

ASTRAZENECA PLC  
Form 6-K  
January 22, 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  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

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) APPROVED IN THE EUROPEAN UNION FOR TYPE 2 DIABETES

First regulatory approval for a sodium-glucose cotransporter 2 (SGLT2) inhibitor and metformin hydrochloride fixed dose combination treatment

AstraZeneca and Bristol-Myers Squibb today announced that Xigduo™ (dapagliflozin and metformin hydrochloride in 5mg/850mg and 5mg/1000mg tablets) has been granted Marketing Authorisation by the European Commission for the treatment of type 2 diabetes in the European Union (EU). Xigduo combines dapagliflozin (trade name Forxiga®), a selective and reversible inhibitor of SGLT2 with metformin hydrochloride, two anti-hyperglycaemic products with complementary mechanisms of action to improve glycaemic control, in a twice daily tablet. This is the first regulatory approval for a fixed dose combination of an SGLT2 inhibitor and metformin.

Xigduo is indicated for adults aged 18 and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control. It is indicated in patients inadequately controlled on their current metformin-based treatment regimen or who are currently being treated with the combination of dapagliflozin and metformin as separate tablets.

Forxiga was the first medicine in the SGLT2 class to gain regulatory approval, having received Marketing Authorisation in the EU for type 2 diabetes in November 2012, and is currently approved for the treatment of type 2 diabetes in 40 countries including the United States (available under the trade name Farxiga™) and Australia.

"Xigduo is an important addition to the range of medicines to help patients manage glycaemic control. We recognise that not all patients are alike and that different treatments are needed, supporting a more personalised approach to disease management," said Elisabeth Björk, Vice President, Head of Late Phase Cardiovascular and Metabolic Development, AstraZeneca. "Metformin has long been a standard of diabetes care, and with the Xigduo approval, we now have an SGLT2 inhibitor and metformin combination product representing an innovative option for treating adults with type 2 diabetes."

"Type 2 diabetes is a growing global concern and a range of treatments are needed in order to appropriately manage this disease," said Fred Fiedorek, Senior Vice President, Head of Development - Cardiovascular & Metabolics, Bristol-Myers Squibb. "The approval of Xigduo offers physicians another valuable treatment choice in the management of this progressive disease."

### 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 hyperglycaemia associated with the disease. Selective inhibition of SGLT2 reduces the reabsorption of excess glucose and enables its removal via the urine.

### About Type 2 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 85% to 95% of all cases of diagnosed diabetes in adults. Type 2 diabetes is a chronic disease characterised by insulin resistance and dysfunction of beta cells in the pancreas, 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.

#### 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 AstraZeneca and Bristol-Myers Squibb at [www.astrazeneca.com](http://www.astrazeneca.com) or [www.bms.com](http://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 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 <http://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](http://www.astrazeneca.com).

## CONTACTS

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22 January 2014

-ENDS-

## SIGNATURES

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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 January 2014

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary