ASTRAZENECA PLC
Form 6-K
March 03, 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 March 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 BYDUREON® PEN (EXENATIDE EXTENDED-RELEASE FOR INJECTABLE SUSPENSION) FOR ONCE-WEEKLY TREATMENT OF ADULTS WITH TYPE 2 DIABETES

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved the BYDUREON® Pen (exenatide extended-release for injectable suspension) 2 mg as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. BYDUREON should not be used for treatment of patients with type 1 diabetes or diabetic ketoacidosis. BYDUREON is not recommended as first-line therapy for patients who have inadequate glycaemic control on diet and exercise. BYDUREON is not a substitute for insulin. The concurrent use of BYDUREON with insulin has not been studied and is not recommended.

BYDUREON is the first and only once-weekly medicine for adults with type 2 diabetes. The BYDUREON Pen is a pre-filled, single-use pen injector, eliminating the need for the patient to transfer the medication between a vial and syringe during the self-injection process. The BYDUREON Pen contains the same formulation and dose as the original BYDUREONsingle-dose tray, providing the same continuous release of exenatide.

BYDUREON has been shown to provide powerful HbA1c (blood glucose level) reduction. In a 24-week, randomised, open-label trial, once-weekly BYDUREON demonstrated an HbA1c reduction of 1.6 percentage points vs 0.9 percentage points for twice-daily BYETTA® (exenatide) injection at 24 weeks (baseline HbA1c 8.5 percent and 8.4 percent, respectively). Additionally, BYDUREON demonstrated a mean weight reduction of 2.3 kg vs 1.4 kg with BYETTA (baseline 97 kg and 94 kg, respectively). BYDUREON is not indicated for the management of obesity, and weight change was a secondary endpoint in clinical trials.

"We're pleased to receive approval for the BYDUREON Pen, which can provide a powerful reduction in blood glucose levels along with the potential benefit of weight loss, through a once-weekly dose in a pre-filled device," said Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer, AstraZeneca. "We are committed to addressing the needs of adults with type 2 diabetes, including ongoing research to develop new treatments and methods of delivery."

The BYDUREON Pen delivers exenatide via microsphere technology in a once-weekly dose requiring no titration. It can be administered at any time of the day, with or without meals.

AstraZeneca plans to make the BYDUREON Pen available for patients in the US later this year. The BYDUREON single-dose tray will remain on the market in the US for patients prescribed BYDUREON.

The FDA approval for BYDUREON was received in 2012. BYDUREON is currently available in 42 countries worldwide, including European Union countries.

About BYDUREON® Clinical Development Program
The FDA approval of BYDUREON was based on the safety and efficacy data from the pivotal DURATION-5 clinical trial, in which treatment with BYDUREON resulted in improvements in glycaemic control. The DURATION-5 trial was a randomised open-label clinical study of 252 adult patients with type 2 diabetes and inadequate glycaemic control with diet and exercise alone or with oral antidiabetic therapy, including metformin, a sulfonylurea, a thiazolidinedione or a combination of two of these oral type 2 diabetes medications comparing BYDUREON to BYETTA (n = 129 and n = 123, respectively). After 24 weeks of treatment, patients taking once-weekly BYDUREON experienced a statistically significant mean reduction in HbA1c of 1.6 percentage points (8.5% baseline), compared to a reduction of 0.9 percentage points (8.4% baseline) for patients taking BYETTA. HbA1c is a measure of average blood sugar over three months. Both treatment groups achieved a reduction in weight by the end of the study, with an average loss of 2.3 kg (97 kg baseline) for patients taking BYDUREON and 1.4 kg (94 kg baseline) for patients taking BYETTA (change in weight was a secondary endpoint). The most frequently reported adverse event in both groups was nausea, reported less frequently by BYDUREON users (14%) than by BYETTA

users (35%). Other common treatment-emergent adverse events in the BYDUREON group included diarrhea (9.3% vs 4.1%) and injection-site erythema (5.4% vs 2.4%, respectively). There were no major hypoglycaemic events in either treatment arm. Minor episodes of hypoglycaemia occurred in BYDUREON 2 mg and BYETTA 10 mcg patients with concomitant sulfonylurea use (12.5% vs 11.8%, respectively).

About GLP-1 Receptor Agonists
An agonist is a molecule, such as a drug or a hormone, which binds to a receptor of a cell and triggers a response by that cell. A glucagon-like peptide-1 (GLP-1) receptor agonist binds to and activates the GLP-1 receptor, which exhibits multiple anti-hyperglycaemic actions.

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 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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3 March 2014

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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: 03 March 2014

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