

ASTRAZENECA PLC
Form 6-K
May 18, 2016

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 May 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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 PROVIDES TOP-LINE RESULTS FROM LYNPARZA GOLD TRIAL IN ADVANCED
GASTRIC CANCER

18 May 2016

AstraZeneca today announced that Lynparza (olaparib) in combination with paclitaxel chemotherapy, compared with paclitaxel chemotherapy alone, did not meet the primary endpoint of overall survival (OS) in the Phase III GOLD trial in advanced gastric cancer patients, in either the overall population or patients whose tumour tested negative for Ataxia-Telangectasia Mutated (ATM) protein. Whilst there was a numerical survival trend in the Lynparza plus paclitaxel arm, it did not meet statistical significance.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "While there was a numerical trend for survival benefit with Lynparza plus paclitaxel in the GOLD trial, we are disappointed that this did not reach statistical significance. The particular regimen in the GOLD study, at a low dose and in combination with chemotherapy, differs from other Phase III trials in the Lynparza programme. We look forward to presenting the GOLD data and remain confident in Lynparza's clinical activity in a range of tumour types, including its approved use in BRCA-mutated ovarian cancer."

GOLD was a randomised, double-blinded, placebo-controlled, multicentre Phase III trial to assess the efficacy and safety of Lynparza in combination with paclitaxel, compared with paclitaxel alone. The trial enrolled Asian patients with advanced HER2-negative gastric cancer (including the gastro-oesophageal junction) who had progressed following 1st-line therapy. The trial, conducted in China, Japan, South Korea and Taiwan where gastric cancer is particularly prevalent, enrolled a total of 525 patients - 18% of whom had tumours that tested ATM negative by immunohistochemistry (IHC). Lynparza was given orally at a dose of 100mg twice daily in combination with paclitaxel IV infusion over 1 hour at 80mg/m² weekly on days 1, 8 and 15 of a 28 day schedule.

The reported incidence of adverse events for Lynparza in combination with paclitaxel compared with paclitaxel alone was similar.

A full evaluation of the data is ongoing and the results will be submitted for presentation at an upcoming medical meeting.

Lynparza is approved in over 40 countries for use as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. It is approved in the US as monotherapy in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

About Gastric Cancer

Gastric and Gastroesophageal Junction (GEJ) adenocarcinomas account for around 84% of all cancers of the stomach. The incidence of gastric cancer (GC) is disproportionately high in East Asia, where annual incidence is around 9 times higher than those in the G6 countries combined.¹

About Lynparza

Lynparza (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that exploits tumour DNA damage response (DDR) pathway deficiencies to preferentially kill cancer cells. Lynparza is the foundation of AstraZeneca's industry-leading portfolio of compounds targeting DNA damage response (DDR) mechanisms in cancer cells. Lynparza is the first PARP inhibitor to be approved by regulatory authorities in the EU and US for the treatment of women with BRCA-mutated (BRCAm) ovarian cancer.

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 6 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 six 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 investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms -- immuno-oncology, the genetic drivers of cancer 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, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

18 May 2016

-ENDS-

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 May 2016

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