ASTRAZENECA PLC
Form 6-K
December 13, 2013

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 December 2013

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-_____

FDA ADVISORY COMMITTEE RECOMMENDS THE INVESTIGATIONAL SGLT2 INHIBITOR DAPAGLIFLOZIN FOR TREATMENT OF TYPE 2 DIABETES IN ADULTS

AstraZeneca and Bristol-Myers Squibb Company today announced the US Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) voted 13-1 that the benefits of dapagliflozin use outweigh identified risks and support marketing of dapagliflozin as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. The Advisory Committee also voted 10-4 that the data provided sufficient evidence that dapagliflozin, relative to comparators, has an acceptable cardiovascular risk profile.

The FDA is not bound by the Advisory Committee's recommendation but takes its advice into consideration when reviewing the application for an investigational agent. The Prescription Drug User Fee Act (PDUFA) goal date for dapagliflozin is 11 January 2014.

Dapagliflozin is being reviewed by the FDA for use as monotherapy, and in combination with other antidiabetic agents, as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. It is a selective and reversible inhibitor of sodium-glucose cotransporter 2 (SGLT2) that works independently of insulin to help remove excess glucose from the body. Dapagliflozin, an investigational compound in the US, was the first SGLT2 inhibitor to be approved anywhere in the world. Dapagliflozin is currently approved under the trade name FORXIGA™ for the treatment of adults with type 2 diabetes, along with diet and exercise, in 38 countries, including the European Union and Australia.

The EMDAC was provided with data from the extensive dapagliflozin global clinical development programme included as part of the New Drug Application (NDA) and resubmission. In response to the FDA's January 2012 complete response letter, the NDA resubmission included several new studies and additional long-term data (up to four years' duration) from previously submitted studies, resulting in an overall increase in patient-years exposure to dapagliflozin of more than 50 percent as compared to exposure in the original NDA. The resubmission included data from the dapagliflozin Phase II/III clinical development programme, which included more than 11,000 adult patients with diabetes (approximately 6,000 patients received dapagliflozin) in 24 clinical trials.

Patient populations examined covered the range of diabetes progression, including drug-naïve patients, patients inadequately controlled on oral therapies and patients on insulin-based regimens. The programme also provided significant experience in elderly patients, patients with a history of cardiovascular (CV) disease, overweight and obese patients, patients with poorly controlled hypertension and patients with mild to moderate renal impairment. In accordance with FDA guidelines, the NDA resubmission also included data assessing the CV safety of dapagliflozin in adults with type 2 diabetes. Additionally, the DECLARE study is being conducted in patients with type 2 diabetes to determine the effect of dapagliflozin, when added to the patients' current anti-diabetes therapy, on the risk of CV events, such as CV death, myocardial infarction or ischaemic stroke, compared with placebo. The randomized, double-blind, placebo-controlled study of more than 17,000 patients initiated enrolment in April 2013 and has an anticipated completion date of 2019.

About Type 2 Diabetes

Diabetes is estimated to affect 26 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. Type 2 diabetes is a chronic disease characterized by several pathophysiologic defects, including insulin resistance and dysfunction of pancreatic beta cells, leading to elevated glucose levels. Over time, this sustained hyperglycaemia contributes to further progression of the disease. Significant unmet needs still exist, as many patients remain inadequately controlled on their current

glucose-lowering regimen.

About SGLT2 Inhibition
The kidney plays an important role in maintaining normal glucose balance, in part by filtering and subsequently reabsorbing glucose back into circulation. SGLT2, a sodium-glucose cotransporter found predominantly in the kidney, is responsible for the majority of glucose reabsorption in the kidneys. In patients with type 2 diabetes, the capacity of the kidney to reabsorb glucose is increased by approximately 20-30 percent, further exacerbating the hyperglycaemia associated with the disease. Selective inhibition of SGLT2 reduces the reabsorption of excess glucose and enables its removal via the urine.

About the AstraZeneca/Bristol-Myers Squibb Diabetes Alliance
Dedicated to addressing the global burden of diabetes by advancing individualised patient care, AstraZeneca and Bristol-Myers Squibb are working in collaboration to develop and commercialise a versatile portfolio of innovative treatment options for diabetes and related metabolic disorders that aim to provide treatment effects beyond glucose control. Find out more about the Alliance and our commitment to meeting the needs of health care professionals and people with diabetes at www.astrazeneca.com or www.bms.com.

About Bristol-Myers Squibb
Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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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13 December 2013

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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: 13 December 2013 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary