ASTRAZENECA PLC
Form 6-K
March 04, 2015

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 2015
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 TO PARTICIPATE IN US FDA ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE

AstraZeneca today announced it will participate in the US Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee meeting on 14 April 2015 to discuss the results of the Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus (SAVOR) trial for ONGLYZA® (saxagliptin) and Kombiglyze® XR (saxagliptin and metformin HCI extended-release).

The topic of the Advisory Committee is based on an ongoing review of a previously submitted supplemental New Drug Application to the FDA for ONGLYZA and Kombiglyze XR.

AstraZeneca welcomes the opportunity to discuss the SAVOR cardiovascular outcomes data with the Advisory Committee.

About SAVOR
The SAVOR (Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus) clinical trial of Onglyza (saxagliptin) was a randomised, double-blind, controlled trial evaluating the effect of saxagliptin on the incidence of major adverse cardiovascular events in patients with type 2 diabetes mellitus and at an elevated risk for CV events. The SAVOR study was conducted as part of the Postmarketing Requirement for the US New Drug Application approval of Onglyza in accordance with the 2008 FDA guidance, "Diabetes Mellitus - Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes." The primary objective of this trial was to determine that the addition of saxagliptin to standard of care in this patient population did not significantly increase the incidence of major cardiovascular events as compared to placebo.

About DPP-4 inhibitors
Saxagliptin belongs to the class of dipeptidyl peptidase-4 (DPP-4) inhibitors. Incretin hormones decrease elevated blood sugar levels (glucose) by increasing the body's utilisation of sugar, mainly through increasing insulin production in the pancreas, and by reducing the liver's production of glucose. DPP-4 inhibitors work by increasing the activity of the incretin hormones, increasing the release of insulin when glucose levels are elevated and reducing the levels of sugar produced by the liver.

About Type 2 Diabetes
Diabetes is estimated to affect 29.1 million people in the US and more than 382 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million people worldwide by 2035. Type 2 diabetes accounts for approximately 90-95 percent of all cases of diagnosed diabetes in the US. Type 2 diabetes is a chronic disease characterised by pathophysiologic defects leading to elevated glucose levels. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen. It is estimated that more than half of people living with type 2 diabetes are not achieving recommended HbA1c goals based on guidelines established by professional societies and advocacy organisations for diabetes management.

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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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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4 March 2015

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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: 04 March 2015

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