of progression-free survival in women with BRCA-mutated advanced ovarian cancer and showed a safety profile consistent with previous trials

AstraZeneca and MSD's Lynparza is the only PARP inhibitor to demonstrate significant activity in the 1st-line maintenance setting

AstraZeneca and Merck & Co., Inc., Kenilworth, N.J., US (Merck: known as MSD outside the US and Canada) today announced positive results from the randomised, double-blinded, placebo-controlled, Phase III SOLO-1 trial of Lynparza (olaparib) tablets.

Women with BRCA-mutated (BRCAm) advanced ovarian cancer treated 1st-line with Lynparza maintenance therapy had a statistically-significant and clinically-meaningful improvement in progression-free survival compared to placebo. The safety and tolerability profile of Lynparza was consistent with previous trials. Based upon these data, AstraZeneca and MSD plan to initiate discussions with health authorities regarding regulatory submissions.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "For the first time, we see a significant and clinically-impactful improvement in progression-free survival in the 1st-line maintenance setting for women with BRCA-mutated ovarian cancer treated with a PARP inhibitor. The SOLO-1 data reinforce the importance of knowing BRCA status at diagnosis, as this may enable women with BRCA-mutated ovarian cancer to receive Lynparza earlier. We would like to thank the investigators, hospitals and most of all the patients who took part in this trial, without whom medical advancements would not be possible."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Building on the strong data we've seen with Lynparza to date, the data from SOLO-1 reinforces Lynparza's ability to provide meaningful disease control with a well-characterised safety and tolerability profile. We look forward to presenting the full data set for SOLO-1 at a future medical meeting and working with regulatory authorities to bring Lynparza to women with ovarian cancer in the 1st-line maintenance setting as quickly as possible."

Additionally, the ongoing GINECO/ENGOTov25 Phase III trial, PAOLA-1, is testing the effect of Lynparza in combination with bevacizumab as a 1st-line maintenance treatment in women with newly-diagnosed advanced ovarian

cancer, regardless of their BRCA status. Results are expected in 2019.

About SOLO-1

SOLO-1 is a Phase III randomised, double-blinded, placebo-controlled, multicentre trial to evaluate the efficacy and safety of Lynparza tablets as 1st-line maintenance monotherapy compared with placebo, in patients with BRCAm advanced ovarian cancer. The trial randomised 391 patients with a deleterious or suspected deleterious BRCA1 or BRCA2 mutation who were in clinical complete or partial response following platinum-based chemotherapy. Eligible patients were randomised (2:1) to receive Lynparza 300mg tablets twice daily or placebo tablets twice daily. The primary endpoint was progression-free survival and key secondary endpoints included time to second disease progression or death and overall survival.

About ovarian cancer

Worldwide, ovarian cancer is the seventh most common cancer and the eighth leading cause of cancer death in women. The five-year survival rate for ovarian cancer worldwide is 30-40%. In 2012, there were nearly 239,000 new cases diagnosed and around 152,000 deaths. For newly diagnosed advanced ovarian cancer, the primary aim of treatment is to delay progression of the disease for as long as possible and maintain the patient's quality of life with the intent of achieving complete remission or cure.

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 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 is being tested in a range of DDR-deficient tumour types.

Lynparza, which is being jointly developed and commercialised by AstraZeneca and MSD, is approved for 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 deliver it as quickly as possible to more patients 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 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

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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. 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.

Media Relations

Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Gonzalo Viña	UK/Global	+44 203 749 5916
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Josie Afolabi		+44 203 749 5631
Craig Marks	Finance; Fixed Income; M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvris	Brilinta; Diabetes	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
Jennifer Kretzmann	Retail investors	+44 203 749 5824
US toll free		+1 866 381 7277

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: 27 June 2018

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