

ASTRAZENECA PLC
Form 6-K
October 23, 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 ☒ 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.

AstraZeneca Extends Innate Pharma Collaboration

This announcement contains inside information

23 October 2018 07:00 BST [CBR issued at 06:00 BST]

AstraZeneca strengthens and expands oncology development

and commercialisation collaboration with Innate Pharma

Full oncology rights to monalizumab

Access to Innate Pharma's anti-CD39 monoclonal antibody,

IPH5201, plus four additional immuno-oncology molecules

Innate Pharma acquires US and EU rights to commercialise Lumoxiti

Purchase of newly-issued 9.8% equity stake in Innate Pharma

AstraZeneca, and its global biologics research and development arm MedImmune, today announced a new multi-term agreement with Innate Pharma (Innate), building on an existing collaboration, aimed at accelerating each company's oncology portfolio and bringing new medicines to patients more quickly. The extended collaboration will enrich AstraZeneca's immuno-oncology (IO) portfolio with pre-clinical and clinical potential new medicines.

AstraZeneca will obtain full oncology rights to the first-in-class humanised anti-NKG2A antibody, monalizumab, expanding its partnership with Innate from the initial collaboration announced in 2015. AstraZeneca also gains option rights to IPH5201, an antibody targeting CD39, as well as four preclinical molecules from Innate's pipeline. Innate is licensing the US and EU commercial rights to recently FDA-approved Lumoxiti (moxetumomab pasudotox) for hairy cell leukaemia (HCL).

Pascal Soriot, Chief Executive Officer, said: "Our expanded collaboration with Innate Pharma enables us to further strengthen our leadership in immuno-oncology, and to explore the potential of next-generation immuno-oncology pathways, together with the world-class scientific team of Innate. Today's agreement also secures the long-term commercialisation of the recently FDA approved rare disease medicine, Lumoxiti, through dedicated focus and investment by Innate Pharma."

Mondher Mahjoubi, Chief Executive Officer of Innate Pharma, said: "Today is a defining moment for Innate Pharma as we transition to become a fully-integrated oncology-focused biotech. Lumoxiti is a major therapeutic innovation for patients who suffer from relapsed/refractory hairy cell leukaemia, and we are proud to be in a position to address a significant unmet medical need. Our commercial team will be focused on rare cancers and generate more value as our

own haemato-oncology proprietary pipeline develops."

Monalizumab

Building on a 2015 collaboration with Innate, AstraZeneca is exercising its option to obtain full oncology rights to monalizumab, a first-in-class humanised anti-NKG2A antibody. NKG2A is a checkpoint receptor expressed on tumour-infiltrating cytotoxic T-cells and natural killer (NK) cells that inhibits their anti-cancer functions. The companies currently share Phase II development for monalizumab in combination trials in both head and neck and colorectal cancer, with additional trials underway in other solid tumours.

Results from a single-arm Phase II trial of monalizumab in combination with cetuximab in head and neck cancer patients were presented at the ESMO 2018 Congress (European Society of Medical Oncology), showing deep and durable responses in 40 patients with ORR of 27.5%, progression free survival of 5.0 and overall survival of 10.3 months, respectively. Among the 40 patients enrolled in the cohort expansion, the safety findings were consistent with previously-presented data at AACR 2017 and 2018 (Abstract #1049PD).

CD39 and additional molecules

AstraZeneca is entering into a development collaboration and option for further co-development and co-commercialisation with Innate for its CD39 monoclonal antibody, IPH5201.

CD39 is a membrane-bound extracellular enzyme overexpressed on both regulatory T-cells and tumour cells in several cancer types. CD39 plays an important role in promoting immunosuppression through the pathway that degrades adenosine triphosphate (ATP) into adenosine. It is increasingly recognised that the adenosine pathway is critical in tumour immunosuppression and will complement AstraZeneca's current portfolio in this area.

In addition, Innate grants AstraZeneca an option to exclusively license four molecules to be agreed upon from Innate's preclinical portfolio, increasing the breadth and depth of AstraZeneca's immuno-oncology portfolio.

Lumoxiti

Innate is licensing the US commercial rights of AstraZeneca's recently FDA-approved treatment for HCL, Lumoxiti. Innate, with support from AstraZeneca, will continue EU development and commercialisation, pending regulatory submission and approval.

Lumoxiti is a CD22-directed cytotoxin and a first-in-class medicine in the US for adult patients with relapsed or refractory HCL who have received at least two prior systemic therapies, including treatment with a purine nucleoside analogue. Approximately 1,000 people are diagnosed with HCL in the US each year, a subset of which would be eligible for Lumoxiti. Innate will recognise revenues and co-commercialise Lumoxiti with AstraZeneca in the US and will take full responsibility by mid-2020.

Financial considerations

Innate will pay AstraZeneca \$50 million upfront for Lumoxiti, and \$25 million for future commercial and regulatory milestones, in consideration for its intellectual property and clinical and manufacturing development of the medicine. This income will be recorded as Other Operating Income by AstraZeneca.

AstraZeneca will pay Innate \$100 million in the first quarter of 2019 for the expansion of the monalizumab collaboration. Additional financial arrangements related to monalizumab are detailed and available in the 2015 collaboration announcement.

Further, AstraZeneca will pay Innate \$50 million upfront for the development collaboration and option for further co-development and co-commercialisation of Innate's CD39 monoclonal antibody, IPH5201, plus an option exercise fee, milestones and royalties. Innate will have the potential for co-promotion and profit sharing in the EU.

AstraZeneca will also pay Innate \$20 million upfront for an exclusive license option on four to-be-agreed molecules from Innate's preclinical portfolio. These options can be exercised before the molecules reach clinical development, triggering an option exercise fee in addition to milestones and royalties. Innate will have the potential for co-promotion and profit sharing in the EU, dependent on future progress.

Given the long-term collaboration between the two companies, AstraZeneca will acquire a 9.8% equity stake in Innate Pharma through the issuance of 6,260,500 new shares to AstraZeneca at €10/share. Issuance of the new shares is expected to take place on or about 25 October 2018.

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 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 MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology, Respiratory, Cardiovascular, Renal & Metabolic Diseases, and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, MD, one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK and South San Francisco, CA. For more information, please visit www.medimmune.com.

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

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: 23 October 2018

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