ASTRAZENECA PLC
Form 6-K
May 21, 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 May 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.
US FDA approves Lokelma for adult hyperkalaemia

21 May 2018 07:00 BST

Lokelma approved in the US for the treatment of adults with hyperkalaemia

Lokelma provides rapid and sustained potassium control for patients
in a condition with high unmet need

The US Food and Drug Administration (FDA) has approved Lokelma (sodium zirconium cyclosilicate), formerly ZS-9, for the treatment of adults with hyperkalaemia,1 a serious condition characterised by elevated potassium levels in the blood associated with cardiovascular, renal and metabolic diseases.2

The risk of hyperkalaemia increases significantly for patients with chronic kidney disease (CKD) and for those who take common medications for heart failure (HF), such as renin-angiotensin-aldosterone system (RAAS) inhibitors, which can increase potassium in the blood.2,3 To help prevent the recurrence of hyperkalaemia, RAAS-inhibitor therapy is often modified or discontinued, which can compromise cardio-renal outcomes and increase the risk of death.3,4

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "We are pleased by today's FDA approval of Lokelma as it enables us to help address a long-standing clinical need with a new medicine that offers rapid and sustained treatment for adults with hyperkalaemia. The consequences of hyperkalaemia can be very serious and it's reassuring for treating physicians that Lokelma has demonstrated lowering of potassium levels in patients with chronic kidney disease, heart failure, diabetes and those taking RAAS inhibitors."

Lokelma is a highly-selective, oral potassium-removing agent.1 The FDA approval is supported by data from three double-blind, placebo-controlled trials and two open-label trials, which showed that for patients receiving Lokelma the onset of action was at 1.0 hour and the median time to achieving normal potassium levels in the blood was 2.2 hours, with 92% of patients achieving normal potassium levels within 48 hours from baseline.1,8 The treatment effect was maintained for up to 12 months.1,5,6,7,8

Steven Fishbane, MD, Professor, Donald and Barbara Zucker School of Medicine at Hofstra Northwell, New York, said: "This FDA approval represents an exciting milestone, as it stands to deliver a rapid, effective and generally well-tolerated treatment option to patients suffering from hyperkalaemia in the US."

The European Commission granted marketing authorisation for Lokelma in the European Union on 22 March 2018.

About Hyperkalaemia
The risk of hyperkalaemia increases significantly for patients with CKD and for those who take common medications for HF, such as RAAS inhibitors, which can increase potassium in the blood. Hyperkalaemia occurs in 23% to 47% of patients with CKD and/or HF, with an estimated 200 million and 38 million people, respectively, living with each condition worldwide. Hyperkalaemia may lead to cardiac arrest and death, with mortality being up to 30% in patients with severe hyperkalaemia, if not treated rapidly.

About Lokelma
Lokelma is an insoluble, non-absorbed sodium zirconium silicate, formulated as a powder for oral suspension, that acts as a highly-selective potassium-removing agent. It is administered orally, is odourless, tasteless and stable at room temperature. It has been studied in three double-blind, placebo-controlled trials and in two 12-month open label clinical trials in adult patients with hyperkalaemia.

About AstraZeneca in Cardiovascular, Renal & Metabolism
Cardiovascular and metabolic diseases are a main therapy area and a key growth platform for AstraZeneca, which is now called Cardiovascular, Renal & Metabolism (CVRM), following the addition of Lokelma to our portfolio of medicines.

By following the science to understand more clearly the underlying links between the heart, kidney 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 these diseases and even regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and CVRM 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. 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

References

1 AstraZeneca. Lokelma Prescribing Information. May 2018.

2 National Kidney Foundation. "Clinical Update on Hyperkalemia." 2014. Accessed 8 May 2018. https://www.kidney.org/sites/default/files/02-10-6785_HBE_Hyperkalemia_Bulletin.pdf.

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6 Packham D, Rasmussen HS, Lavin P, et al. "Sodium Zirconium Cyclosilicate in Hyperkalemia." New Engl J Med. 2015; 372:222-31. doi: 10.1056/NEJMoa1411487.

7 Ash S, Bhupinder S, Lavin P, et al. "A phase 2 study on the treatment of hyperkalemia in patients with chronic kidney disease suggests that the selective potassium trap, ZS-9, is safe and efficient." Kidney Int. 2015; 88, 404-411. doi:10.1038/ki.2014.382.

8 Fishbane S, Pergola PE, Packham DK, et al. Long-term efficacy and safety of sodium zirconium cyclosilicate for hyperkalemia: 12-month, open-label, phase 3 study. Poster presentation at: American Society of Nephrology Kidney Week 2017; November 2017; New Orleans, LA. Abstract #2759765.

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: 21 May 2018

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