ASTRAZENECA PLC
Form 6-K
November 14, 2012

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 2012

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-_____

FORXIGA™ (DAPAGLIFLOZIN), FIRST-IN-CLASS SGLT2 THAT WORKS INDEPENDENTLY OF INSULIN, NOW APPROVED IN EUROPEAN UNION FOR TREATMENT OF TYPE 2 DIABETES

AstraZeneca and Bristol-Myers Squibb Company today announced that the European Commission has approved FORXIGA™ (dapagliflozin) tablets for the treatment of type 2 diabetes in the European Union (EU). FORXIGA 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, a unique mode of action not seen in any other currently available treatments for type 2 diabetes. This is the first medicine in the new SGLT2 class to gain regulatory approval for the treatment of type 2 diabetes, a disease in which high unmet medical need exists.

FORXIGA tablets are indicated as a once-daily oral medication to improve glycaemic control in adult patients with type 2 diabetes. FORXIGA is intended to be used as an adjunct to diet and exercise in combination with other glucose-lowering medicinal products, including insulin, or as a monotherapy in metformin-intolerant patients.

"Many Europeans with type 2 diabetes are not reaching treatment goals, increasing their risk of developing complications, so there is a critical need for new treatments. FORXIGA provides physicians with a completely new option to help improve glycaemic control that complements commonly used glucose-lowering treatments like metformin and insulin with additional benefits of weight loss and blood pressure lowering," said John Wilding, DM, FRCP, Professor of Medicine and Honorary Consultant Physician, Head of Diabetes and Endocrinology Clinical Research Unit, University Hospital Aintree, UK. "The approval of FORXIGA represents a significant advance in the treatment of type 2 diabetes."

FORXIGA works in the kidney to selectively inhibit SGLT2, resulting in the removal of excess glucose and its associated calories in the urine. Through the removal of excess glucose, FORXIGA helps to reduce blood sugar levels. In clinical studies, FORXIGA also showed reductions in weight and blood pressure. Bristol-Myers Squibb and AstraZeneca are currently seeking regulatory approval for FORXIGA in several other countries.

"Diabetes is a progressive disease that requires a combination of treatment approaches over time," said Lamberto Andreotti, Chief Executive Officer, Bristol-Myers Squibb. "FORXIGA is the first of a new class of type 2 diabetes medication that works independently of insulin and represents a new treatment option for patients and physicians across Europe."

"We are excited about the approval of FORXIGA in Europe, and thesignificant advancement it represents for the many millions of European patients with type 2 diabetes who need new options to manage this progressive disease," said Pascal Soriot, Chief Executive Officer, AstraZeneca. "FORXIGA is an important addition to the growing range of Bristol-Myers Squibb and AstraZeneca diabetes treatments and further demonstrates our commitment to addressing the unmet needs of adults with type 2 diabetes."

Clinical Trial Programme

The approval of FORXIGA in the EU is based on the results of a broad clinical development programme that included 11 double-blind, randomised, placebo-controlled Phase III clinical trials assessing the safety and efficacy of FORXIGA as a once-daily oral therapy. These 11 trials involved 5,693 patients worldwide with type 2 diabetes, including 3,939 patients treated with FORXIGA. A higher proportion of patients with type 2 diabetes treated with FORXIGA compared to placebo achieved the goal of HbA1c < 7%. The extensive clinical development programme

also demonstrated that FORXIGA had a positive benefit-risk profile, with a low risk of hypoglycaemia, across a wide range of patient populations. Researchers also found additional benefits, such as reductions in body weight and systolic blood pressure in double-blind, randomised, placebo-controlled clinical trials.

The overall incidence of adverse events in patients treated with FORXIGA 10 mg was similar to placebo. Few adverse events led to discontinuation of treatment and incidences were balanced across study groups. The most commonly reported events leading to discontinuation in patients treated with FORXIGA 10 mg were increased blood creatinine (0.4%), urinary tract infections (0.3%), nausea (0.2%), dizziness (0.2%) and rash (0.2%). Vulvovaginitis and balanitis were more common with FORXIGA. Most episodes of vulvovaginitis and balanitis were mild to moderate, responded to standard treatment, and rarely resulted in discontinuation from FORXIGA treatment. The most frequently reported adverse reaction was hypoglycaemia, which was affected by the type of background therapy used in each study. Thus, FORXIGA treatment led to higher rates of hypoglycaemia compared to placebo primarily when used in addition to background insulin or sulphonylurea therapies. However, FORXIGA used as monotherapy or in combination with metformin did not demonstrate a tendency to cause hypoglycaemia, and the frequency of hypoglycaemia events with FORXIGA in these settings was similar to placebo.

About FORXIGA

FORXIGA was discovered by Bristol-Myers Squibb and is the latest product to be approved under the collaboration between Bristol-Myers Squibb and AstraZeneca, to research, develop and commercialise select investigational drugs for type 2 diabetes.

FORXIGA tablets are approved as a once-daily oral medication in adult patients with type 2 diabetes to improve glycaemic control:

- As a monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance; or
- In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

FORXIGA is not indicated as a weight loss product or for the management of obesity or high blood pressure, and has only been studied for the treatment of type 2 diabetes.

About Type 2 Diabetes

At the end of 2011, diabetes was estimated to affect nearly 53 million people aged 20-79 in Europe, and this figure is projected to rise to more than 64 million by 2030. Type 2 diabetes accounts for at least 85% to 95% of all cases of diagnosed diabetes in adults. Type 2 diabetes is a chronic disease characterised by insulin resistance and/or dysfunction of beta cells in the pancreas, which decreases insulin sensitivity and secretion, leading to elevated blood glucose levels. Over time, this sustained hyperglycaemia contributes to worsening insulin resistance and further beta cell dysfunction. Significant unmet need exists as many patients remain uncontrolled on their current glucose-lowering regimen.

Bristol-Myers Squibb and AstraZeneca Collaboration

Bristol-Myers Squibb and AstraZeneca entered into a collaboration in January 2007 to research, develop and commercialise select investigational drugs for type 2 diabetes. The Bristol-Myers Squibb/AstraZeneca diabetes collaboration is dedicated to global patient care and improving patient outcomes in the treatment of type 2 diabetes. The portfolio of type 2 diabetes products developed as a part of the Bristol-Myers Squibb and AstraZeneca collaboration includes the first-in-class SGLT2 inhibitor FORXIGA™ (dapagliflozin), the DPP4 inhibitor ONGLYZA® (saxagliptin), KOMBOGLYZE™ (saxagliptin and metformin HCl immediate-release fixed dose combination) and KOMBIGLYZE XR™ (saxagliptin and metformin HCl extended-release fixed dose combination), which is only available outside the European Union.

In August 2012, Bristol-Myers Squibb completed the acquisition of Amylin Pharmaceuticals. Bristol-Myers Squibb and AstraZeneca then expanded their existing alliance in diabetes to incorporate Amylin's portfolio of diabetes products, which includes GLP1s BYETTA (exenatide injection) and BYDUREON (exenatide extended-release for injectable suspension), both the first to be approved in their class and now available in the US and Europe, as well as the first-in-class Amylin mimetic SYMLIN (pramlintide acetate injection), which is only available in the US. Eli Lilly and Amylin amicably terminated their joint collaboration in November 2011 for exenatide and began to transition global responsibility for the exenatide franchise to Amylin, starting in the US and targeting the transition for all markets by the end of 2013. Bristol-Myers Squibb and AstraZeneca are now working to transition markets outside the US in which Lilly markets and sells exenatide into the expanded Bristol-Myers Squibb and AstraZeneca alliance.

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.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

CONTACTS

Media Enquiries
Esra Erkal-Paler +44 20 7604 8030 (24 hours)
Vanessa Rhodes +44 207 604 8037 (24 hours)

Media Enquiries Sweden
Ann-Leena Mikiver +46 8 553 260 20

Investor Enquiries UK
James Ward-Lilley +44 20 7604 8122 mob: +44 7785 432613
Karl Hård +44 20 7604 8123 mob: +44 7789 654364
Nicklas Westerholm +44 20 7604 8124 mob: +44 7585 404950

Investor Enquiries US
Ed Seage +1 302 886 4065 mob: +1 302 373 1361

14 November 2012

- 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: 14 November 2012 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary