ASTRAZENECA PLC
Form 6-K
May 27, 2016

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 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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 RECEIVES COMPLETE RESPONSE LETTER FROM US FDA FOR SODIUM ZIRCONIUM CYCLOSILICATE (ZS-9) FOR ORAL SUSPENSION FOR TREATMENT OF HYPERKALAEMIA

27 May 2016

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 sodium zirconium cyclosilicate (ZS-9), the investigational medicine being developed for the treatment of hyperkalaemia (high potassium level in the blood serum) by ZS Pharma, a wholly-owned subsidiary of AstraZeneca.

The CRL refers to observations arising from a pre-approval manufacturing inspection. The FDA also acknowledged receipt of recently-submitted data which it has yet to review. The CRL does not require the generation of new clinical data. AstraZeneca and ZS Pharma are evaluating the content of the CRL and will work closely with the FDA to determine the appropriate next steps for the NDA.

AstraZeneca remains committed to the development of sodium zirconium cyclosilicate as a treatment option for patients with hyperkalaemia. Interactions are ongoing with other health authorities in the European Union and Australia, where sodium zirconium cyclosilicate is currently under separate regulatory review.

About sodium zirconium cyclosilicate (ZS-9) for oral suspension

Sodium zirconium cyclosilicate (ZS-9) is an insoluble, non-absorbed compound with a structure that was designed to preferentially trap potassium ions. The unique potassium selectivity of sodium zirconium cyclosilicate enables high in-vitro binding capacity for potassium ions even in the presence of other competing ions. Sodium zirconium cyclosilicate has been studied in three double-blind, placebo controlled trials and in one ongoing 12 month open label clinical trial in patients with hyperkalemia which represents over 1,600 patients treated. Sodium zirconium cyclosilicate is an investigational product that is not currently approved for any indication in any market.

About Hyperkalaemia
Hyperkalaemia (high potassium levels > 5.0 mEq/L in the blood serum) occurs in 23-47% of patients with advanced chronic kidney disease and/or chronic heart failure, and may lead to cardiac arrest and death (mortality of up to 30% in patients with severe hyperkalaemia if not treated rapidly). Treatment with common heart medicines (RAAS inhibitors) can also be responsible for increases in hyperkalaemia. Current therapeutic options are limited, leaving high unmet medical need.

About ZS Pharma
ZS Pharma was founded in 2008, became a public company in 2014 and, in December 2015, joined the AstraZeneca Group. ZS Pharma is focused on the development and commercialisation of highly selective, non-absorbed drugs to treat renal, cardiovascular, liver and metabolic disorders. Additional information about ZS Pharma is available at www.zspharma.com.

About AstraZeneca in Cardiovascular & Metabolic Disease (CVMD)
Cardiovascular, metabolic disease and chronic kidney disease are key areas of focus for AstraZeneca as part of the company's strategy for achieving scientific leadership and returning to growth. Our patient-led strategy is focused on addressing the multiple risk factors facing CVMD and CKD patients at different stages of their disease, with the goal of reducing morbidity and mortality through life changing medicines.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

27 May 2016

-ENDS-

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: 27 May 2016

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