ASTRAZENECA PLC
Form 6-K
January 13, 2014

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 January 2014

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-_____

US FDA APPROVES FARXIGA™ (DAPAGLIFLOZIN) TABLETS FOR THE TREATMENT OF ADULT PATIENTS WITH TYPE 2 DIABETES

In clinical trials, new once-daily FARXIGA, in addition to diet and exercise, improved glycaemic control by removing glucose from the body

AstraZeneca and Bristol-Myers Squibb Company announced the US Food and Drug Administration (FDA) approved FARXIGA™ [far-SEE-ga] (dapagliflozin), a once-daily oral treatment indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. FARXIGA should not be used for the treatment of patients with type 1 diabetes or diabetic ketoacidosis.

The recommended starting dose of FARXIGA is 5 mg once daily, taken in the morning, with or without food. In patients tolerating FARXIGA 5 mg once daily who require additional glycaemic control, the dose can be increased to 10 mg once daily. FARXIGA is part of a newer class of medicines called sodium-glucose cotransporter 2 (SGLT2) inhibitors, which remove glucose via the kidneys.

"With the diabetes epidemic escalating and many people with type 2 diabetes struggling to reach their blood sugar goals, FARXIGA offers an important new option for healthcare professionals and adult patients," said Brian Daniels, Senior Vice President, Global Development and Medical Affairs, Bristol-Myers Squibb. "In clinical trials, FARXIGA helped improve glycaemic control, and offered additional benefits of weight and blood pressure reductions."

FARXIGA is contraindicated in patients with a history of a serious hypersensitivity reaction to FARXIGA or with severe renal impairment, end stage renal disease, or patients on dialysis.

"The addition of FARXIGA to our US treatment portfolio is a step forward as we work to help reduce the burden of type 2 diabetes by offering a range of treatment options with different modes of action," said Briggs Morrison, Executive Vice President, Global Medicines Development & Chief Medical Officer, AstraZeneca. "We aim to help adults with type 2 diabetes, and their doctors, create individualised treatment programmes that will help patients lower their glucose levels."

Dapagliflozin (marketed outside of the United States as FORXIGA®) is approved for the treatment of adults with type 2 diabetes, along with diet and exercise, in 40 countries, including European Union countries and Australia.

FARXIGA Clinical Development Programme

The robust FARXIGA clinical development programme included 24 clinical studies evaluating safety and efficacy. The studies included more than 11,000 adults with type 2 diabetes, including more than 6,000 patients treated with FARXIGA.

FARXIGA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating FARXIGA particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics. Before initiating FARXIGA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms of hypotension after initiating therapy. FARXIGA increases serum creatinine and decreases eGFR. Elderly patients and patients with impaired renal function may be more susceptible to these changes. Adverse reactions related to renal function can occur after initiating FARXIGA. Renal function should be evaluated prior to initiation of FARXIGA and monitored periodically thereafter.

In a 24-week, add-on to metformin clinical trial, adult patients with type 2 diabetes treated with FARXIGA 5 mg (n=137; baseline HbA1c 8.2%) or 10 mg (n=135; baseline HbA1c 7.9%) had significant reductions in HbA1c of -0.7% and -0.8%, respectively, compared with placebo plus metformin reductions of -0.3% (n=137; baseline HbA1c 8.1%). In the same study, the placebo-adjusted reduction in body weight was -2.2 kg with FARXIGA 5 mg (baseline 84.7 kg) and -2.0 kg with 10 mg (baseline 86.3 kg). Also, mean changes from baseline in systolic blood pressure relative to placebo plus metformin were -4.5 mmHg and -5.3 mmHg with FARXIGA 5 mg or 10 mg plus metformin, respectively. No major episodes of hypoglycaemia were seen in any of the treatment arms. Minor episodes of hypoglycaemia were reported in 1.5%, 0.7%, and 0% with FARXIGA 5 mg, 10 mg, and placebo plus metformin, respectively.

In addition to the clinical development programme, the AstraZeneca/Bristol-Myers Squibb Diabetes Alliance has initiated DECLARE, a large, randomised, placebo-controlled study of more than 17,000 adult patients with type 2 diabetes designed to determine the effect of FARXIGA, 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 study, which will also provide additional data on the long-term safety profile, initiated enrolment in April 2013 and has an anticipated completion date of 2019.

About Type 2 Diabetes

Diabetes is estimated to affect 25.8 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 characterised by pathophysiologic defects 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 a contributing 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. Selective inhibition of SGLT2 reduces the reabsorption of glucose and enables its removal via the urine, which is associated with reductions in HbA1c, weight and systolic blood pressure.

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.

On 19 December 2013 AstraZeneca and Bristol-Myers Squibb announced an agreement under which AstraZeneca will acquire the entirety of Bristol-Myers Squibb's interests in the companies' diabetes alliance to consolidate worldwide ownership of the diabetes business within AstraZeneca. The closing of the transactions contemplated by the agreement is subject to customary terms and conditions, and is expected to occur during the first quarter of 2014.

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.

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.

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13 January 2014

-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: 13 January 2014 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary