ASTRAZENECA PLC
Form 6-K
November 22, 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 November 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-_____

XIGDUO™ (DAPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE) RECEIVES POSITIVE CHMP OPINION IN THE EUROPEAN UNION FOR THE TREATMENT OF TYPE 2 DIABETES

AstraZeneca and Bristol-Myers Squibb today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of Xigduo™ (dapagliflozin and metformin hydrochloride) for adults aged 18 and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their current metformin-based treatment regimen or who are currently being treated with the combination of dapgliflozin and metformin as separate tablets.

XigduoTM combines dapagliflozin (tradename Forxiga®), a selective and reversible inhibitor of sodium-glucose cotransporter 2 (SGLT2), and metformin hydrochloride in a twice daily tablet. This is the first CHMP recommendation for a SGLT2 and metformin hydrochloride fixed dosage combination. The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The final decision will be applicable to all 28 European Union member countries plus Iceland and Norway.

XigduoTM combines Forxiga and metformin hydrochloride, two anti-hyperglycaemic products with complementary mechanisms of action to improve glycaemic control. Forxiga, the first medicine in the SGLT2 class to gain regulatory approval, is currently approved for the treatment of type 2 diabetes in the European Union, Argentina, Australia, Brazil, Mexico and New Zealand.

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

About Diabetes
In 2013, diabetes was estimated to affect more than 380 million people worldwide. The prevalence of diabetes is projected to reach more than 592 million by 2035. Type 2 diabetes accounts for approximately 90% to 95% of all cases of diagnosed diabetes in adults. Type 2 diabetes is a chronic disease characterized by insulin resistance and dysfunction of beta cells in the pancreas, leading to elevated glucose levels. Over time, this sustained hyperglycemia contributes to further progression of the disease. Significant unmet needs still exist, as many patients remain inadequately controlled on their current glucose-lowering regimen.

AstraZeneca/Bristol-Myers Squibb Diabetes Alliance
Dedicated to addressing the global burden of diabetes by advancing individualized patient care, AstraZeneca and Bristol-Myers Squibb are working in collaboration to research, develop and commercialize 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 AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization 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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22 November 2013

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: 22 November 2013 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary