ASTRAZENECA PLC
Form 6-K
October 30, 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 October 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 ONCE-DAILY XIGDUO™ XR TABLETS
FOR ADULTS WITH TYPE 2 DIABETES

First US approval for once-daily tablet combining SGLT2 inhibitor and metformin HCl extended-release

AstraZeneca today announced that the US Food and Drug Administration has approved once-daily XIGDUO™ XR (dapagliflozin and metformin hydrochloride extended-release) for the treatment of adults with type 2 diabetes.

XIGDUO XR combines two anti-hyperglycaemic agents with complementary mechanisms of action, dapagliflozin (trade name in the US, FARXIGATM), an inhibitor of sodium-glucose cotransporter 2 (SGLT2), and metformin hydrochloride (HCl) extended-release, a biguanide, in a once-daily oral tablet. SGLT2 inhibitors are a relatively new class of medicines that remove glucose from the body via the kidneys.

XIGDUO XR is the first and only once-daily combination tablet of an SGLT2 inhibitor and metformin HCl extended-release to be approved in the United States. XIGDUO XR is indicated as an adjunct therapy to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

"The addition of XIGDUO XR to our US diabetes portfolio is further evidence of AstraZeneca's commitment to develop new treatment options for patients with type 2 diabetes," said Elisabeth Björk, Head of Cardiovascular & Metabolism, Global Medicines Development, AstraZeneca. "The approval of once-daily XIGDUO XR provides prescribers and adult patients with another treatment choice, supporting a more personalised approach to disease management."

XIGDUO XR is already approved in Australia for the treatment of adults with type 2 diabetes, along with diet and exercise. XIGDUO (dapagliflozin and metformin hydrochloride), which uses an immediate-release form of metformin, is approved in the European Union.

About XIGDUO XR Dosing
XIGDUO XR is approved with multiple dosage strengths of dapagliflozin and metformin HCl extended release, respectively, including 5 mg/500 mg, 5 mg/1000 mg, 10 mg/500 mg, and 10 mg/1000 mg, and the starting dose should be individualised based on each patient's current treatment regimen. XIGDUO XR should be taken once daily in the morning with food with gradual dose escalation to reduce the risk of gastrointestinal (GI) side effects due to metformin. The maximum daily recommended dose is 10 mg for dapagliflozin and 2,000 mg for metformin HCl.

About the Clinical Development Programme
The co-administration of dapagliflozin and metformin has been studied in adults with type 2 diabetes. The US FDA approved once-daily XIGDUO XR based upon four Phase III clinical trials, which provided clinical evidence for the efficacy and safety of dapagliflozin and metformin IR or XR tablets in treatment-naïve patients, in patients inadequately controlled on metformin, as well as compared to a sulfonylurea (glipizide) plus metformin. There have been no clinical studies conducted with XIGDUO XR combination tablets. Bioequivalence was demonstrated in healthy adults between XIGDUO XR and dapagliflozin plus metformin XR as separate tablets.

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.

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.

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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30 October 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: 30 October 2014

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