ASTRAZENECA PLC
Form 6-K
December 20, 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 December 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 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): _____

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 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.
Phase III ROCKIES and OLYMPUS roxadustat trials

This announcement contains inside information

20 December 2018 07:00 GMT

Phase III OLYMPUS and ROCKIES trials for roxadustat met their primary endpoints in chronic kidney disease patients with anaemia

OLYMPUS demonstrated a statistically-significant and clinically-meaningful improvement in haemoglobin vs. placebo in non-dialysis-dependent patients

ROCKIES demonstrated a statistically-significant improvement in haemoglobin vs. epoetin alfa in dialysis-dependent patients

AstraZeneca today announced that the Phase III OLYMPUS and ROCKIES trials for roxadustat each met their primary efficacy endpoints for the treatment of patients with anaemia in chronic kidney disease (CKD) that are either non-dialysis-dependent or dialysis-dependent, respectively. Roxadustat is a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) and a potential first-in-class new medicine to treat anaemia in CKD being jointly developed and commercialised by AstraZeneca and FibroGen, Inc.

OLYMPUS is a Phase III, randomised, double-blinded, placebo-controlled trial designed to evaluate the efficacy and safety of roxadustat vs. placebo for the treatment of patients with anaemia in CKD stages 3, 4 and 5 whose disease progression is moderate to severe and who are non-dialysis dependent.1 The trial met its primary efficacy endpoint by demonstrating a statistically-significant and clinically-meaningful improvement in mean change from baseline in haemoglobin (Hb) levels averaged over weeks 28 to 52 vs. placebo.1 The trial evaluated 2,781 patients in 26 countries.

ROCKIES is a Phase III, randomised, open-label, active-controlled trial designed to assess the efficacy and safety of roxadustat vs. epoetin alfa, for the treatment of patients with anaemia in CKD who are dialysis dependent.2 The trial met its primary efficacy endpoint by demonstrating a statistically-significant improvement in mean change from baseline in Hb levels averaged over weeks 28 to 52 vs. epoetin alfa.2 The trial evaluated 2,133 patients in 18 countries.

The global Phase III programme consists of more than 9,000 patients in trials conducted by AstraZeneca, FibroGen and Astellas. In September 2018, Astellas announced high-level results from the Phase III ALPS trial. FibroGen and Astellas anticipate reporting high-level results from their remaining trials in due course. These trials will contribute to the combined pooled safety analysis, including major adverse cardiovascular event (MACE) outcomes, anticipated during H1 2019.

Sean Bohen, Executive Vice-President, Global Medicines Development and Chief Medical Officer, said: "These results add to the growing body of evidence for roxadustat, which is part of the largest clinical programme worldwide in evaluating the novel class of HIF-PHI. This is a significant milestone in the role roxadustat can play to help address a high unmet need in anaemia associated with chronic kidney disease, which today is under diagnosed and in many cases under treated."

Data from the Phase III OLYMPUS and ROCKIES trials, together with the efficacy and pooled safety data from the global Phase III programme, will be part of the regulatory submission package in the US and other major countries. Results from these trials will be presented at forthcoming medical meetings.

About roxadustat
Roxadustat is a first-in-class, orally-administered small-molecule medicine recently approved in China for the treatment of patients with anaemia from CKD on dialysis. Roxadustat is a HIF-PHI that promotes erythropoiesis by increasing endogenous production of erythropoietin and improving iron regulation and overcoming the negative impact of inflammation on haemoglobin synthesis and red blood cell production by downregulating hepcidin. Administration of roxadustat has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range, in multiple subpopulations of CKD patients, including in the presence of inflammation and without a need for supplemental intravenous (IV) iron.

AstraZeneca and FibroGen, Inc. are collaborating on the development and commercialisation of roxadustat for the treatment of anaemia in patients with CKD in the US, China, and other global markets. FibroGen and Astellas are collaborating on the development and commercialisation of roxadustat for the treatment of anaemia in patients with CKD in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.

About anaemia in CKD
Anaemia can be a serious medical condition in which patients have insufficient red blood cells and low levels of Hb, a protein in red blood cells that carries oxygen to cells throughout the body.3,4Anaemia in CKD is associated with increased risk of hospitalisation, cardiovascular complications and death,5 also frequently causing significant fatigue, cognitive dysfunction and decreased quality of life.6 Severe anaemia is common in patients with CKD, cancer, myelodysplastic syndrome, inflammatory diseases, and other serious illnesses.

Anaemia is particularly prevalent in patients with CKD, which affects more than 200 million people worldwide and is generally a progressive disease characterised by gradual loss of kidney function that may eventually lead to kidney failure.

In the US, according to the United States Renal Data System (USRDS), a majority of dialysis-eligible CKD patients are currently on dialysis. Of the approximately 507,000 patients receiving dialysis in the US as of 2016, approximately 80% were being treated with ESAs for anaemia.7Patients seldom receive ESA treatment until they initiate dialysis therapy.

About FibroGen
FibroGen, Inc., headquartered in San Francisco, California, with subsidiary offices in Beijing and Shanghai, People's Republic of China, is a leading biopharmaceutical company discovering and developing a pipeline of first-in-class therapeutics. The company applies its pioneering expertise in hypoxia-inducible factor (HIF), connective tissue growth factor (CTGF) biology, and clinical development to advance innovative medicines for the treatment of anemia, fibrotic disease, and cancer. Roxadustat, the company's most advanced product candidate, is an oral small molecule inhibitor of HIF prolyl hydroxylase activity, completing worldwide Phase 3 clinical development for the treatment of anemia in chronic kidney disease (CKD), with a New Drug Application (NDA) now approved by the National Medical Products Administration (NMPA) in China. FibroGen's partner Astellas submitted an NDA for the treatment of anemia in CKD patients on dialysis in Japan in September 2018, currently under review by the Pharmaceuticals and

Medical Devices Agency (PMDA). Roxadustat is in Phase 3 clinical development in the U.S. and Europe and in Phase 2/3 development in China for anemia associated with myelodysplastic syndromes (MDS). Pamrevlumab, an anti-CTGF human monoclonal antibody, is advancing towards Phase 3 clinical development for the treatment of idiopathic pulmonary fibrosis (IPF) and pancreatic cancer, and is currently in a Phase 2 trial for Duchenne muscular dystrophy (DMD). FibroGen is also developing a biosynthetic cornea in China. For more information, please visit www.fibrogen.com.

About AstraZeneca in Cardiovascular, Renal & Metabolism (CVRM)
Cardiovascular, renal and metabolism together form one of AstraZeneca's main therapy areas and a key growth driver for the Company. By following the science to understand more clearly the underlying links between the heart, kidneys and pancreas, AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling co-morbidities. Our ambition is to modify or halt the natural course of CVRM diseases and potentially regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and cardiovascular health for millions of patients worldwide.

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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1. Clinicaltrials.gov. Safety and Efficacy Study of Roxadustat to Treat Anemia in Patients With Chronic Kidney Disease (CKD), Not on Dialysis. [Online]. Available at: https://clinicaltrials.gov/ct2/show/record/NCT02174627. Last accessed: September 2018.
2. Clinicaltrials.gov. Safety and Efficacy Study of Roxadustat to Treat Anemia in Patients With Chronic Kidney Disease, on Dialysis. [Online]. Available at: https://clinicaltrials.gov/ct2/show/record/NCT02174731. Last accessed: September 2018.
3. National Kidney Foundation. "Managing Anaemia When You Have Kidney Disease or Kidney Failure." 2014.
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5. Babitt JL, Lin HY. Mechanisms of Anemia in CKD. J Am Soc Nephrol (2012); 23:1631-1634
6. KDOQI Clinial Practice Guidelines and Clinical Practice Recommendations for Anaemia in Chronic Kidney Disease. Am J Kidney Dis. 2006 May;47(5):S1-S132
7. United States Renal Data System. "Annual Data Report." 2017.

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: 20 December 2018

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