ASTRAZENECA PLC
Form 6-K
December 18, 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):

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Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

INDEX TO EXHIBITS

Roxadustat approved in China for the treatment of anaemia in chronic kidney disease patients on dialysis

18 December 2018 09:00 GMT

Roxadustat approved in China for the treatment of
anaemia in chronic kidney disease patients on dialysis

China is the first country to approve roxadustat

AstraZeneca today announced that its partner FibroGen (China) Medical Technology Development Co., Ltd. (FibroGen China) has now received formal marketing authorisation from the National Medical Products Administration (NMPA) for roxadustat, a first-in-class hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) and new oral treatment for patients with anaemia caused by chronic kidney disease (CKD) that are on dialysis. The medicine can be prescribed to patients who use haemodialysis or peritoneal dialysis.

Anaemia caused by CKD is associated with cardiovascular disease, hospitalisation, cognitive impairment and reduced quality of life, and has been shown consistently to increase the mortality risk in patients with CKD.1 Anaemia becomes increasingly common among individuals with CKD as their disease progresses, affecting nearly all patients at the dialysis stage.1

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "Roxadustat is a long-awaited, first-in-class medicine for patients with anaemia in chronic kidney disease that are on dialysis. This first approval of roxadustat in China is a significant step towards achieving our ambition to transform care in a condition where prevalence in China is increasing."

Roxadustat is the first approved oral HIF-PHI medicine for patients with anaemia from CKD. This approval is supported by an open-label, active-control 26-week Phase III trial in dialysis dependent-CKD (DD CKD) patients with anaemia who were previously treated with various forms of a generic erythropoiesis-stimulating agent (ESA). In the trial, these DD-CKD patients were then randomised to receive either roxadustat or epoetin alfa, an ESA. Rates of adverse events related to roxadustat observed in the trial were generally low (<5%), and mostly of Grade 1-2 severity. The adverse events observed were consistent with underlying diseases in patients with CKD.

Anaemia commonly develops in association with CKD and is estimated to affect 120 million patients in China, with an estimated 0.5 million patients on dialysis who may be suffering from anaemia, a number that is increasing significantly.2,3

AstraZeneca and FibroGen China are collaborating on the development and commercialisation of roxadustat in China. FibroGen China, based in Beijing, is a wholly-owned subsidiary of FibroGen Inc. that sponsored the development and registration of roxadustat. FibroGen China conducted the China Phase III clinical trials and submitted the New Drug Application for registration of roxadustat to the Chinese regulatory authorities. Following this approval, AstraZeneca will manage commercialisation activities in China, and FibroGen China will manage commercial manufacturing and medical affairs as well as continued clinical development and regulatory affairs. AstraZeneca and FibroGen expect to launch roxadustat in China during the second half of 2019.

About roxadustat

Roxadustat is a first-in-class, orally-administered small molecule currently 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 iron.

FibroGen, Inc., the originator, and AstraZeneca 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 Pharma Inc. are collaborating on the development and commercialisation of roxadustat for the treatment of anaemia in patients with CKD in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.

About anaemia in CKD in China
Anaemia commonly develops in association with CKD and is linked to significant morbidity and mortality in both the dialysis and non-dialysis populations. CKD affects an estimated 120 million patients in China.2 Although CKD may occur at any age, it is more common in aging populations, and its prevalence is increasing. CKD can be both a cause and a consequence of cardiovascular disease and is a critical healthcare issue. There is no treatment available that is curative or has the ability to stop kidney deterioration.

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. Our partner Astellas submitted a NDA for the treatment of anemia in CKD patients on dialysis in Japan and 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 key growth drivers. 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
Company Secretary
AstraZeneca PLC

References

1. Babitt JL, Lin HY. Mechanisms of Anemia in CKD. J Am Soc Nephrol (2012); 23:1631-1634.
2. Zhang L, Wang F, Wang L, et al. Prevalence of chronic kidney disease in China: a cross-sectional survey. Lancet2012; 379: 815-22.
3. China National Renal Data System (CNRDS), 2016.

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 December 2018

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