

ASTRAZENECA PLC
Form 6-K
July 27, 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 July 2017

Commission File Number: 001-11960

AstraZeneca PLC

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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-_____

This announcement contains inside information

27 July 2017 07:05 BST

ASTRAZENECA AND MERCK ESTABLISH STRATEGIC ONCOLOGY COLLABORATION

Collaboration aims to maximise the potential of PARP and MEK inhibitors in combination with PD-L1/PD-1 medicines, based on growing scientific evidence that these combinations offer new potential for the treatment of a range of tumour types

AstraZeneca and Merck will independently develop and commercialise Lynparza and potential medicine selumetinib in combinations with companies' respective PD-L1/PD-1 immuno-oncology medicines Imfinzi and Keytruda

Collaboration will significantly expand the potential of Lynparza, the world's first and leading PARP inhibitor, as a backbone of combination treatments for multiple cancer types; agreement also includes AstraZeneca's selumetinib, a MEK inhibitor

The companies will share development and marketing costs equally, as well as gross profits from Lynparza and selumetinib

AstraZeneca and Merck & Co., Inc., (Merck; known as MSD outside of the US and Canada) today announced that they have entered a global strategic oncology collaboration to co-develop and co-commercialise AstraZeneca's Lynparza (olaparib) for multiple cancer types.

Lynparza is an innovative, first-in-class oral poly ADP ribose polymerase (PARP) inhibitor currently approved for BRCA-mutated ovarian cancer in multiple lines of treatment.

Lynparza's pipeline has grown significantly in the last few years, with 14 indications currently being developed across several tumour types, including breast, prostate and pancreatic cancers. The strategic collaboration is expected to further increase the number of treatment options available to patients.

The companies will develop and commercialise Lynparza jointly, both as monotherapy and in combination with other potential medicines. Independently, the companies will develop and commercialise Lynparza in combination with their respective PD-L1 and PD-1 medicines, Imfinzi (durvalumab) and Keytruda (pembrolizumab).

The companies will also jointly develop and commercialise AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications including thyroid cancer.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "Our strategic collaboration builds on scientific evidence that PARP and MEK inhibitors can be combined with PD-L1/PD-1 inhibitors for a range of tumours.

By bringing together the expertise of two leading oncology innovators, we will accelerate Lynparza's potential to become the preferred backbone of many immuno-oncology combination therapies as the world's first and leading PARP inhibitor. This is a truly exciting step and we are pleased to work with Merck, a company that shares our passion for science to deliver new medicines for cancer patients."

Kenneth C. Frazier, Chief Executive Officer of Merck, said: "This global collaboration between AstraZeneca and Merck, two oncology leaders, will increase the possibilities for patients to have more treatment options for more cancers. Merck continues to build its leadership in immuno-oncology with Keytruda as foundational in monotherapy and combination therapy, and this collaboration expands our oncology leadership into the growing targeted therapies of PARP and MEK inhibitors. We look forward to working with AstraZeneca to create greater value for patients and shareholders than if both companies worked independently."

Financial considerations

Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialisation costs for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities. Gross profits from Lynparza and selumetinib Product Sales generated through monotherapies or combination therapies will be shared equally.

Merck will fund all development and commercialisation costs of Keytruda in combination with Lynparza or selumetinib. AstraZeneca will fund all development and commercialisation costs of Imfinzi in combination with Lynparza or selumetinib.

AstraZeneca will continue to manufacture Lynparza and selumetinib.

As part of the agreement, Merck will pay AstraZeneca up to \$8.5 billion in total consideration, including \$1.6 billion upfront, \$750 million for certain license options and up to \$6.15 billion contingent upon successful achievement of future regulatory and sales milestones. Under the terms of the agreement, AstraZeneca anticipates approximately \$1 billion to be recorded under Externalisation Revenue in 2017.

AstraZeneca will book all Product Sales of Lynparza and selumetinib; gross profits due to Merck under the collaboration will be recorded under Cost of Sales. The initial, regulatory and commercial milestone payments will be recorded under Externalisation Revenue. The transaction does not impact AstraZeneca's 2017 financial guidance. AstraZeneca continues to anticipate that the sum of Externalisation Revenue and Other Operating Income in FY 2017 will be ahead of that in FY 2016.

The collaboration agreement was completed upon signing on 26 July 2017.

For the purposes of the UK Listing Authority's Listing Rule LR 10.4.1 R (Notification of class 2 transactions), the book value of gross assets subject to the license and collaboration is approximately \$242 million. In view of the development and early growth phase of the medicines, a pre-tax loss of \$231 million was attributable to Lynparza and selumetinib in aggregate in the year to 31 December 2016.

About Lynparza

Lynparza (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour DDR pathway deficiencies to preferentially kill cancer cells.

Lynparza is the foundation of AstraZeneca's industry-leading portfolio of potential new medicines that target DDR mechanisms in cancer cells. Lynparza is currently approved by regulatory health authorities in the EU 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 also approved in the US as a monotherapy for patients with deleterious, or suspected deleterious, germline BRCA-mutated (as detected by a US FDA test) advanced

ovarian cancer, who have been treated with three or more lines of chemotherapy.

The Company recently presented positive results for Lynparza from its Phase III OlympiAD trial that showed a statistically-significant and clinically-meaningful improvement in progression-free survival for patients treated with Lynparza tablets (300mg twice daily), compared to treatment with physician's choice of a standard of care chemotherapy. OlympiAD, a randomised, open label, multi-centre Phase III trial assessing the efficacy and safety of Lynparza in patients with HER2-negative metastatic breast cancer with germline BRCA1 or BRCA2 mutations, which are predicted or suspected to be deleterious, was the first positive Phase III trial to evaluate the efficacy and safety of PARP inhibitor beyond ovarian cancer. Lynparza is currently being investigated in another separate non-metastatic breast cancer Phase III trial called OLYMPIA. This trial is still open and recruiting patients internationally.

Lynparza generated Product Sales in 2016 of \$218 million.

About selumetinib

Selumetinib, licensed by AstraZeneca from Array BioPharma Inc. in 2003, inhibits the MEK enzyme in the RAS/RAF/MEK/ERK pathway in cancer cells to prevent the tumour from growing. Selumetinib is in Phase III development for differentiated thyroid cancer, for which it was granted Orphan Drug Designation by the FDA in May 2016.

Selumetinib is also being tested in a separate Phase II trial in patients with paediatric neurofibromatosis type-1, and in a Phase I trial with patients suffering from advanced solid tumours.

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 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 main 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

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 July 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary