ASTRAZENECA PLC
Form 6-K
March 17, 2017

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 2017

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-_____

This announcement contains inside information

17 March 2017 07:00 GMT

ASTRAZENECA RECEIVES COMPLETE RESPONSE LETTER FROM US FDA FOR ZS-9 (SODIUM ZIRCONIUM CYCLOSILICATE) FOR HYPERKALAEMIA

AstraZeneca today announced that the US Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for ZS-9 (sodium zirconium cyclosilicate). Sodium zirconium cyclosilicate is being developed for the treatment of hyperkalaemia by ZS Pharma, a wholly-owned subsidiary of AstraZeneca. Hyperkalaemia is characterised by high potassium levels in the blood serum.

The CRL followed an inspection by the FDA of the ZS-9 manufacturing facility. The CRL does not require the generation of any new clinical data. AstraZeneca and ZS Pharma are committed to working with the FDA to resolve the remaining matters under review as soon as possible.

AstraZeneca remains dedicated to developing and commercialising sodium zirconium cyclosilicate for patients with hyperkalaemia, and is confident in the profile of this potential medicine. As announced on 24 February 2017, sodium zirconium cyclosilicate received a positive opinion by the Committee for Medicinal Products for Human Use in the European Union. Any potential implications for ongoing regulatory submissions are being assessed.

About ZS-9 (sodium zirconium cyclosilicate)
ZS-9 (sodium zirconium cyclosilicate) is a powder for oral suspension. The active ingredient is a non-absorbed zirconium silicate that preferentially exchanges potassium for hydrogen and sodium. Clinical trials indicate that it is stable at room temperature and has a rapid onset of action. The FDA approval is supported by data from double-blinded, placebo-controlled trials and an 11-month open label extension study in adults with hyperkalaemia.

About Hyperkalaemia
Hyperkalaemia (high potassium levels in the blood serum) occurs in 23 to 47% of patients with chronic kidney disease and/or chronic heart failure, and may lead to cardiac arrest and death (mortality up to 30% in patients with severe hyperkalaemia if not treated).1 Treatment with common heart medicines can also be responsible for increases in hyperkalaemia.

About ZS Pharma
ZS Pharma, founded in 2008, was a publicly traded biopharmaceutical company until it entered an agreement with AstraZeneca in November 2015 to be fully acquired. The transaction completed in December 2015. For more information, please visit: www.zspharma.com

About AstraZeneca in Chronic Kidney Disease

Chronic kidney disease (CKD) is a key strategic area of focus within AstraZeneca's Cardiovascular and Metabolic Diseases (CVMD) therapy area. By leveraging our expertise in diabetes and cardiovascular disease, AstraZeneca is able to better understand the interplay of these conditions and CKD to advance our scientific leadership in the cardio-renal space. Through novel therapies and therapy combinations that target both the complications of CKD and the underlying mechanisms of CKD progression, we are building a portfolio to aggressively prevent, treat, manage and modify this global public health issue.

About AstraZeneca in Cardiovascular and Metabolic Diseases
Cardiovascular, renal and metabolic diseases are key areas of focus for AstraZeneca as part of the company's strategy for achieving scientific leadership and returning to growth. By collaborating across therapeutic disciplines within the CVMD therapy area, we are addressing the underlying disorders that drive CVMD risk, with the goal of reducing morbidity, mortality and organ damage through innovative therapies.

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 main therapy areas - Oncology, Cardiovascular & Metabolic Diseases 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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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.

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: 17 March 2017 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary