ASTRAZENECA PLC
Form 6-K
March 22, 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 March 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.
Lokelma approved in the EU

22 March 2018 16:45 GMT

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

Patients will benefit from Lokelma's rapid reduction and sustained control of potassium levels in the blood4,5

AstraZeneca today announced that the European Commission has granted marketing authorisation for Lokelma (formerly ZS-9, sodium zirconium cyclosilicate) for the treatment of adults with hyperkalaemia. Hyperkalaemia is a serious condition characterised by elevated potassium levels in the blood associated with cardiovascular, renal and metabolic diseases.1,2,3,4

Lokelma is a highly-selective, oral potassium-removing agent. The approval is supported by data from three double-blind, placebo-controlled trials and one open-label trial, where patients with hyperkalaemia were treated for up to 12 months. In these trials, for patients receiving Lokelma the median time to achieving normal potassium levels in the blood was 2.2 hours, with 98% achieving normal levels within 48 hours from baseline. Lokelma also demonstrated sustained potassium control for up to one year.4,5

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

Elisabeth Björk, Vice President, Head of Cardiovascular, Renal and Metabolism, Global Medicines Development, AstraZeneca, said: "The consequences of hyperkalaemia can be serious, even life-threatening, and can occur in patients either with chronic kidney disease or as a result of taking some medications for heart failure. Today's approval of Lokelma addresses a significant unmet need by bringing a rapid and sustained therapeutic option for patients with hyperkalaemia."

Lokelma is currently under separate regulatory review in the US, with a decision expected in the first half of 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 one 12-month open label clinical trial in patients with hyperkalaemia. The recommended starting dose of Lokelma is 10g, administered three times daily. Once normokalaemia (normal potassium levels in the blood) has been achieved, a maintenance dose of 5g once daily is recommended with possible titration up to 10g daily or down to 5g once every other day to maintain a normal potassium level.

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 Kosiborod M, Rasmussen HS, Lavin P, et al. 'Effect of Sodium Zirconium Cyclosilicate on Potassium Lowering for 28 Days Among Outpatients With Hyperkalemia.' JAMA. 2014. doi:10.1001/jama.2014.15688.
2 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.
3 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.
4 National Kidney Foundation. 'Clinical Update on Hyperkalemia." 2014. Accessed 5 January 2017. https://www.kidney.org/sites/default/files/02-10-6785_HBE_Hyperkalemia_Bulletin.pdf.
5 Fishbane S, Pergola PE, Packham DK, et al. 'Long-term Efficacy and Safety of Sodium Zirconium Cyclosilicate for Hyperkalemia: A 12-Month, Open-Label, Phase 3 Study'. Poster presentation at: American Society of Nephrology Kidney Week; November 2017; New Orleans, LA. TH-PO1112.

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: 22 March 2018

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